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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

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I. INTRODUCTION

This Commission Staff Working Document accompanies "2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017", which summarises the data and conclusions presented in this document.

The objective of the report is to present statistical information on the use of animals in procedures in the European Union under Directive 2010/63/EU[1] of 22 September 2010 on the protection of animals used for scientific purposes ("the Directive"). The obligation of the Member States to collect statistical data is covered by Article 54(2) of the Directive.

Regulation (EU) 2019/1010[2] ("the Regulation") amended Article 54(2) of the Directive. This report is based on data provided by Member States in accordance with the previous wording of Article 54(2) requiring the collection on an annual basis of statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. The amended Article 54(2) requires Member States to submit the statistical data by electronic transfer in a non-summarised format to the Commission.

As the Regulation was adopted in June 2019, the first annual dataset in line with the new wording of Article 54(2) will be collected in 2020 and is required to be submitted to the Commission by 10 November 2021. That Member State data will then be made available through an open access database in 2022 accompanied by a summary report thereof.

The Regulation also removed the obligation of the Commission to submit a statistical report to the European Parliament and the Council. However, since improved transparency is one of the key objectives of the Directive, the Commission considers it appropriate, as well as necessary in support of the other objectives of the Directive, that the data submitted by the Member States is made available on a yearly basis until 2022.

This first report under Directive 2010/63/EU contains the results of the data collected by all 28 Member States between 2015 and 2017.

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data Submitted by the Member States

The data were collected according to the Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and the Council on the protection of animals used for scientific purposes.

II.2. General Considerations

The Section A of this report aims at providing a comprehensive overview on the use of animals in procedures in the European Union between 2015 and 2017. The purposes of the use of animals have

[1] Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79
[2] OJ L 170, 25.6.2019, p. 115–127

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been analysed at EU level, and some of these purposes have been broken down into more precise sub-categories.

In this report, data are presented either in the form of figures or summary tables providing information on a specific aspect of the Directive. Overall numbers are given for the three reported years. However, where the statistics focus on a more detailed breakdown to get a better understanding of the area being analysed (for example breakdown of animal species used for the first time), these are based on data from the year 2017. This decision was taken for two main reasons: the first is that 2017 is the most recent year with a comprehensive dataset, the second is that due to the changed reporting criteria, it is expected that the data from 2017 would be of the highest accuracy. Key findings are presented in the form of tables and graphics. However, in some cases, further information in the text may have been drawn both from annexed tables and Member State narratives (see Section C of this Staff Working Document). Member State narratives have been helpful in providing information such as for the content of 'other' categories (for example, 'other rodents', 'other basic research').

It is important to note in this context that the introduction of new reporting criteria represents a number of challenges. Good data quality requires clear understanding, by all involved, of all new requirements (such as severity reporting), any terms used and data categorization. Furthermore, the way in which the reporting requirements have been implemented at the national level, including any additional support (national guidance, training) play an important role in the data quality.

Some elements of the new reporting have proven extremely demanding, having required extensive efforts by Member States and the Commission. One such example concerns the reporting of animals used for the maintenance of genetically altered animals, and uses that should be covered under this category. Another example concerns the reporting of actual, experienced severity.

The two main issues when reporting actual severity were: confusion between prospective severity classification (for the purposes of a project evaluation) assigned for an entire group of animals versus the actual experienced severity, which is assigned to each animal individually on the basis of observed and recorded adverse effects; and how to incorporate expert judgement in the severity assessment in a consistent manner over time and between establishments, regions and Member States.

To help in this process, some Member States have been particularly active in their efforts to improve data quality. Furthermore, some stakeholder organisations have offered workshops to address issues around severity reporting. With these and other efforts, the statistical data quality is expected to continue to improve. As errors are being detected and consistency improved, it is clear that some of the fluctuations in numbers, or even what may seem to appear as trends at this early stage, may indeed instead be due to improved understanding of the reporting obligations. Finally, for these same reasons it is too early to draw conclusions on any firm trends on the basis of the first three years of data.

II.2.1 Link to the previous statistical reports under Directive 86/609/EEC[3]

As there are significant differences from the previous reporting requirements, the data presented in this report are not, in general, comparable with the information presented in reports published under the former Directive 86/609/EEC.

[3] OJ L 358 , 18/12/1986 P. 0001 - 0028

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The new reports were developed to provide significantly more detailed and tailored information on animal use. They include aspects of animal use, which have not previously been available, for example, on the genetic status of animals and the actual severity experienced by the animals during their use in procedures. In terms of numbers, some uses of animals, which were previously grouped together, are now covered by different sections of this report. Moreover, the new reports cover areas of animal use that were not included in the reports under the previous legislation.

With this in mind, the only limited comparison which may be attempted concern the numbers of animals used for the first time for the purposes of research and testing[4]. However, even here the comparison is not obvious, because (1) invertebrate species were not included in the past reports and they are now, and (2) the previous numbers included partly those animals that were used for the creation of genetically altered animal lines (which are now separate), leaving the comparison between 2011 and current numbers of animals only as an estimate.

The main differences from previous reports are summarised below:

1. **The scope** of the Directive and subsequently the related reporting requirements have changed considerably. The new reports include new classes of animals, namely all species of Cephalopods (for example octopus, squid and cuttlefish). In addition, the maintenance (breeding) of certain types of genetically altered animals is covered. Neither of these categories was included in previous reports.
2. **The time of reporting.** The data published previously reported the numbers of animals at the start of their use ("procedure"). However, Directive 2010/63/EU requires that information is reported on the actual impact on the welfare of the animals used for scientific purposes. For this reason, in contrast to previous reporting, the information is submitted when a **use of an animal is complete**. Therefore, the data under Directive 2010/63/EU are **reported at the end** of the procedure.
3. **Each use of an animal is counted.** The data captured by the new reporting criteria include both the numbers of uses of new animals (not previously used in a procedure) and "reuses" (animals that have already previously been used in a procedure). "Uses" therefore includes both the "first use" and all subsequent "reuses".

   Furthermore, previously, the details were reported only from the first use and therefore, no information was captured on any subsequent uses. Although the majority of animals are used only once, the Directive provides for a possibility to reuse animals under certain conditions (Article 16 of the Directive). Reuse can reduce the overall number of animals, where this does not detract from the scientific objective or cause significant welfare compromise. However, the benefit of re-using animals (a reduction in numbers) needs to be carefully balanced against any adverse effects on their welfare, taking into account the lifetime experience of each individual animal. Reuse must be considered on a case-by-case basis (recital 25 of the Directive).
4. **The actual severity experienced by an animal** during a procedure is one of the key innovations of the new report. The severities are categorised as "non-recovery", "mild", "moderate" or "severe". "Non-recovery" means that the animal has undergone a procedure that has been performed entirely under a general anaesthesia and from which the animal has not

[4] "Research and testing" covers animals used for research, testing, routine production and education (including animals used for training purposes)

recovered. This includes also the situation where the animal has failed to recover consciousness from anaesthesia during the first step of a planned recovery procedure.

The following table presents the differences between the reporting requirements of the two Directives:

Reporting	*Former Directive (86/609/EEC)*	*Current Directive (2010/63/EU)*
Scope – species	Only vertebrate species	Vertebrate species and Cephalopods
Scope – purpose	No reporting of breeding of genetically altered animals	Maintenance (breeding) of genetically altered (GA) animals with intended harmful phenotype (characteristic/trait) and which have experienced suffering
First use and reuse **(animals used versus uses of animals)**	Number of new animals, and only the number of reuses of the species covered by the Annex I of Directive 86/609/EEC with no related details of the reuse	Number of new animals, and in addition all reuses. All uses reported with full datasets
Source of Non-human primates (NHPs)	Information on European origins but not from other geographical regions	More detailed information on where NHPs have been obtained, in particular outside Europe
Generation of NHP breeding	Not reported	Information on progress from wild caught (F0), to first generation purpose-bred (F1), second generation purpose-bred animals (F2), to self-sustaining colonies.
Genetic Status	Not reported	• No genetic alteration (GA) • GA with a non-harmful phenotype • GA with a harmful phenotype
Purposes	Broad headings	More detailed information of previously reported categories with further sub-categorisation, such as for ecotoxicity, routine production and GA maintenance
Creation of a new genetically altered (GA) line	Not reported	Creation of a new GA line together with the intended purpose

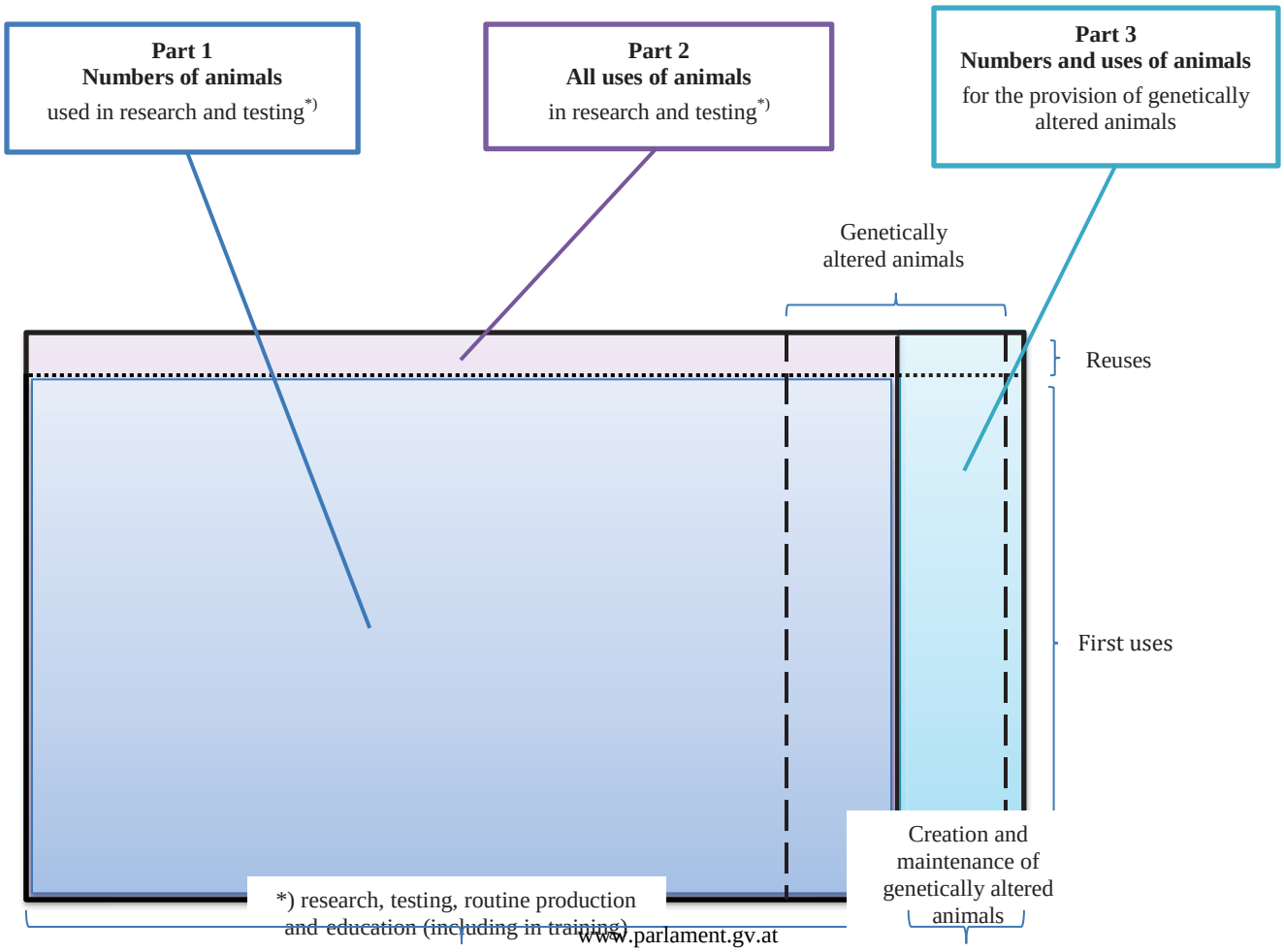
Actual severity	Not reported	Actual severity reported under four categories • Non-recovery • Mild • Moderate • Severe

II.3. Report structure

For the first time at the level of the EU, the statistical information is collected, not only on the scientific uses of animals for the purposes of research and testing, but also on the scientific uses for the creation and maintenance of genetically altered animal lines in support of research needs. Equally, it is the first time that full datasets are available for each use of an animal, allowing for a much more precise reporting.

It is therefore the objective of this report to present all these data structured in a manner that allows for an improved understanding of when and how animals are still used in science today. It is hoped that, in line with the Directive aims, this way of reporting will better facilitate the identification of animal use areas on which efforts for the development and validation of alternative approaches can be focused.

Therefore, Section A of the report is composed of three parts as illustrated in the picture below:



Numbers of animals used for research, testing, routine production and educational purposes[5] in the EU – Part 1 (III.1)

The first part focuses on the *numbers of animals* used, for the first time, for the purposes of research, testing, routine production and education (term 'education' in the context of this report also includes animals used for the purposes of training). These animals can be both conventional animals or those that have been genetically altered. This part reports on their numbers and origins. It excludes animals that have been used for the creation of a new genetically altered animal line, or maintenance of an existing genetically altered animal line. These are covered in part three below.

Details of all uses of animals for research, testing, routine production and educational purposes in the EU – Part 2 (III.2)

The second part focuses on the way in which animals are used in these scientific procedures, *covering all uses, both the first and any subsequent reuse.* This serves to draw an overall picture of all uses of animals for the purposes of research, testing, routine production and education in the EU. This part takes into account the nature of the procedures, their legislative context, reuse of animals, the genetic status of the animals, and the severities experienced by the animals.

Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU – Part 3 (III.3)

The third part focuses on the provision of *genetically altered animals* needed to support scientific research in the Union. It reports, on one hand, on animals used in procedures for *the creation* of new genetically altered animal lines and, on the other, *the maintenance* of colonies of existing genetically altered animals. Like in part one of this report, it provides the actual numbers of animals, used for the first time, as well as more detailed information taking into account all uses (first, and any subsequent reuse) for the purposes of creation and maintenance of genetically altered animal lines. It also provides further information on the type of research for which new genetically altered animal lines are being created. These animals have not been used in other scientific procedures, in other words the data are separate from those covered in parts one and two of this report.

Section B of this report contains EU level data that have been used as the basis for conclusions in Section A of the report. Section C of this report provides data from the Member States together with their respective narratives.

Information outside of the scope of the statistical report

What remains outside of the scope of annual statistical reporting – even if covered by the scope and provisions of the Directive, are:

- Foetal forms of mammals;

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[5] In this context 'Research' means basic, applied and translational research, animals used for the purposes of protection of the natural environment in the interests of the health or welfare of human beings or animals, preservation of the species and forensic enquiries; 'testing' refers to regulatory use of animals and 'education' includes animals used for training purposes. Glossary in III.4. provides further information on some of the categories of scientific use purposes.

- Animals killed solely for organs and tissues, and sentinels, unless the killing is performed under a project authorisation using a method not included in Annex IV of Directive 2010/63/EU;
- Animals bred and killed without being used, apart from genetically altered animals with intended and exhibited harmful phenotype, and those having been genotyped with an invasive method before being killed.

Additional information on animals bred and killed without being used will be reported in the five-year report on the implementation of the Directive in line with Article 54(1) of the Directive.

SECTION A: COMPILATION AND OVERVIEW OF THE EU DATA BETWEEN 2015 AND 2017

III.1 Numbers of animals used for research, testing, routine production and educational purposes in the EU

This part focuses on the numbers of animals used *for the first time* in procedures for the purposes of research, testing, routine production and education. Therefore, it excludes all reuses of animals that are considered in the second part. It also excludes animals that are used either for the creation of new genetic altered lines or the maintenance of colonies of established genetically altered animal lines. However, animals used for research, testing, routine production and educational purposes can be conventional or genetically altered.

In addition to the numbers of animals, this part also provides information on the species in relation to their origin, and for non-human primates, information on progress to purpose-bred animals, by recording generation.

III.1.1. Numbers of animals used for the first time

Between 2015 and 2017, the number of animals used for the first time in the EU annually is below 10 million. The total number of animals decreased slightly from 9.59 million in 2015 to 9.39 million in 2017 (-2%). However, there was a small increase to 9.82 million in 2016, preventing the identification of a clear trend (Table 1.1).

	2015	2016	2017
Total	9,590,379	9,817,946	9,388,162

Table 1.1: Total numbers of animals used for the first time for research, testing, routine production and education purposes in the EU between 2015 and 2017

In 2017, the main species used for the first time for research, testing, routine production and educational purposes were mice, fish, rats and birds that together represented 92% of the total number of animals. Species of particular public concern (dogs, cats and non-human primates (NHP)) represented less than 0.3% of the total number of animals. No great apes are used for scientific purposes in the European Union (Figure 1.1).

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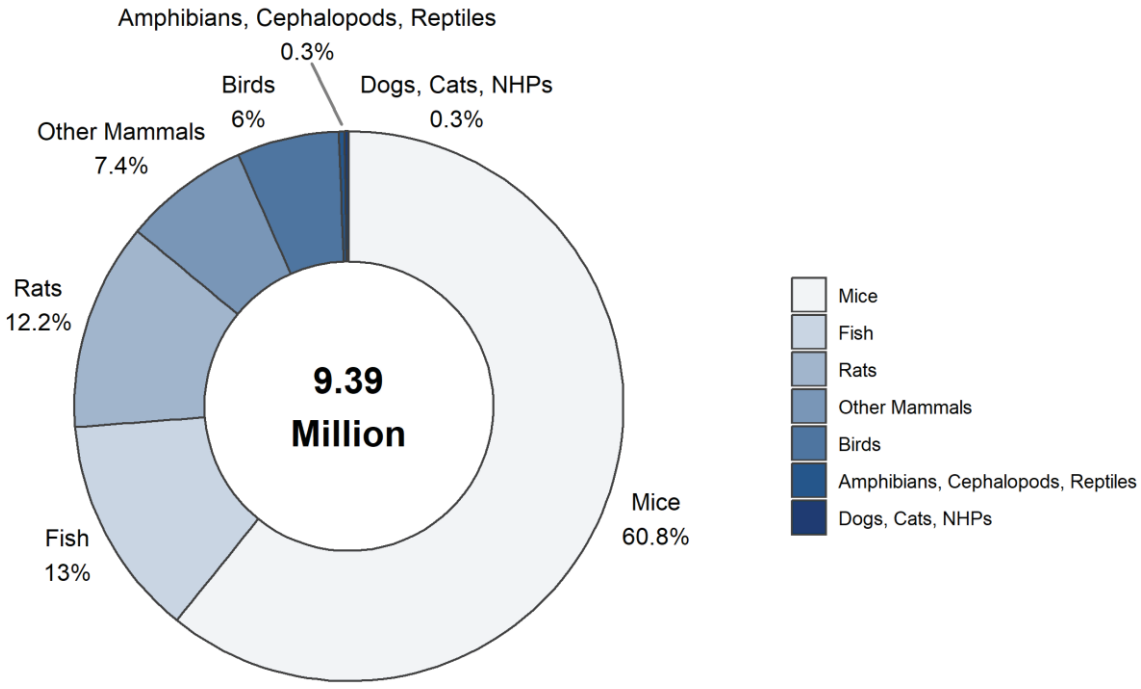

Figure 1.1: Numbers of animals used for the first time by main classes of species in 2017

Looking at this higher level of grouping from 2015 to 2017 (table 1.2), the number of birds decreased (-11%) as well as the number of amphibians, cephalopods, reptiles (together) (-42%) due to a significant drop in cephalopods in 2016. However, the actual number of cephalopods remains low (15,862 in 2015 to 514 in 2017 - Table 1.4). As a general remark, it is important to note that numbers can fluctuate year to year, particularly so with fish, amphibian and cephalopods where studies on immature forms may involve large numbers (thousands) of animals.

	2015	2016	2017
Mice	5,711,612	5,989,413	5,707,471
Rats	1,201,189	1,173,135	1,146,299
Other mammals	713,113	700,262	719,576
Fish	1,275,067	1,304,737	1,219,695
Birds	635,211	595,724	563,963
Amphibians, Cephalopods, Reptiles	54,187	54,675	31,158
Total	**9,590,379**	**9,817,946**	**9,388,162**

Table 1.2: Numbers of animals used for the first time by main classes of species

For fish, the Directive distinguishes zebra fish (41% of fish in 2017) from other fish species. The main "other" fish species (719,932 in 2017 - Table 1.4) reported during the period (2015-2017) were seabass, guppies, trout and salmon.

For birds, the Directive distinguishes domestic fowls (82% of birds in 2017) from other birds. The main species reported as "Other birds" (99,410 in 2017 – Table 1.4) were turkey and the Great Tit (*Parus major*).

For amphibians, the Directive distinguishes rana (13% of amphibians in 2017) and xenopus (49% of amphibians in 2017) from other amphibians. The main species reported as "Other amphibians" (10,683 – Table 1.4) during the period was bufo (toads).

First uses of mammals between 2015 and 2017 are reported in more detail in table 1.3 below.

	2015	2016	2017
Mice	5,711,612	5,989,413	5,707,471
Rats	1,201,189	1,173,135	1,146,299
Guinea-Pigs	149,328	150,985	144,824
Other rodents	52,512	38,490	43,298
Rabbits	346,052	350,405	351,961
Cats	1,975	1,951	1,879
Dogs	14,501	15,691	13,688
Other carnivores	5,860	2,974	4,402
Farm animals	126,214	128,890	124,954
Non-human primates	7,136	7,239	8,235
Other mammals	9,535	3,637	26,335
Total	**7,625,914**	**7,862,810**	**7,573,346**

Table 1.3: Numbers of animals used for the first time in the Mammal category

Farm animals include horses, donkeys and cross-breeds, pigs, goats, sheep and cattle. "Other carnivores" (4,402 in 2017) reported were ferrets, mink and badgers while "Other rodents" (43,298) were hamsters and wild species of rodents and "Other mammals" mainly bats.

Between 2015 and 2017, the numbers of farm animals remained stable. There was an increase (+14%) in cattle use, while remaining farm animals saw a decrease (-25% for horses, donkeys and cross breed).

The numbers of "Other carnivores" showed some fluctuation but no obvious reason could be identified from the statistics.

Numbers of "Other mammals" increased significantly between 2015 and 2017 due to a high number of bats in 2017 used in procedures to study human infectious disorders.

The species of non-human primates reported during the period were: prosimians, marmoset and tamarins, squirrel monkey, other species of new world monkey (*ceboidea*), cynomolgus monkey, rhesus monkey, vervets chlorocebus, baboons, and other species of old world monkeys (*cercopithecoidea*). In line with the general ban on the use of great apes, introduced by the Directive, no such use was reported during that period.

Between 2015 and 2017, the numbers of non-human primates saw an increase (+15%). The cynomolgus monkey (representing 88% of non-human primates in 2017 – Table 1.4) was the most commonly used species of non-human primates and had a 16% increase between 2015 and 2017. Numbers of marmosets, rhesus monkeys and other old world monkeys (mainly *macaca nemestrina* and *macaca silenus*) also increased slightly. Numbers of other non-human primate species decreased between 2015-2017.

	2015	2016	2017
Mice	5,711,612	5,989,413	5,707,471
Rats	1,201,189	1,173,135	1,146,299
Guinea-Pigs	149,328	150,985	144,824
Hamsters (Syrian)	20,195	18,614	12,700
Hamsters (Chinese)	30	519	187
Mongolian gerbil	6,199	5,645	5,239
Other rodents	26,088	13,712	25,172
Rabbits	346,052	350,405	351,961
Cats	1,975	1,951	1,879
Dogs	14,501	15,691	13,688
Ferrets	2,212	1,530	2,016
Other carnivores	3,648	1,444	2,386
Horses, donkeys and cross-breeds	3,217	3,474	2,414
Pigs	73,895	80,029	71,522
Goats	2,233	1,365	1,563
Sheep	20,106	21,240	18,812
Cattle	26,763	22,782	30,643
Prosimians	169	44	98
Marmoset and tamarins	429	285	465
Squirrel monkey	13	8	8
Other species of New World Monkeys (Ceboidea)	0	0	3
Cynomolgus monkey	6,221	6,503	7,227
Rhesus monkey	211	318	353
Vervets (Chlorocebus spp.)	56	19	33
Baboons	37	62	25
Other species of Old World Monkeys (Cercopithecoidea)	0	0	23
Other mammals	9,535	3,637	26,335
Domestic fowl	515,834	500,920	464,553
Other birds	119,377	94,804	99,410
Reptiles	2,414	3,240	2,937
Rana	4,884	4,482	3,485
Xenopus	10,837	18,511	13,539
Other amphibians	20,190	19,558	10,683
Zebra fish	338,815	513,011	499,763
Other Fish	936,252	791,726	719,932
Cephalopods	15,862	8,884	514
Total	**9,590,379**	**9,817,946**	**9,388,162**

Table 1.4: Numbers of animals used for the first time by species

III.1.2. Origin of animals used for the first time

The origin (place of birth) of animals is divided into two categories depending on whether the species belongs to the category of non-human primates or not. For non-human primates, more detailed information is collected on their origin (continent of origin) and in addition their generation is reported (see Part III.1.2.2.).

III.1.2.1. Place of birth of animals (other than non-human primates)

In 2017, almost 90% of the animals used for scientific purposes for the first time were born in the EU at registered breeders and less than 2% were born outside of the EU (either in the rest of Europe or outside of Europe). Category 'animals born in the EU but not at a registered breeder' includes animals from, for example, farms, and studies carried out using wild animals (Figure 1.2).

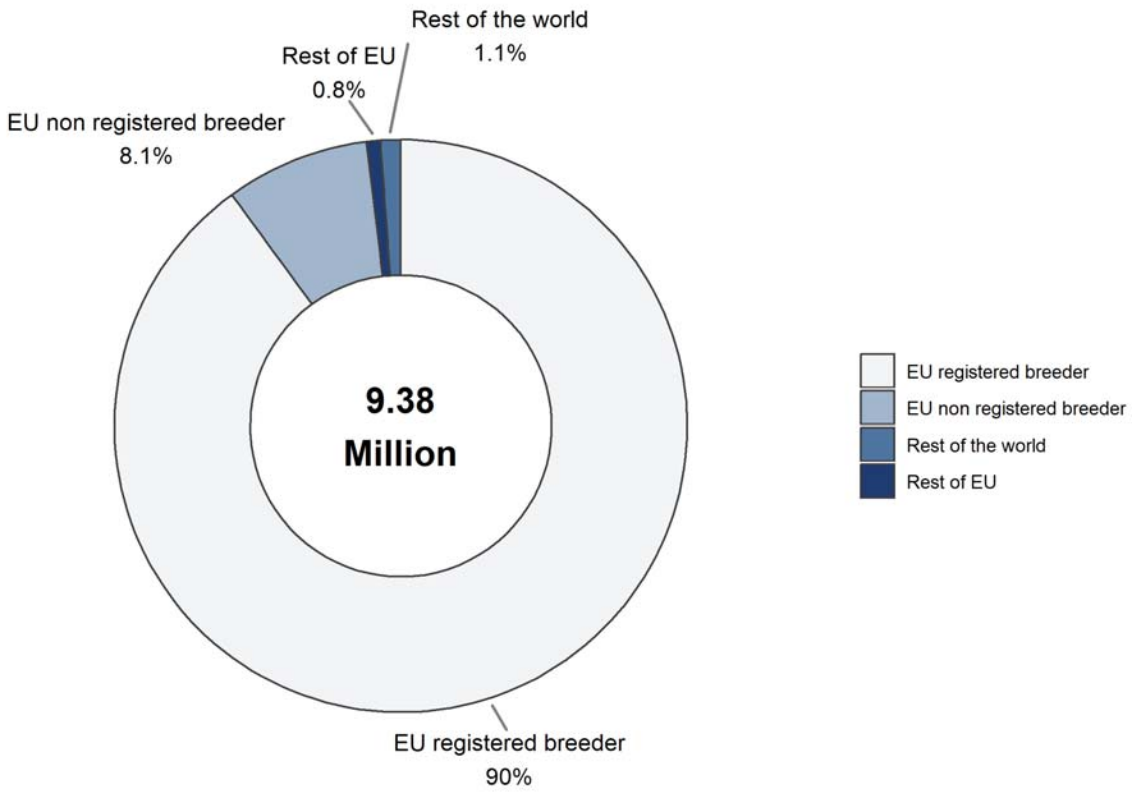

Figure 1.2: Place of birth of animals other than non-human primates in 2017

Between 2015 and 2017, animals born in the EU but not at a registered breeder decreased slightly (-20%) and animals born in the rest of the world increased (+61%) partly due to a significant import of bats (18,000).

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	2015	2016	2017
Animals born in the EU at a registered breeder	88% (8,466,666)	90% (8,874,852)	90% (8,437,271)
Animals born in the EU but not at a registered breeder	10% (955,563)	8% (773,612)	8% (762,288)
Animals born in rest of Europe	1% (94,219)	1% (82,219)	1% (72,952)
Animals born in rest of world	1% (66,795)	1% (80,024)	1% (107,416)
Total	**100% (9,583,243)**	**100% (9,810,707)**	**100% (9,379,927)**

Table 1.5: Place of birth of animals other than non-human primates

Annex I of the Directive contains a list of animals that may only be used where those animals have been bred for use in procedures (see Article 10). Figure 1.3 shows all the animal species listed in Annex I, except non-human primates.

In 2017, amongst the species listed in Annex I, rodents, rabbits and zebra fish were, for the vast majority, born at EU registered breeders (Figure 1.3). Dogs (32%), cats (44%) and to a lesser extent frogs (10%) had a higher proportion of animals born in the EU but at a non-registered breeder (Section B – Table 2). The most common reason for using dogs and cats that came from non-registered breeders in the EU were procedures in pet dogs and cats, which had blood samples taken for studies of genetic disorders, or pet animals, which were involved in patient studies for better treatment methods.

Last, 33% of dogs, 19% of frogs, 9% of hamsters (Syrian) and 8% of cats were imported from the rest of the world, with a significant decrease for cats (-60%) between 2015-2017 (Section B – Table 2).

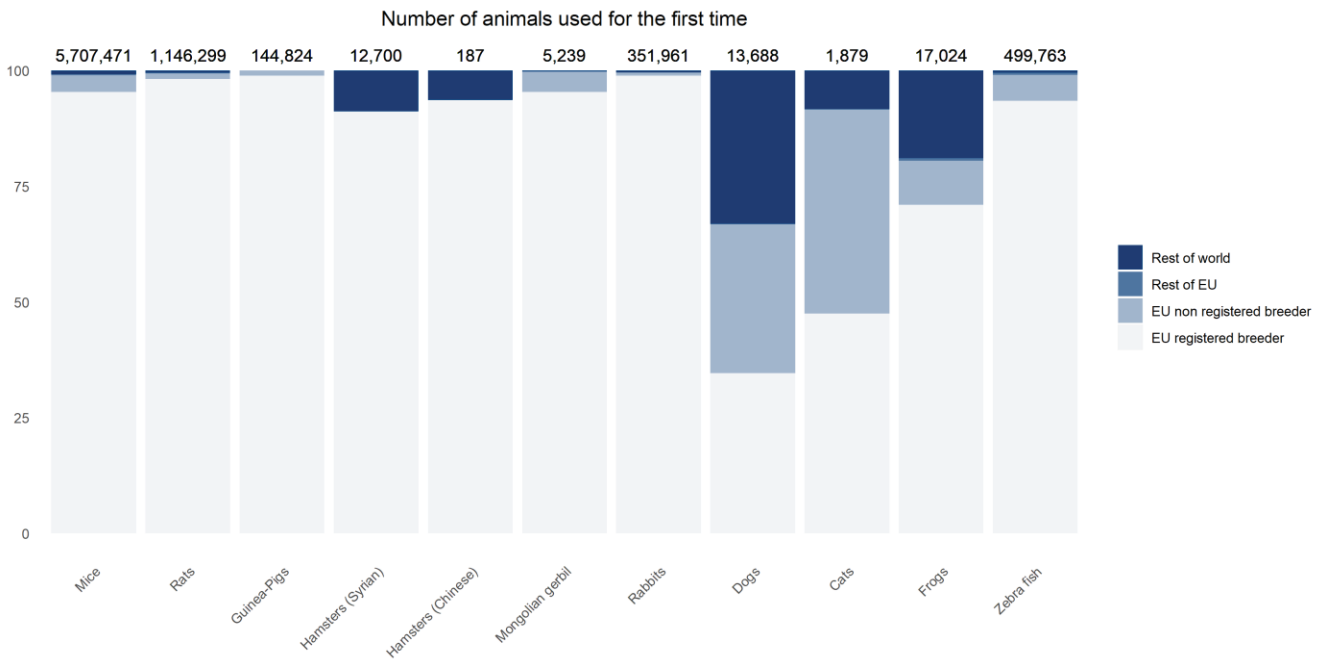

Figure 1.3: Place of birth of animals other than non-human primates listed in Annex I in 2017

III.1.2.2. Origin of non-human primates

The Directive provides additional protection for non-human primates due to their genetic proximity to human beings, their highly developed social skills and capacity to experience pain, suffering and distress. Furthermore, the Directive recognises that the capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport. In order to end the capture of animals from the wild including for the purposes of breeding, the Directive introduced provisions with the objective of moving towards using non-human primates that have been bred, ultimately, in self-sustaining colonies, from parents who themselves have been bred in captivity (see Article 10 of the Directive).

In order to monitor progress, more detailed information is collected on both the origin and generation of non-human primates used in scientific procedures in the EU.

III.1.2.2.1. Non-human primates - Source

In 2017, the three main sources of non-human primates were Africa, Asia and EU registered breeders representing more than 97% of non-human primates used for scientific purposes (Figure 1.4).

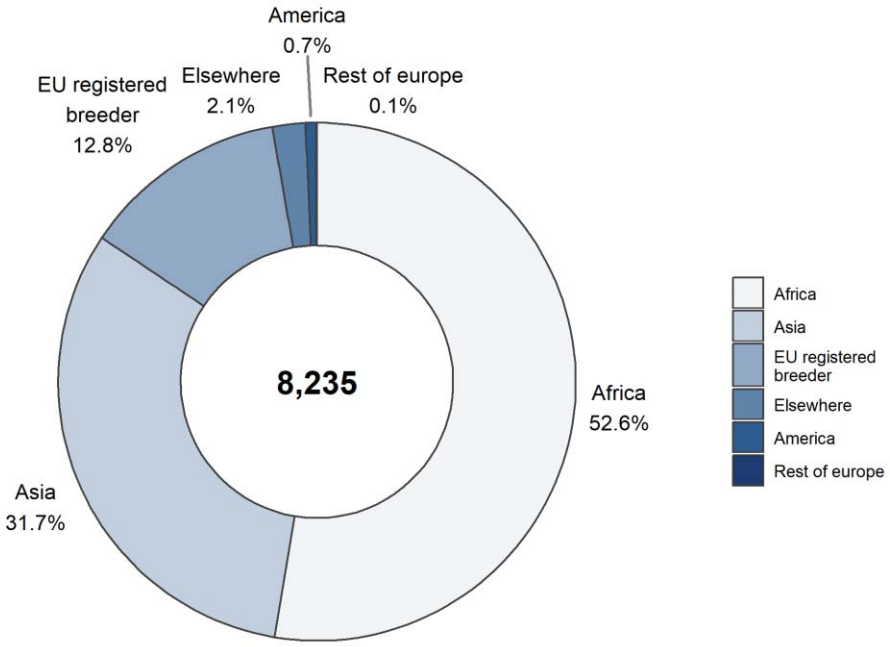

Figure 1.4: Source of non-human primates in 2017

In 2017, cynomolgus monkeys represented 88% of non-human primates used for the first time. These were sourced almost entirely from outside of the EU (Table 1.6). In contrast, other species of non-human primates were mainly sourced from EU registered breeders.

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	Animals born at a registered breeder within EU	Animals born in rest of Europe	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total
Prosimians	100% (98)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	100% (98)
Marmoset and tamarins	81% (377)	0% (0)	0% (0)	0% (0)	9% (42)	10% (46)	100% (465)
Squirrel monkey	62% (5)	0% (0)	0% (0)	25% (2)	0% (0)	12% (1)	100% (8)
Other species of New World Monkeys (Ceboidea)	100% (3)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	100% (3)
Cynomolgus monkey	3% (218)	<1% (5)	36% (2,591)	0% (0)	59% (4,290)	2% (123)	100% (7,227)
Rhesus monkey	90% (317)	0% (0)	4% (14)	5% (19)	1% (3)	0% (0)	100% (353)
Vervets (Chlorocebus spp.)	0% (0)	0% (0)	0% (0)	100% (33)	0% (0)	0% (0)	100% (33)
Baboons	100% (25)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	100% (25)
Other species of Old World Monkeys (Cercopithecoidea)	61% (14)	0% (0)	39% (9)	0% (0)	0% (0)	0% (0)	100% (23)
Total	**13% (1,057)**	**0% (5)**	**32% (2,614)**	**1% (54)**	**53% (4,335)**	**2% (170)**	**100% (8,235)**

Table 1.6: Source of non-human primates by species in 2017

III.1.2.2.2. Non-human primates - Generation

With regard to the generation of non-human primates being bred in captivity in 2017, the majority of non-human primates were sourced either from self-sustaining colonies (30%) or as second or higher generation purpose-bred (53%). No non-human primates were sourced from the wild (Table 1.7) in 2017.

Between 2015 and 2017, non-human primates coming from self-sustaining colonies decreased slightly (-9%). In line with the Directive objectives, those being second or higher generation purpose-bred increased significantly (+67%) and those being of first generation purpose-bred decreased (-23%).

	2015	2016	2017
Self-sustaining colony	39% (2,748)	31% (2,271)	30% (2,504)
F2 or greater	37% (2,614)	47% (3,435)	53% (4,368)
F1	25% (1,773)	21% (1,528)	17% (1,363)
F0	0% (1)	0% (5)	0% (0)
Total	**100% (7,136)**	**100% (7,239)**	**100% (8,235)**

Table 1.7: Generation of non-human primates in 2017

Looking at non-human primate species and their generation:

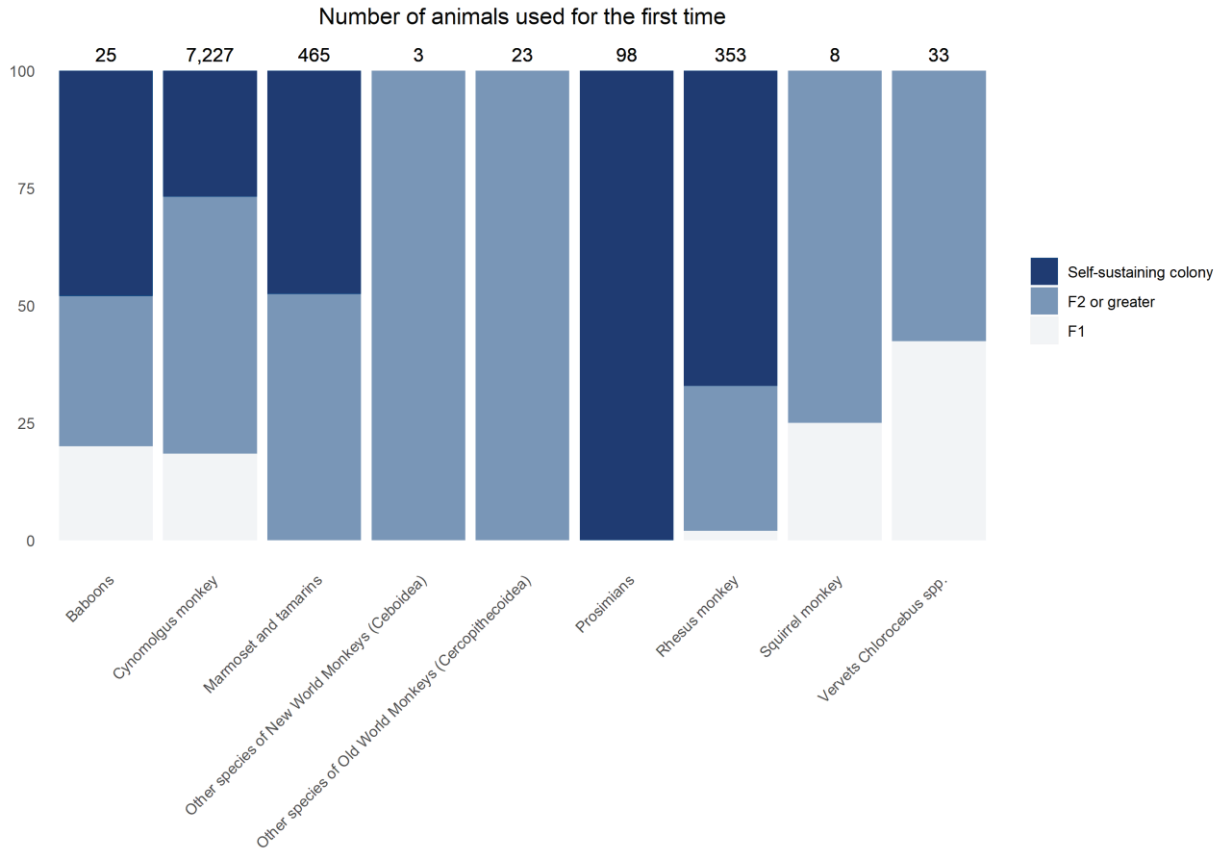

Figure 1.5: Generation of non-human primates by species in 2017

For non-human primates born at a registered breeder in the EU, only 3% of non-human primates used for the first time were from the first generation, in Africa first generation of animals represented 26% in 2017 and first generation non-human primates from elsewhere represented 47% (Table 1.8).

	Animals born at a registered breeder within EU	Animals born in rest of Europe	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere
F1	3% (32)	0% (0)	3% (88)	30% (16)	26% (1,147)	47% (80)
F2 or greater	40% (418)	100% (5)	75% (1,948)	70% (38)	44% (1,915)	26% (44)
Self-sustaining colony	57% (607)	0% (0)	22% (578)	0% (0)	29% (1,273)	27% (46)
Total	**100% (1,057)**	**100% (5)**	**100% (2,614)**	**100% (54)**	**100% (4,335)**	**100% (170)**

Table 1.8: Generation of non-human primates by source in 2017

III.2. Details of all uses of animals for research, testing, routine production and educational purposes in the EU

This part focuses on all uses of animals for the purposes of research, testing, routine production and education, including the first and any subsequent reuse. It provides detailed information on the reason for use (for example the specific research area, or type of testing) as well as additional information related to the actual severity experienced by the animals, their genetic status and reuse. In addition, information on the use of animals to satisfy legislative requirements is collected.

III.2.1. Overview of the main scientific purposes and the related severities

Between 2015 and 2017, the total number of all uses (first use and any subsequent reuse) for the purposes of research, testing, routine production and education decreased from 9.78 million in 2015 to 9.58 million uses in 2017 (-2%). However, an increase to 10.03 million in 2016 prevents drawing of firm conclusion with regard to a trend in the number of uses (Table 2.1).

	2015	2016	2017
Total	9,782,570	10,028,498	9,581,741

Table 2.1: Total number of uses of animals between 2015 and 2017

III.2.1.1. Main categories of scientific purposes

In 2017, 9.58 million uses of animals for scientific purposes were reported by Member States in the European Union.

Most uses were conducted for research purposes (68%) with 45% of the uses being carried out for basic research and 23% for translational and applied research purposes. A further 23% of animal uses in procedures were carried out for regulatory use to satisfy legislative requirements, followed by routine production (5%).

Other categories (4%) include the protection of the natural environment in the interest of the health or welfare of human beings or animals, the preservation of species, the higher education or training for the acquisition, maintenance or improvement or vocational skills and the forensic enquiries (Figure 2.1).

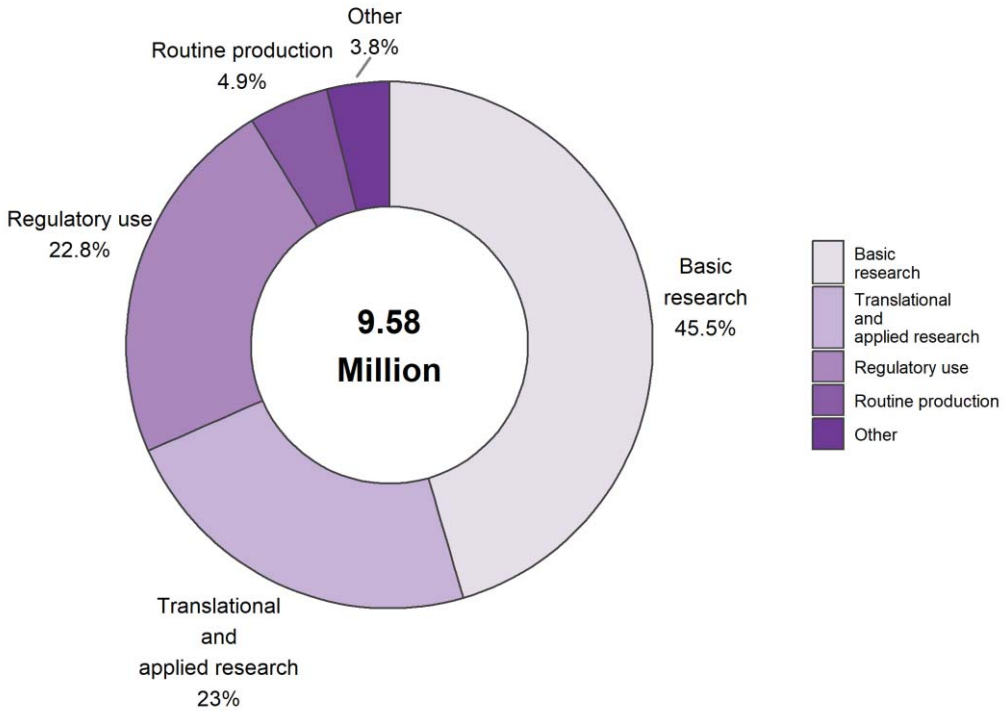

Figure 2.1: Uses of animals used for scientific purpose in 2017

Throughout the entire reporting period (between 2015 and 2017), no clear trend can be identified as the variability across purposes is more significant than the yearly changes. Variations in the "protection of the natural environment in the interests of health or welfare of human being and animals" (+19%) and "preservation of species" (+107%) are related to procedures involving fish larvae (Table 2.2).

	2015	2016	2017
Basic research	4,513,820	4,828,533	4,357,653
Translational and applied research	2,151,261	2,214,034	2,199,956
Regulatory use	2,356,352	2,214,832	2,186,859
Routine production	455,494	455,434	469,358
Higher education or training for the acquisition, maintenance or improvement of vocational skills	162,424	164,495	163,762
Protection of the natural environment in the interests of the health or welfare of human beings or animals	104,834	78,403	124,787
Preservation of species	38,070	71,852	78,893
Forensic enquiries	315	915	473
Total	**9,782,570**	**10,028,498**	**9,581,741**

Table 2.2: Uses of animals by main scientific purposes

III.2.1.2. Severity of uses

Directive 2010/63/EU requires the reporting of the actual severity experienced by the animal when used for scientific purposes. In 2017, just over half, 51% of uses, were reported as 'mild' (up to and including), 32% as 'moderate', and 11% as 'severe'. 6% of uses were reported as 'non-recovery'.

The number of uses reported as severe increased proportionally between 2015 and 2016 (Table 2.3). Almost 35% of this increase can be attributed to an increase in the severe uses for the diagnosis of diseases (85,000). The proportion of severe uses remained the same between 2016 and 2017.

It is important to note that the reporting of actual severities is probably the most challenging element of the Directive to achieve consistent reporting within and between Member States as well as over time. Therefore, any firm conclusions on the results of these early years of reporting should be discouraged.

Furthermore, since the actual severities are linked to the type of uses, and the use patterns vary between Member States, it is not advisable to compare overall actual severities between Member States. As an example, a Member State with high proportion of animal use for the purposes of regulatory testing is likely to have higher proportion of severe uses compared to another Member State having mainly uses in the areas of routine production or education and training.

	2015	2016	2017
Non-recovery	6% (622,034)	6% (620,848)	6% (621,054)
Mild [up to and including]	54% (5,330,549)	52% (5,239,321)	51% (4,865,721)
Moderate	31% (3,010,980)	31% (3,101,054)	32% (3,071,828)
Severe	8% (819,007)	11% (1,067,275)	11% (1,023,138)
Total	**100% (9,782,570)**	**100% (10,028,498)**	**100% (9,581,741)**

Table 2.3: Severity of uses

In 2017, when looking at high level purposes, most of the uses reported as severe were conducted for regulatory purposes (16% of regulatory uses), while routine production were mostly mild. Uses in translational and applied research tended to be more severe than those reported in basic research (Figure 2.2).

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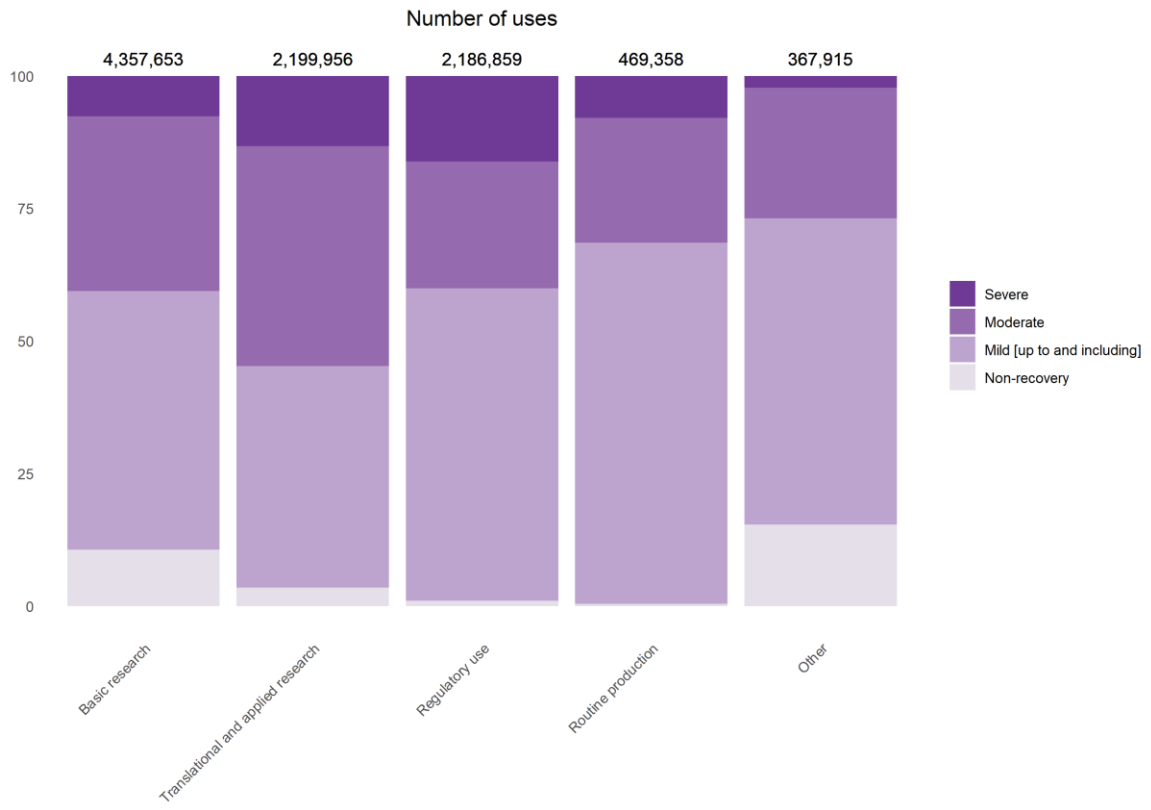

Figure 2.2: Uses of animals by severity and main categories of scientific purposes in 2017

When analysing all the sub-categories of purposes, batch potency testing resulted in the highest number of severe uses (over 264K uses - Figure 2.6), followed by studies on nervous system (over 87K uses - Figure 2.4) and diagnosis of diseases (over 81K uses - Figure 2.5).

When analysing the proportion of severe uses within a sub-category: the production of monoclonal antibodies was the highest (70% of all uses for the production of monoclonal antibodies were severe – Figure 2.10), followed by diagnosis of diseases (54% - Figure 2.5) and acute toxicity studies in the area of ecotoxicity (37% - Figure 2.7).

Taking into account sub-categories with more than 30,000 uses, the lowest severities (severe uses below 1% of all uses within the sub-category) can be found in production of blood based products (0.1% of 260,000 uses – Figure 2.10), followed by preservation of species (0.5% of 79,000 uses – Figure 2.11), education and training (0.5% of 164,000 uses – Figure 2.11) and toxicity testing for skin sensitisation (0.7% of 47,000 uses – Figure 2.7)

III.2.1.3. Main animal species used by high level purpose categories

In 2017, the main species used in basic research were mice (70%), zebra fish (8%), other fish (8%), rats (7%) and domestic fowl (3%). Similar species feature for applied and translational research with proportionally similar uses of mice (70%) and rat (11%). For regulatory use, the distribution changes again slightly with mice covering now only less than half (48%), followed by rat (26%), domestic fowl

(7%), other fish (6%) and rabbits (4%). Routine production has a relatively different pattern compared with the other purpose groups, with rabbits accounting for half (50%), followed by domestic fowl (22%), mice (11%) and sheep (10%).

When looking at different groups of species and the likely purposes they will be used for, fish, mice, amphibians, cephalopods, reptiles and rodents are most likely to be used in basic research. Other mammals (bats), other carnivores are most likely to be used for the purposes of applied and translational research. Rabbits, farmed species and birds are mostly used in routine production and finally guinea-pigs, non-human primates and rats for regulatory purposes (Figure 2.3).

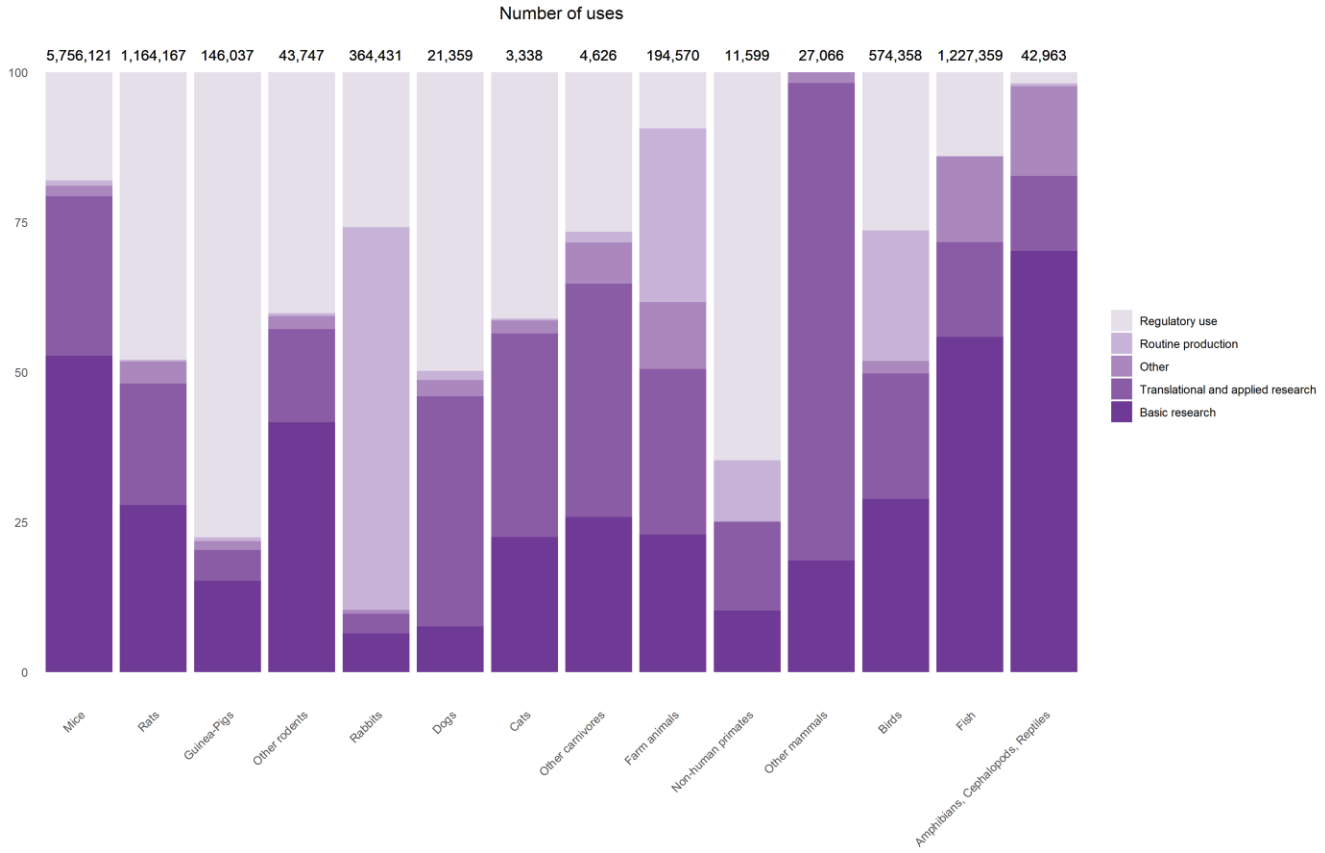

Figure 2.3: Uses of animals grouped by main classes of species and the main scientific purpose categories in 2017

Looking at the details of the uses of non-human primates, 65 % are to satisfy legislative requirements for medicinal products for human use (of these 64% are on studies for repeated dose toxicity and 19% for kinetics). In the areas of basic and applied research, non-human primates are mainly used for studying human infectious disorders (7% of all non-human primate uses), nervous system (3%) and non-regulatory toxicology and ecotoxicology (3%). Routine production, of mostly blood based products, represents 10% of non-human primate uses. Some uses of non-human primates were reported for the purposes of education and training, prohibited under the Directive. However, this may have taken place within the transitional provisions under Article 64 of the Directive, allowed until 31.12.2017. The actual reported severities of uses of non-human primates are lower than the EU averages for all species. In 2017, 54% were of mild severity. Only 1,6% of uses were assessed as severe.

III.2.2. Detailed information on use purposes

III.2.2.1. Research related uses

Research-related uses are split between basic research on one side and translational and applied research on the other. Results on these purpose categories are presented with information on related reported actual severities.

III.2.2.1.1 Basic research

Basic research was the main area for which animals were used with more than 4.3 million uses in 2017.

The four main domains of basic research using most animals are nervous system, immune system, oncology and ethology/animal behaviour/animal biology that all together account for more than half of the uses in basic research (Figure 2.4).

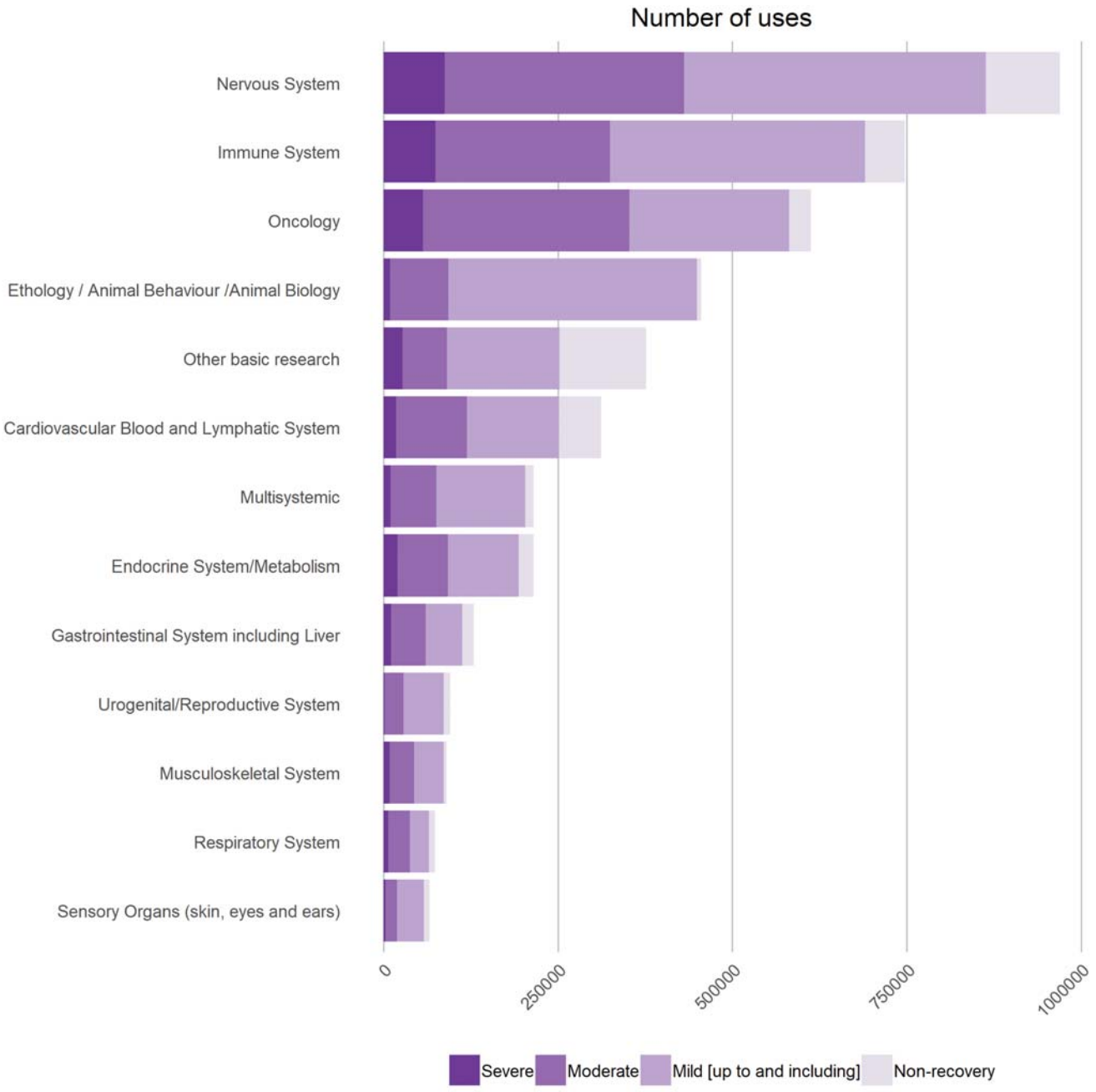

Figure 2.4: Basic research related uses by type of research and severity in 2017

In 2017 compared to 2015, there was an increase in the number of uses of animals for oncology (+19%) and nervous system studies (+13%).

During the same period, the sub-categories gastrointestinal system including liver (-38%), urogenital / reproductive system (-31%), ethology/animal behaviour/animal biology (-25%) and immune system (-7%) saw some regular decreases in terms of uses of animals (Table 2.4).

In 2017, in the area of basic research, proportionally highest severities were reported in following sub-categories: immune system (10%), endocrine system/metabolism (9%), oncology (9%), nervous system (9%) and respiratory system (9%).

Proportionally lowest severities were reported for urogenital/reproductive system, ethology/ animal behavior/animal biology, sensory organs and multisystemic (Figure 2.4).

"Other basic research" includes for example research on nutrition, infectious diseases or embryology.

	2015	2016	2017
Nervous System	857,813	940,453	969,275
Immune System	804,352	753,296	746,907
Oncology	516,404	572,117	612,344
Ethology / Animal Behaviour /Animal Biology	605,239	564,042	455,475
Other basic research	274,083	414,466	376,584
Cardiovascular Blood and Lymphatic System	338,606	351,636	311,676
Multisystemic	297,605	423,227	215,262
Endocrine System/Metabolism	209,128	301,727	215,212
Gastrointestinal System including Liver	208,033	153,751	129,593
Urogenital/Reproductive System	137,957	112,294	95,475
Musculoskeletal System	92,670	93,387	90,403
Respiratory System	85,778	75,577	73,946
Sensory Organs (skin, eyes and ears)	86,152	72,560	65,501
Total	**4,513,820**	**4,828,533**	**4,357,653**

Table 2.4: Basic research related uses by type of research

III.2.2.1.2. Translational and applied research

Translational and applied research accounted for about 2.2 million uses of animals in 2017.

The four main areas of translational and applied research were human cancer, human nervous and mental disorders, human infectious disorders and animal diseases and disorders.

In 2017, in the area of translational and applied research, proportionally highest severities were reported in following sub-categories: diagnosis of diseases (54%), animal diseases disorders (24%), human immune disorders (22%), human musculoskeletal disorders (16%) and other human disorders (15%).

Proportionally lowest severities were reported for plant diseases, human sensory organs and non-regulatory toxicology and ecotoxicology (Figure 2.5).

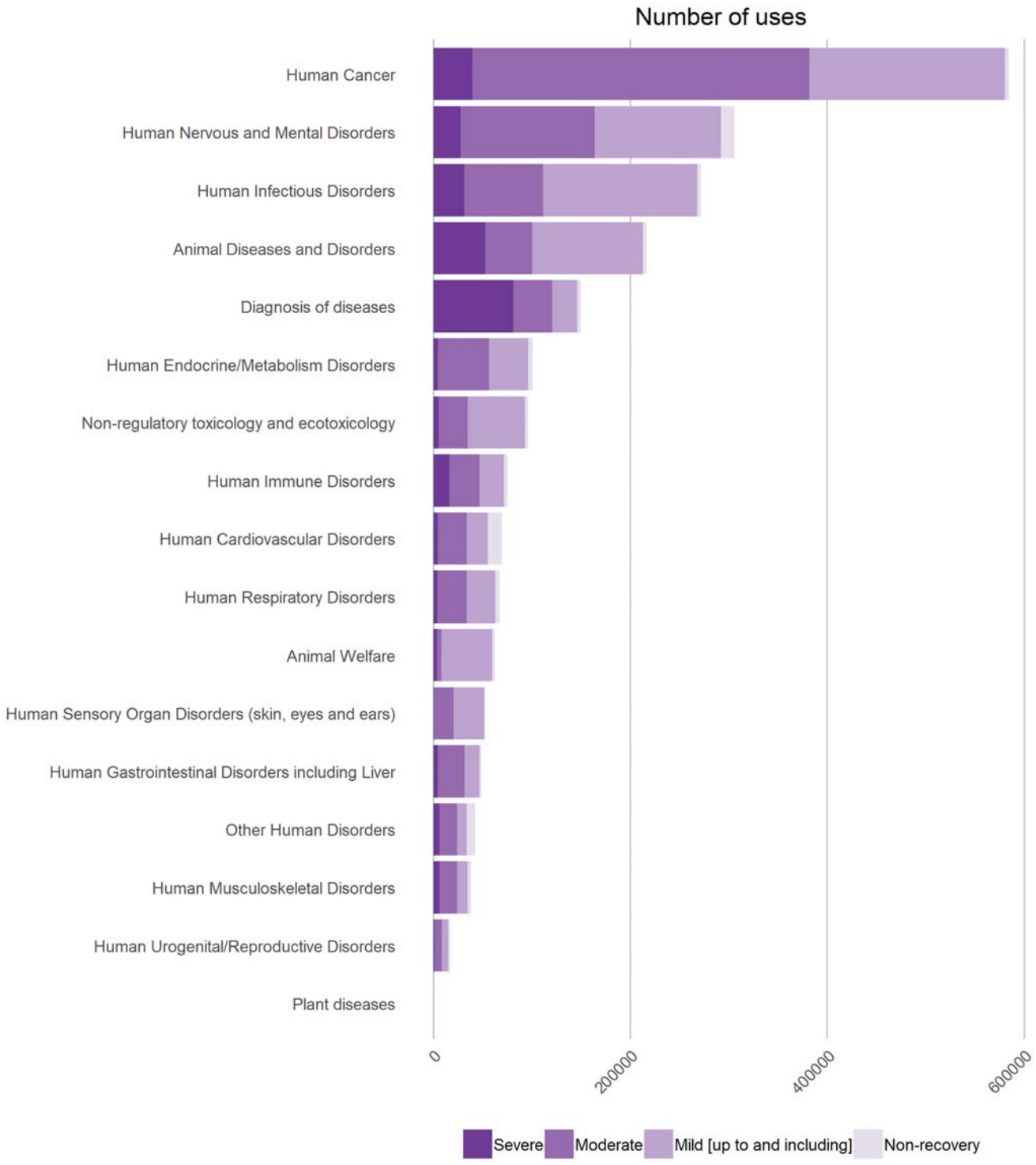

Figure 2.5: Translational and applied research related uses by type of research and severity in 2017

Between 2015 and 2017, the sub-categories diagnosis of disease (+76%) and human gastrointestinal disorders including liver (+50%) saw a significant increase. Animal uses for non-regulatory toxicology and ecotoxicology (+20%) as well as human cancer (+19%) showed also an increase.

Sub-categories animal welfare (-20%), human endocrine/metabolism disorders (-18%) and human nervous and mental disorders (-12%) decreased over the same period (Table 2.5).

	2015	2016	2017
Human Cancer	492,320	538,261	584,601
Human Nervous and Mental Disorders	345,899	307,087	305,782
Human Infectious Disorders	282,202	283,098	271,847
Animal Diseases and Disorders	223,813	259,986	216,721
Diagnosis of diseases	84,963	170,738	149,687
Human Endocrine/Metabolism Disorders	123,813	107,704	100,663
Non-regulatory toxicology and ecotoxicology	79,911	87,350	96,160
Human Immune Disorders	77,250	71,555	75,342
Human Cardiovascular Disorders	62,163	64,505	69,606
Human Respiratory Disorders	66,384	65,857	67,395
Animal Welfare	78,515	73,754	62,367
Human Sensory Organ Disorders (skin, eyes and ears)	46,386	52,977	52,841
Human Gastrointestinal Disorders including Liver	32,210	43,687	48,630
Other Human Disorders	105,773	38,528	42,654
Human Musculoskeletal Disorders	31,274	36,142	38,315
Human Urogenital/Reproductive Disorders	17,905	12,679	17,169
Plant diseases	480	126	176
Total	**2,151,261**	**2,214,034**	**2,199,956**

Table 2.5: Translational and applied research related uses by type of research

“Other Human Disorders” includes areas such as haemophilia, pharmacokinetics or pain disorders.

III.2.2.2. Uses of animals for regulatory purposes

Regulatory uses cover the use of animals in procedures with a view to satisfying regulatory requirements, that is to say for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. It also includes tests carried out on products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because these were deemed unsuitable for the market by the developer and thus failed to reach the end of the development process.

Between 2015 and 2017, the total number of uses for regulatory purposes decreased (-7%).

In 2017, regulatory uses accounted for 2.18 million uses, just below translational and applied research. 52% of these uses were related to quality control (including batch safety and potency testing), 39% related to toxicity and other safety testing including pharmacology and the remainder (9%) were for other efficacy and tolerance testing (Table 2.6).

	2015	2016	2017
Quality control (incl batch safety and potency testing)	1,332,536	1,218,170	1,131,580
Toxicity and other safety testing including pharmacology	873,587	831,683	843,375
Other efficacy and tolerance testing	150,229	164,979	211,904
Total	**2,356,352**	**2,214,832**	**2,186,859**

Table 2.6: Regulatory uses by main types of uses

III.2.2.2.1. Details of the regulatory use purposes

III.2.2.2.1.1. Quality control related uses

Quality control includes uses of animals in the testing of purity, stability, efficacy, potency and other quality control parameters product (and its constituents) such as vaccines, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer.

Quality control related uses represented 1.1 million uses in 2017. A large majority of these uses were related to batch potency-testing purposes (79%).

With more than 261,000 severe uses, batch potency testing was the most severe type of procedure, representing more than 25% of all severe uses in EU (Figure 2.6).

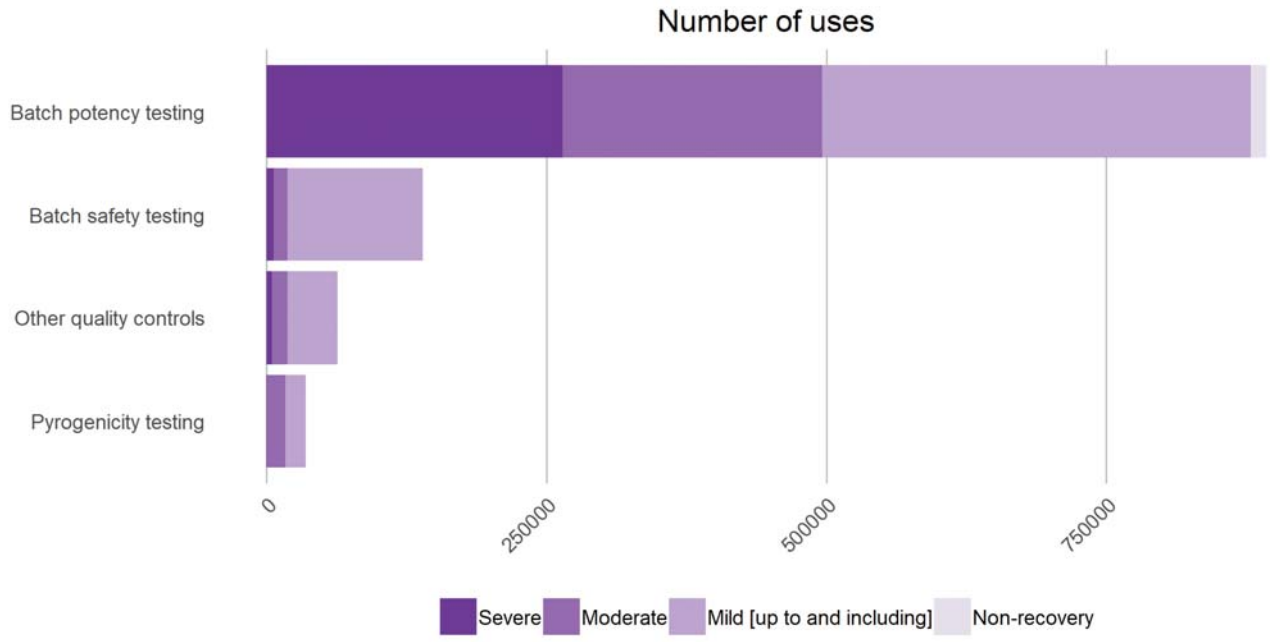

Figure 2.6: Quality control related uses by type of use and severity in 2017

Overall, quality control related uses decreased between 2015 and 2017 (-15%) with a decrease for batch safety testing (-39%), for batch potency testing (-14%) and for pyrogenicity testing (-24%) (Table 2.7).

"Other quality controls" are related for example to stability testing of vaccines. Increase in "Other quality controls" (+157%) was mainly due to studies involving fish larvae and no clear trend can be determined.

	2015	2016	2017
Batch potency testing	1,032,235	945,013	892,723
Batch safety testing	228,817	152,443	139,602
Other quality controls	24,931	81,280	64,083
Pyrogenicity testing	46,553	39,434	35,172
Total	**1,332,536**	**1,218,170**	**1,131,580**

Table 2.7: Quality control related uses by type of use

III.2.2.2.1.2. Toxicity and other safety testing including pharmacology

Toxicity and other safety testing (including safety evaluation of products and devices for human medicine and dentistry and veterinary medicine) covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, manufacture or as a potential or actual contaminant in the environment.

Toxicity and other safety testing including pharmacology represented more than 840,000 uses of animals in 2017, which corresponds to 9% of all uses of animals.

Most of the uses in this area were related to reproductive toxicity, repeated dose toxicity, pharmaco-dynamics, developmental toxicity, ecotoxicity and acute and sub-acute toxicity.

In 2017, proportionally highest severities were reported in following sub-categories: safety testing in food and feed area (24%), neurotoxicity (23%), ecotoxicity (21%), acute and sub-acute toxicity (18%).

Proportionally lowest severities were reported for skin irritation/corrosion, skin sensitisation, animal safety, kinetics, carcinogenicity, eye irritation/corrosion and reproductive toxicity (Figure 2.7).

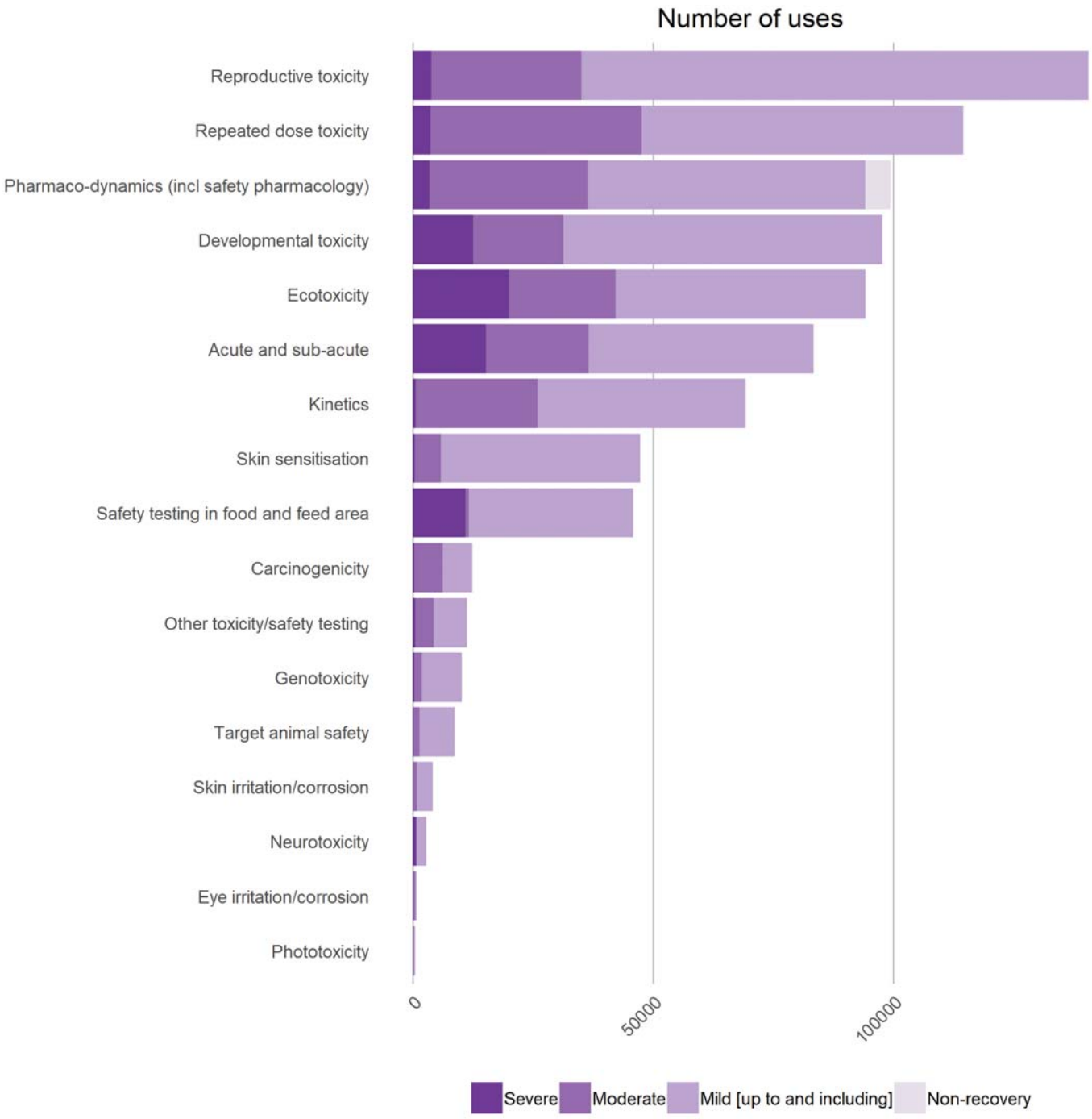

Figure 2.7: Toxicity and other safety testing including pharmacology by type of use and severity in 2017

Between 2015 and 2017 (Table 2.8), the total number of uses for toxicity and other safety testing including pharmacology slightly decreased (-4%).

Reproductive toxicity related uses saw a significant increase (+45%) as well as safety testing in the food and feed area (+28%).

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A significant decrease in the number of uses was observed in 2017 compared to 2015 for the following areas carcinogenicity (-48%), target animal safety (-42%), neurotoxicity (-72%) and eye irritation/corrosion (-46%) (Table 2.8).

"Other toxicity/safety testing" are related for example to metabolism pharmacokinetic or radiopharmacology.

	2015	2016	2017
Reproductive toxicity	96,926	102,815	140,513
Repeated dose toxicity	119,910	111,720	114,573
Pharmaco-dynamics (incl safety pharmacology)	110,764	114,208	99,353
Developmental toxicity	113,026	117,435	97,671
Ecotoxicity	105,145	88,179	94,347
Acute and sub-acute	94,261	99,716	83,405
Kinetics	64,522	60,917	69,373
Skin sensitisation	49,549	51,645	47,341
Safety testing in food and feed area	35,723	40,310	45,800
Carcinogenicity	24,023	5,328	12,493
Other toxicity/safety testing	15,528	9,959	11,258
Genotoxicity	12,405	9,597	10,303
Target animal safety	15,118	12,022	8,717
Skin irritation/corrosion	4,773	3,222	4,120
Neurotoxicity	9,800	3,066	2,769
Eye irritation/corrosion	1,518	1,075	814
Phototoxicity	596	469	525
Total	**873,587**	**831,683**	**843,375**

Table 2.8: Toxicity and other safety testing including pharmacology by type of use

Acute and sub and sub-acute testing methods uses

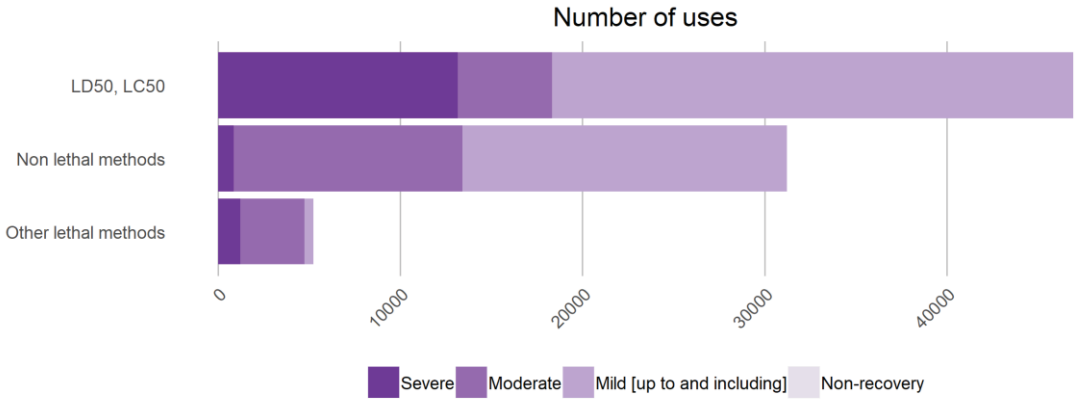

Figure 2.8: Acute and sub-acute uses testing methods by type of uses and severity in 2017

	2015	2016	2017
LD50, LC50	58,311	63,152	46,939
Non-lethal methods	32,120	31,406	31,218
Other lethal methods	3,830	5,158	5,248
Total	**94,261**	**99,716**	**83,405**

Table 2.9: Acute and sub-acute uses testing methods by type of use

Repeated dose toxicity uses

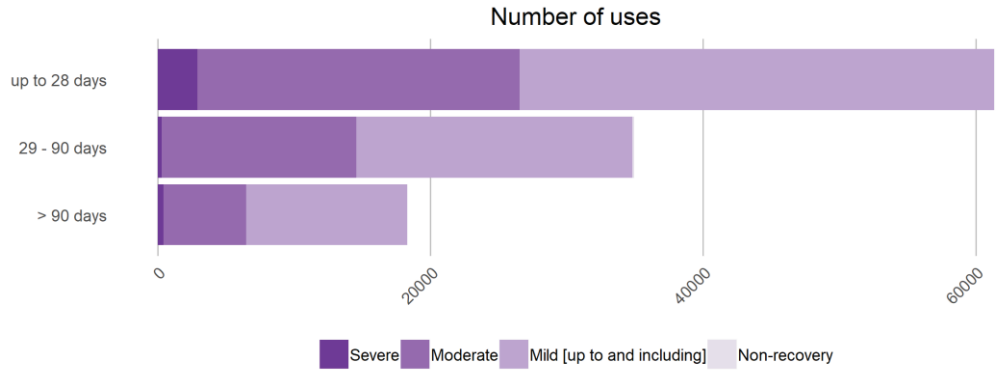

Figure 2.9: Repeated dose toxicity by type of uses and severity in 2017

	2015	2016	2017
up to 28 days	73,692	55,323	61,344
29 - 90 days	28,023	34,558	34,931
> 90 days	18,195	21,839	18,298
Total	**119,910**	**111,720**	**114,573**

Table 2.10: Repeated dose toxicity by type of use

Ecotoxicity

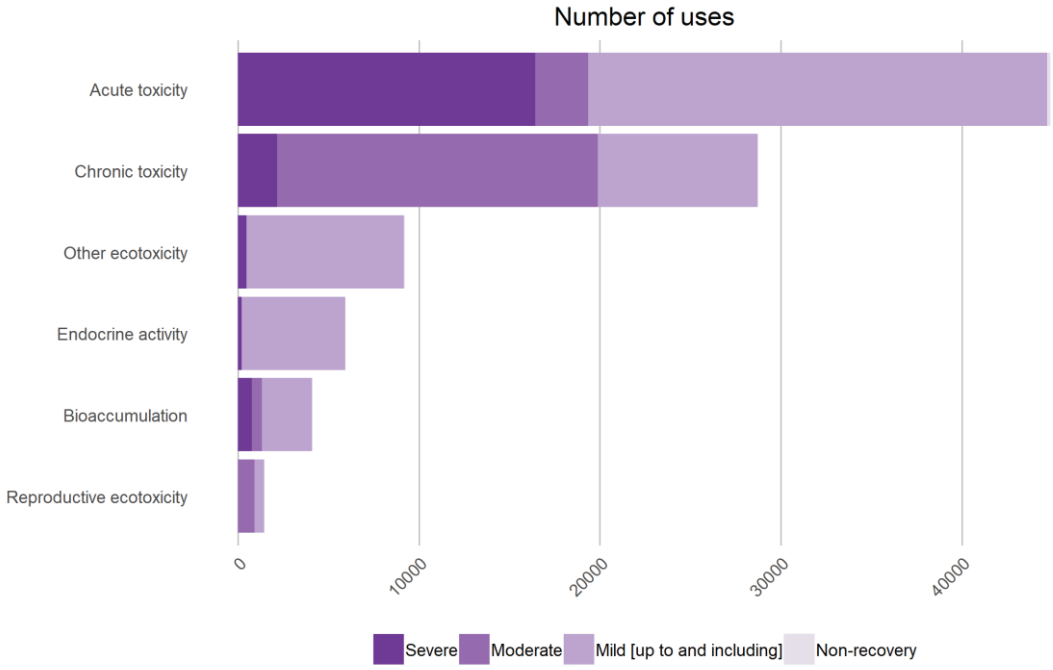

Figure 2.10: Ecotoxicity by type of uses and severity in 2017

	2015	2016	2017
Acute toxicity	60,094	46,581	44,915
Chronic toxicity	20,161	23,235	28,738
Other ecotoxicity	8,377	2,261	9,210
Endocrine activity	9,910	7,769	5,924
Bioaccumulation	2,950	4,258	4,110
Reproductive ecotoxicity	3,653	4,075	1,450
Total	**105,145**	**88,179**	**94,347**

Table 2.11: Ecotoxicity by type of use

III.2.2.2.1.3. Other efficacy and tolerance testing

This category of regulatory use refers to uses that are neither linked to quality control nor to toxicity testing. These uses are related to, for example, efficacy testing of biocides and pesticides as well as tolerance testing of additives in animal nutrition. They represented little more than 210,000 uses in 2017.

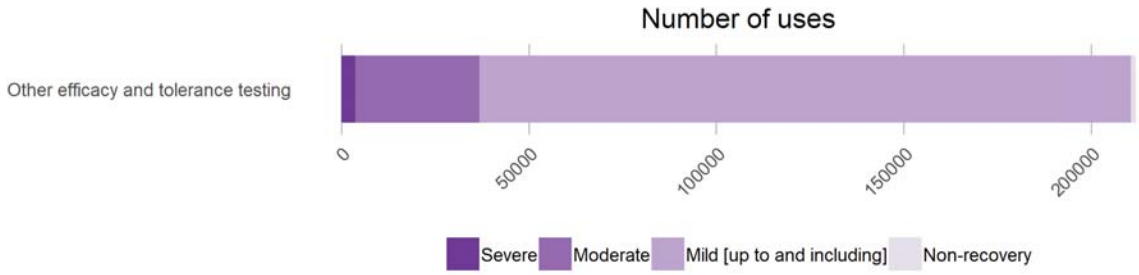

Figure 2.11: Other efficacy and tolerance testing by type of use and severity in 2017

Between 2015 and 2017, the total number of uses for other efficacy and tolerance testing increased (+29%) mostly due to the use of fish larvae for nutritional tests in 2016. In 2017, most of the procedures were mild (82%) with particularly low proportion of severe (2%) and non-recovery (0.6%) uses (Table 2.12).

	2015	2016	2017
Other efficacy and tolerance testing	150,229	164,979	211,904

Table 2.12: Other efficacy and tolerance testing

III.2.2.2.2. Legislative aspects of regulatory uses

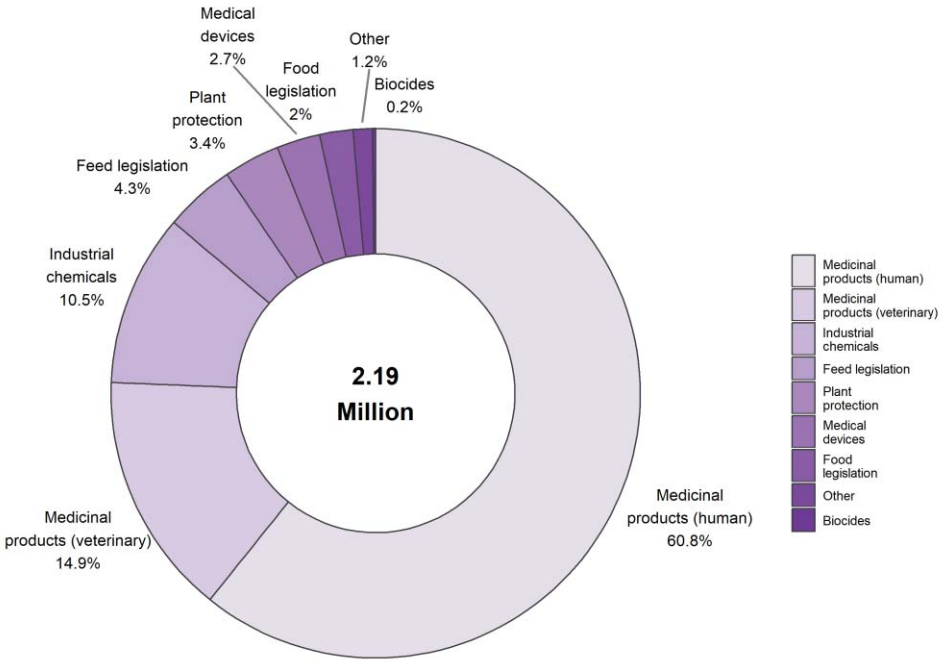

Figure 2.12: Regulatory uses by type of legislation in 2017

In 2017, the majority of uses to satisfy legislative requirements of specific sector legislation occurred in relation to placing on the market of medicinal products for humans (61%), veterinary medicinal products (15%) and industrial chemicals (11%) (Figure 2.12).

Between 2015 and 2017, the uses to satisfy legislative requirements for medical products for human use decreased (-12%) while those related to medical device legislation uses (+23%) and industrial chemicals legislation uses (+17%) saw an increase. No uses were reported under cosmetics legislation (Table 2.13).

	2015	2016	2017
Legislation on medicinal products for human use	1,518,123	1,422,456	1,328,948
Legislation on medicinal products for veterinary use and their residues	368,571	337,054	325,486
Industrial chemicals legislation	195,950	214,772	230,177
Feed legislation including legislation for the safety of target animals, workers and environment	40,252	36,586	94,515
Plant protection product legislation	72,084	61,502	75,205
Medical devices legislation	47,270	48,944	58,312
Food legislation including food contact material	47,342	43,555	44,273
Other legislation	61,864	42,875	25,814
Biocides legislation	4,896	7,088	4,129
Total	**2,356,352**	**2,214,832**	**2,186,859**

Table 2.13: Regulatory uses by type of legislation

In 2017, the majority of regulatory uses were performed to satisfy regulatory requirements originating from the EU (95%). Non-EU requirements accounted for 4% and national requirements for 1% (Table 2.14).

The sub-category on legislation satisfying EU requirements also includes any requirements for which international harmonisation has been achieved, such as for testing to OECD, ICH[6] and VICH[7] standards. Harmonisation of testing requirements at a global level is of utmost importance when aiming to avoid unnecessary duplication of testing.

6 The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

7 The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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	2015	2016	2017
Legislation satisfying EU requirements	94% (2,222,617)	93% (2,058,553)	95% (2,081,082)
Legislation satisfying Non-EU requirements only	4% (92,161)	5% (110,848)	4% (82,895)
Legislation satisfying national requirements only [within EU]	2% (41,574)	2% (45,431)	1% (22,882)
Total	**100% (2,356,352)**	**100% (2,214,832)**	**100% (2,186,859)**

Table 2.14: Regulatory uses by origin of regulatory requirement

Legislation on medicinal products for human or veterinary uses is mainly related to quality controls. Industrial chemical legislation and other legislations focus more specifically on toxicity testing. Feed legislation is mainly related to other efficacy testing.

It is important to note in this context that some of the data submissions still contained entries, which seem to indicate legislation irrelevant to the type of testing being carried out. Further efforts are being undertaken to improve the accuracy of the reporting (Table 2.15).

	Quality control (incl batch safety and potency testing)	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing
Legislation on medicinal products for human use	889,709	353,824	85,415
Legislation on medicinal products for veterinary use and their residues	239,687	46,810	38,989
Medical devices legislation	1,591	55,733	988
Industrial chemicals legislation	100	229,891	186
Plant protection product legislation	0	74,763	442
Biocides legislation	260	3,219	650
Food legislation including food contact material	0	44,187	86
Feed legislation including legislation for the safety of target animals, workers and environment	19	9,889	84,607
Other legislation	214	25,059	541
Total	**1,131,580**	**843,375**	**211,904**

Table 2.15: Regulatory use by type of legislation in 2017

In terms of severity levels, in 2017, for the legislative context, 16% of total uses in the area of regulatory testing were reported as severe, 24% as moderate, 59% mild (and up to mild) and 1% as non-recovery (Figure 2.2).

Even if the total numbers of uses are not the most significant in the area of food legislation, the proportion of severe uses is relatively high. This category included still in 2017 the use of mouse bioassay for the purposes of shellfish toxin testing. In the area of 'Other' legislations, 25% of procedures were reported as severe concerning mainly waste water toxicity studies on fish.

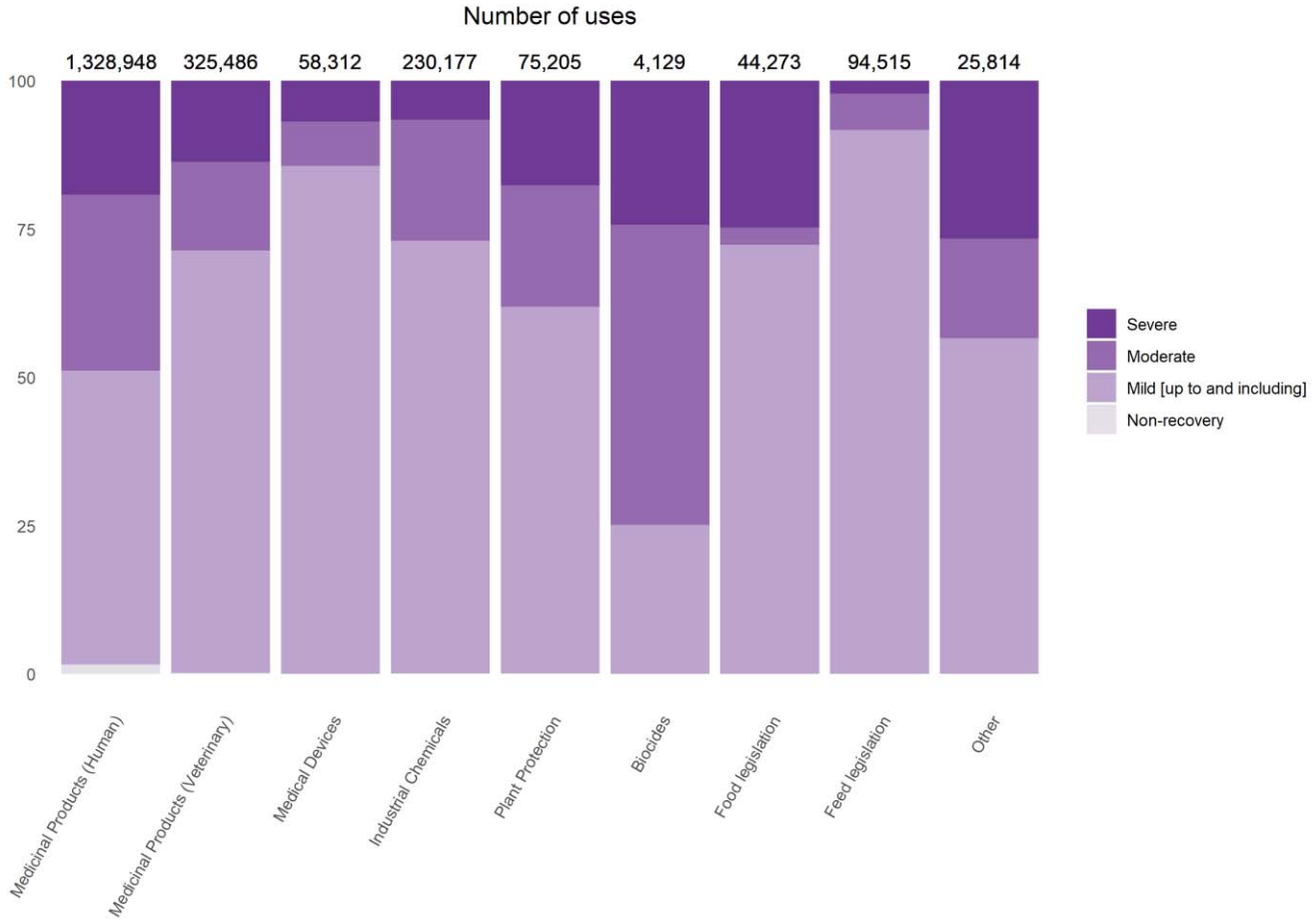

Figure 2.13: Regulatory use by type of legislation and severity in 2017

III.2.2.3. Routine production uses

Routine production includes the production of antibodies and blood products, including polyclonal antisera by established methods.

In 2017, there were about 469,000 routine production uses, which represented 5% of all uses of animals in the EU. 55% of routine uses were related to the production of blood-based products and 10% for monoclonal antibodies production by mouse ascites method (Figure 2.14).

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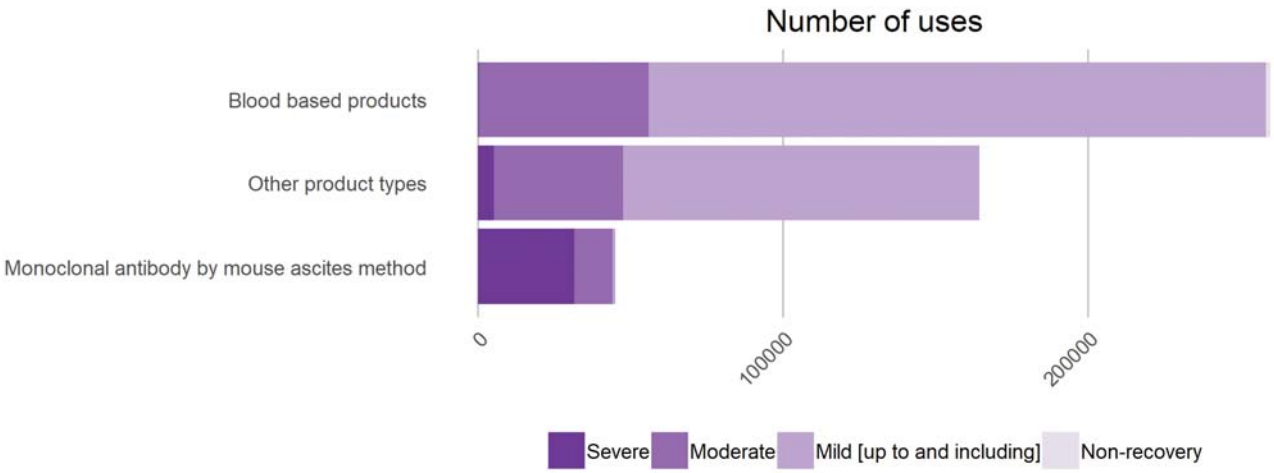

Figure 2.14: Routine production uses by product type and severity in 2017

While blood based products involved only mild and moderate levels of severity, monoclonal antibody production by mouse ascites method involved mostly severe uses (70%) (Figure 2.14).

	2015	2016	2017
Blood based products	271,393	260,228	259,780
Other product types	156,768	146,272	164,554
Monoclonal antibody by mouse ascites method	27,333	48,934	45,024
Total	**455,494**	**455,434**	**469,358**

Table 2.16: Routine production uses by product type

Other product types that represented 35% of the uses were mostly related to antigen and protein production.

Between 2015 and 2017, monoclonal antibody production by mouse ascites method saw an increase of 66%.

III.2.2.4. Other types of uses

Lastly, four categories of other uses are also reported as part of the Directive covering more than 367,000 uses: higher education and training for the acquisition, maintenance or improvement of vocational skills; protection of the natural environment in the interests of the health or welfare of human beings or animals; preservation of species; and forensic enquiries.

With 163,000 uses in 2017, higher education and training is the biggest category of the remaining purposes. At the same time, it is important to note that the severities linked to higher education and training, and on studies on preservation of species, are some of the lowest. Higher education has the

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largest proportion of non-recovery uses (31%). Forensic inquiry uses are limited to just a few hundreds. (Figure 2.15).

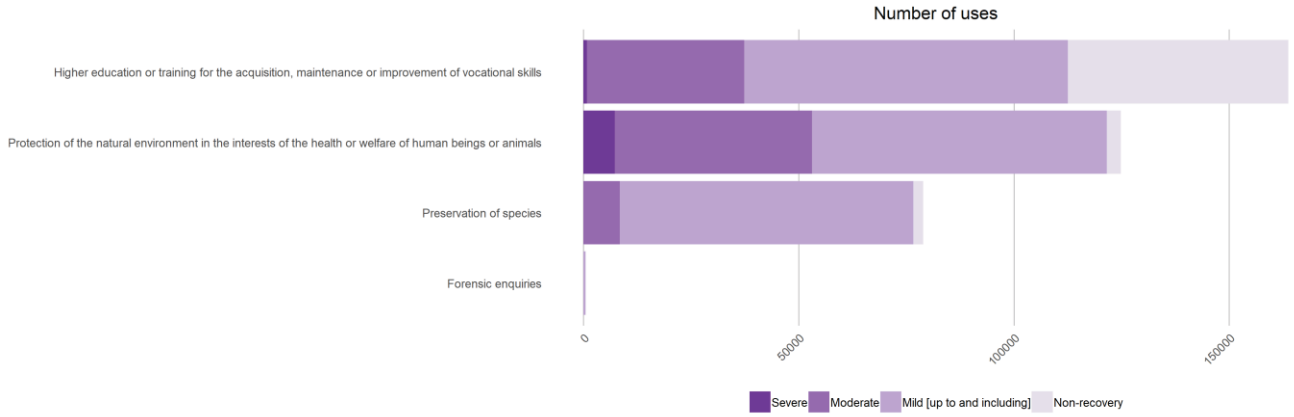

Figure 2.15: Other types of uses in 2017 including their severity

Between 2015 and 2017, there was an increase in the number of uses for the preservation of species (+107%) and protection of the natural environment (+16%), with important variations from one year to another due to studies on fish larvae where a single study can contain thousands of fish larvae (Table 2.17).

	2015	2016	2017
Higher education or training for the acquisition, maintenance or improvement of vocational skills	162,424	164,495	163,762
Protection of the natural environment in the interests of the health or welfare of human beings or animals	104,834	78,403	124,787
Preservation of species	38,070	71,852	78,893
Forensic enquiries	315	915	473
Total	**305,643**	**315,665**	**367,915**

Table 2.17: Other types of uses

III.2.3. Information on reuses and genetic status of animals

The Directive requires additional elements to be recorded related to the use of animals for scientific purposes, such as reuse and information on the genetic status of the animals.

III.2.3.1. Reuses

In line with the principle of the Three Rs[8], the total number of animals used in procedures can be reduced by performing procedures on animals more than once. However, this should only take place

[8] To Replace, Reduce and Refine the use of animals in scientific procedures

when this does not result in poor animal welfare, and is evaluated on a case-by-case basis. Under Directive 2010/63/EU, reuse of animals in procedures is permitted only under specific conditions related to the actual level of severity the animal has experienced in a previous procedure, and the health and well-being of the animal, taking into account the lifetime experience of the individual animal. A reuse cannot be authorised for a procedure, in which the animal may reach 'severe' level of pain, suffering or distress. Also, an animal may be reused following a severe procedure only in exceptional circumstances and after a veterinary examination of that animal.

Between 2015 and 2017, the proportion of reuses remained stable at 2% (Table 2.18)

	2015	2016	2017
No	98% (9,590,379)	98% (9,817,946)	98% (9,388,162)
Yes	2% (192,191)	2% (210,552)	2% (193,579)
Total	**100% (9,782,570)**	**100% (10,028,498)**	**100% (9,581,741)**

Table 2.18: Reuses of animals used for research, testing, routine production and educational purposes

III.2.3.2.1. Animal species reused

In absolute numbers, the main species reused for scientific purposed in 2017 were mice, sheep, rats, rabbits, horses, donkeys and cross-breeds.

In proportions, large mammals are more often reused such as horses, donkeys and cross-breeds (82%), sheep (71%), cats (44%), dogs (36%) and cynomolgus monkeys (28%).

Reptiles (55%) and xenopus (37%) amongst amphibians were also often reused (Table 2.19).

	Total number of uses	Number of reuses	Proportion of reuses
Mice	5,756,121	48,650	1%
Rats	1,164,167	17,868	2%
Guinea-Pigs	146,037	1,213	1%
Hamsters (Syrian)	12,723	23	0%
Mongolian gerbil	5,385	146	3%
Other Rodents	25,452	280	1%
Rabbits	364,431	12,470	3%
Cats	3,338	1,459	44%
Dogs	21,359	7,671	36%
Ferrets	2,112	96	5%
Other carnivores	2,514	128	5%
Horses, donkeys and cross-breeds	13,624	11,210	82%
Pigs	75,875	4,353	6%
Goats	2,268	705	31%
Sheep	65,527	46,715	71%
Cattle	37,276	6,633	18%

Prosimians	173	75	43%
Marmoset and tamarins	646	181	28%
Other species of New World Monkeys (Ceboidea)	3	0	0%
Cynomolgus monkey	10,007	2,780	28%
Rhesus monkey	628	275	44%
Vervets (Chlorocebus spp.)	53	20	38%
Baboons	46	21	46%
Other species of Old World Monkeys (Cercopithecoidea)	35	12	34%
Other Mammals	27,066	731	3%
Domestic fowl	472,012	7,459	2%
Other birds	102,346	2,936	3%
Reptiles	6,562	3,625	55%
Rana	3,498	13	0%
Xenopus	21,443	7,904	37%
Other Amphibians	10,946	263	2%
Zebra fish	504,183	4,420	1%
Other Fish	723,176	3,244	0%
Total	**9,581,032**	**193,579**	**100%**

Table 2.19: Reuses by type of species in 2017

III.2.3.2.2. Reuse by purposes of procedures

In 2017, routine production had the largest proportion of reuses (12%) mainly for blood-based products. The second most common use purpose for which animals have been reused was higher education and training (Table 2.20).

	Total number of uses	Number of reuses	Proportion
Basic research	4,357,653	58,499	1%
Translational and applied research	2,199,956	29,798	1%
Regulatory use	2,186,859	34,863	2%
Routine production	469,358	55,826	12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	163,762	13,323	8%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	124,787	1,259	1%
Preservation of species	78,893	11	0%
Forensic enquiries	473	0	0%

Table 2.20: Reuses by purposes in 2017

III.2.3.2.3. Severity of reuse

According to the Directive, reuse of an animal is not allowed in a procedure classified prospectively as severe. In 2017, most of the reuses, the actual reported severities were mild (74%) or moderate (19%) (Figure 2.16).

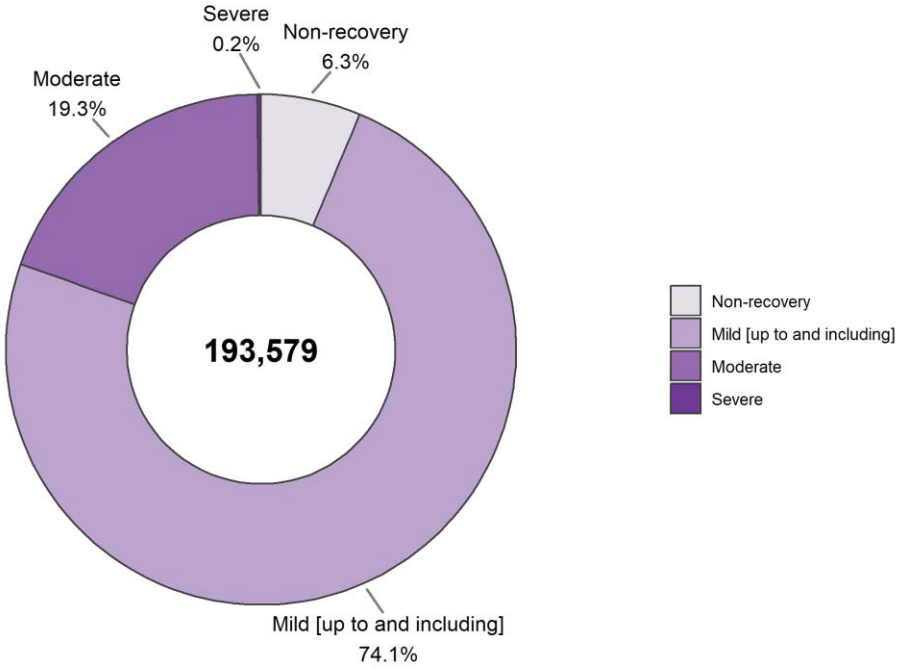

Figure 2.16: Reuses by severity in 2017

However, in some cases, even if the procedure is prospectively classified in a lower severity category, an individual animal may reach severity category "severe" due to unforeseen events occurring during the procedure. Only a very small number of such cases (<1 %) was reported.

These cases should be investigated by the user to eliminate any recurrence of any repetitive unforeseen adverse effects. Furthermore, these events, if recurring, may suggest a need for a revision of the prospective classification for future uses.

	2015	2016	2017
Non-recovery	3% (5,067)	6% (12,157)	6% (12,240)
Mild [up to and including]	80% (152,817)	80% (168,387)	74% (143,478)
Moderate	18% (33,983)	14% (29,743)	19% (37,411)
Severe	0% (324)	0% (265)	0% (450)
Total	**100% (192,191)**	**100% (210,552)**	**100% (193,579)**

Table 2.21: Severity classification of reuse procedures

Between 2015 and 2017, the number of reuses remained stable in total with an increase of non-recovery reuses (+39%).

III.2.3.2. Use of genetically altered animals

Some of the animals used in procedures for purposes of research, testing, routine production and education are genetically altered. This section presents the types of genetic alteration reported. A welfare assessment is required to be performed on a newly created genetically altered animal line to establish whether the line is expected to have an intended non-harmful or harmful phenotype.

Intended non-harmful phenotypes include animal models where no adverse effects are noted during development, breeding and maintenance under conventional laboratory animal conditions. In addition, non-harmful phenotype lines include inducible and cre-lox lines, which require an active intervention for the harmful phenotype to be expressed.

Intended harmful phenotypes include animal models where gene alteration induces a specific genetic disorder or disease, or increases incidence of / susceptibility to for example tumour development. Other examples of harmful phenotype lines include those that require a specific bio-secure environment (for example, special housing arrangements to protect animals that are particularly sensitive to infection as a consequence of the gene alteration) or additional care beyond that required for conventional animals to maintain their health and well-being.

III.2.3.2.1. Type of genetic alteration

In 2017, 2.57 million uses for the purposes of research were carried out on animals that were genetically altered. Of these, 17% were of a harmful phenotypic alteration.

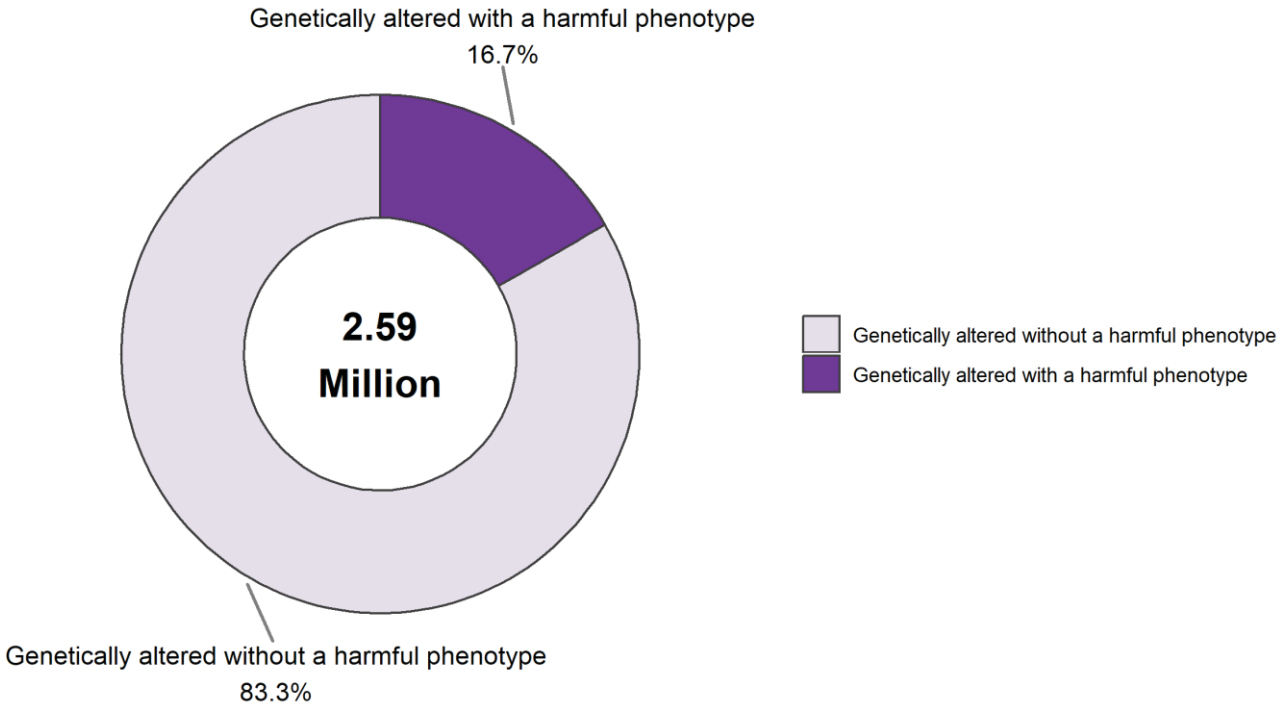

Figure 2.17: Uses of animals by type of genetic alteration in 2017

Between 2015 and 2017, the proportion of the uses of genetically altered animals for scientific purposes increased slightly. The percentage of the uses of such animals with a harmful phenotype increased from 4% to 5%, and the uses of such animals without a harmful phenotype increased from 21% to 23%.

	2015	2016	2017
Genetically altered with a harmful phenotype	4% (397,525)	4% (435,075)	5% (432,206)
Genetically altered without a harmful phenotype	21% (2,038,618)	23% (2,344,954)	23% (2,157,696)
Not genetically altered	75% (7,346,427)	72% (7,248,469)	73% (6,991,839)
Total	**100% (9,782,570)**	**100% (10,028,498)**	**100% (9,581,741)**

Table 2.22: Genetic status of animals used

III.2.3.2.2. Genetically altered animals by species

Amongst the species, which have been genetically altered, uses of mice accounted for the highest numbers, followed by zebra fish and rats.

Even if mice accounts for the most animals being genetically altered, in proportion, 64% of zebra fish was genetically altered, followed by mice (38%), while only 3% of rats were genetically altered used in procedures for purposes of research, testing, routine production in 2017 (Table 2.23).

	Total number of uses	Uses of genetically altered animals	Proportion
Zebra fish	504,183	323,741	64%
Mice	5,756,121	2,196,801	38%
Xenopus	21,443	2,146	10%
Rabbits	364,431	27,630	8%
Other Amphibians	10,946	671	6%
Rats	1,164,167	32,399	3%
Hamsters (Syrian)	12,723	187	1%
Other Fish	723,176	5,029	1%
Pigs	75,875	501	1%
Dogs	21,359	132	1%
Domestic fowl	472,012	637	<1%
Other Mammals	27,066	23	<1%
Sheep	65,527	5	<1%

Table 2.23: Genetically altered animals by species in 2017

This situation is mainly explained by the fact that genetically altered animals are used almost exclusively for research purposes. Indeed, in 2017, basic research accounted for 75% of uses of genetically altered animals and translational and applied research for 21% (Table 2.24).

	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total
Basic research	55% (2,413,441)	38% (1,642,212)	7% (302,000)	**100% (4,357,653)**
Translational and applied research	75% (1,655,814)	19% (416,794)	6% (127,348)	**100% (2,199,956)**
Regulatory use	98% (2,139,622)	2% (45,466)	0% (1,771)	**100% (2,186,859)**
Routine production	94% (441,479)	6% (27,879)	0% (0)	**100% (469,358)**
Higher education or training for the acquisition, maintenance or improvement of vocational skills	92% (150,292)	8% (12,769)	0% (701)	**100% (163,762)**
Preservation of species	84% (65,948)	16% (12,567)	0% (378)	**100% (78,893)**
Protection of the natural environment in the interests of the health or welfare of human beings or animals	100% (124,778)	0% (9)	0% (0)	**100% (124,787)**
Forensic enquiries	98% (465)	0% (0)	2% (8)	**100% (473)**

Table 2.24: Genetic status of animals by use purposes in 2017

III.3. Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

In the context of Directive 2010/63/EU, Member States are also required to report the animals used in procedures for the creation of new genetically altered animal lines and the maintenance of colonies of established genetically altered animal lines to support the research needs in the EU.

Diagram in part III.3 provides further understanding of the reporting requirements for both creation and maintenance of genetically altered animal lines.

III.3.1. Numbers of animals used for the creation and maintenance of genetically altered animals

In 2017, 1,276,587 animals were used for the provision of genetically altered animals for the purposes of scientific research.

This included 634,705 animals used for the first time for the creation of new genetically altered animal lines (Table 3.5), and 641,882 animals used for the first time for the maintenance of colonies of established genetically altered animal lines (Table 3.9).

III.3.2. All uses of animals for the creation of new genetic altered animal lines

The creation of a new genetic altered animal line is reported under the research purpose category for which the line is being created for. The reporting covers all animals carrying the genetic alteration. In addition, those used for superovulation, vasectomy and embryo implantation are equally reported (these may or may not be genetically altered themselves). Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line are not reported in the annual statistics. (Diagram in Part III.4).

Counting all uses, the main species that were used for the creation of new genetic altered animal lines were mice and zebra fish, 75% and 23% respectively. Other species, although in small numbers, include rats, other species of fish, domestic fowl, rabbits, xenopus and pigs.

In 2017, the use of non-human primates (marmosets) for the creation of a new genetically altered line was reported for the first time in the EU.

Between 2015 and 2017, the creation of new genetic lines increased overall by 7% (Table 3.1).

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	2015	2016	2017
Mice	477,783	359,894	490,717
Zebra fish	124,359	122,082	150,596
Rats	4,381	6,039	9,960
Other Fish	2,556	10,737	4,569
Domestic fowl	279	515	647
Rabbits	272	967	475
Xenopus	7,259	1,100	250
Pigs	350	284	227
Other Mammals	4	0	61
Sheep	31	191	17
Marmoset and tamarins	0	0	10
Guinea-Pigs	0	47	0
Other Rodents	0	6	0
Total	**617,274**	**501,862**	**657,529**

Table 3.1: Uses of animals for the creation of new genetically altered animal lines by species

III.3.2.1. Creation of new genetically altered animal lines by genetic status

Animals that are not genetically altered but reported under the category creation of a new genetically altered animal lines include, for example, genetically normal parent animals or a part of the offspring that does not carry the genetic alteration. Of those that were genetically altered, over 86% were of a non-harmful phenotype.

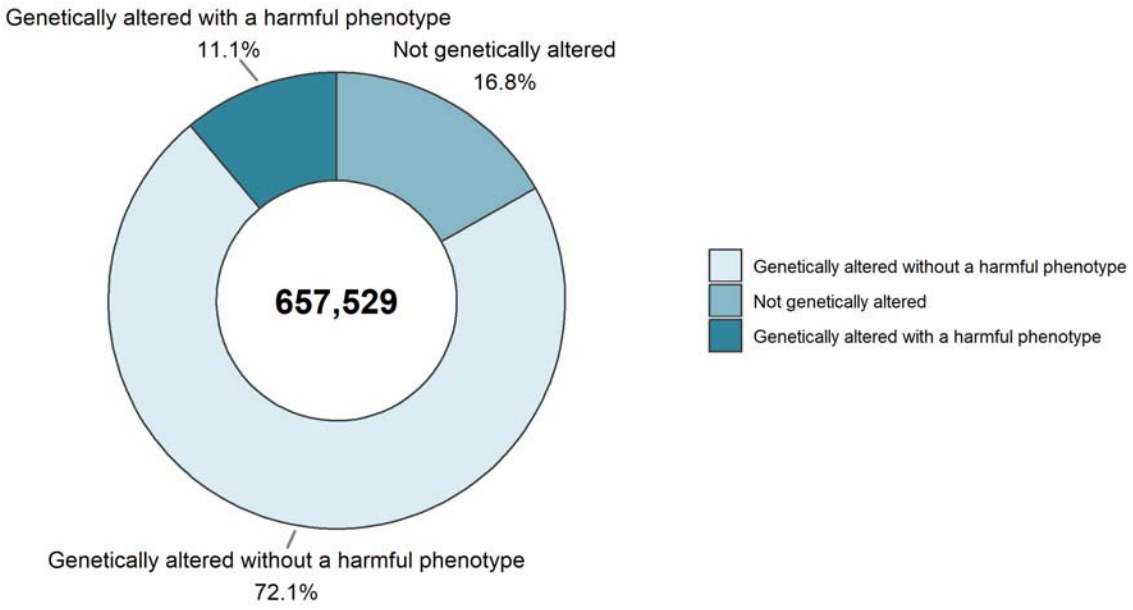

Figure 3.1: Creation of new genetically altered animal lines: genetic types of animal used in 2017

	2015	2016	2017
Not genetically altered	19% (114,485)	20% (102,718)	17% (110,523)
Genetically altered without a harmful phenotype	68% (421,006)	64% (320,567)	72% (474,189)
Genetically altered with a harmful phenotype	13% (81,783)	16% (78,577)	11% (72,817)
Total	**100% (617,274)**	**100% (501,862)**	**100% (657,529)**

Table 3.2: Creation of new genetically altered animal lines: genetic types of animal used

III.3.2.2. Creation of new genetically altered animals lines by scientific purposes

The creation of new genetic lines is only carried out for research purposes. In 2017, 658,000 uses (first and any subsequent reuses) were reported for the purposes of creating new genetically altered animal lines.

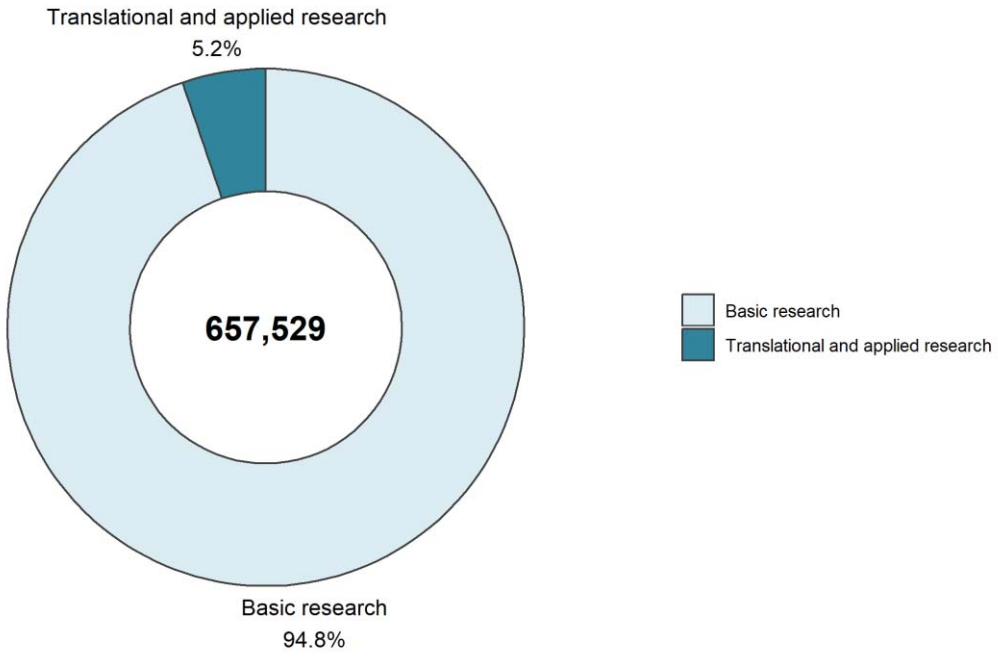

Figure 3.2: Creation of new genetically altered animal lines: uses for research purposes in 2017

95% of the new genetically altered lines were created for purposes covered under basic research. The table below presents all sub-categories from both basic and translational and applied research together.

In 2017, for basic research purposes, 21% concerned the multisystemic research (where more than one body system is the primary interest of the research, such as in some infectious diseases), 14% nervous system, 12% oncology and 10% cardiovascular, blood and lymphatic system (Table 3.3).

The most important sub-category under translational and applied research for which new genetically altered animal lines were created was human cancer (1%). Due to the relatively low number of uses for the creation of new genetically altered animal lines for the applied and translational research purposes, Table 3.3 combines all research purposes both from basic, and translational and applied research.

Between 2015 and 2017, the uses of animals for the creation of new genetic lines increased slightly (+7%), but with an important decrease in 2016 preventing the identification of any meaningful trend.

	2015	2016	2017
Multisystemic	185,617	115,807	139,844
Nervous System	56,223	79,174	93,284
Oncology	62,747	63,869	81,862
Other basic research	124,948	41,976	81,265
Cardiovascular Blood and Lymphatic System	32,479	39,993	65,759

Immune System	33,598	45,225	59,533
Urogenital/Reproductive System	18,766	20,584	27,948
Sensory Organs (skin, eyes and ears)	8,859	27,505	18,974
Endocrine System/Metabolism	16,497	16,275	18,749
Musculoskeletal System	20,417	7,620	16,651
Gastrointestinal System including Liver	7,717	6,858	10,696
Human Cancer	15,392	14,162	9,416
Ethology / Animal Behaviour /Animal Biology	2,066	2,513	7,391
Human Endocrine/Metabolism Disorders	832	6,247	4,706
Human Nervous and Mental Disorders	2,569	2,950	4,090
Human Cardiovascular Disorders	4,887	2,491	3,712
Human Gastrointestinal Disorders including Liver	574	1,117	2,544
Human Immune Disorders	836	745	2,265
Animal Diseases and Disorders	916	465	1,851
Respiratory System	17,236	235	1,228
Human Infectious Disorders	1,652	847	1,220
Human Sensory Organ Disorders (skin, eyes and ears)	1,072	1,879	1,168
Human Musculoskeletal Disorders	353	965	881
Human Urogenital/Reproductive Disorders	262	481	654
Other Human Disorders	99	1,139	546
Non-regulatory toxicology and ecotoxicology	57	2	510
Diagnosis of diseases	229	239	502
Human Respiratory Disorders	263	407	263
Animal Welfare	111	92	17
Total	**617,274**	**501,862**	**657,529**

Table 3.3: Uses of animals for the creation of new genetically altered animal lines by type of research

III.3.2.3. Creation of new genetically altered animal lines by severity

Severities reported under the creation of new genetically altered animal lines include impacts from surgical techniques used during creation (embryo transfer; vasectomy), tissue sampling (using an invasive method for genotyping) and effects caused by the phenotype of the genetic alteration.

	2015	2016	2017
Non-recovery	3% (17,031)	3% (16,007)	4% (25,467)
Mild [up to and including]	83% (514,080)	79% (394,322)	79% (519,551)
Moderate	12% (77,108)	16% (80,162)	15% (96,917)
Severe	1% (9,055)	2% (11,371)	2% (15,594)
Total	**100% (617,274)**	**100% (501,862)**	**100% (657,529)**

Table 3.4: Uses of animals for the creation of new genetically altered animal lines by severities

III.3.2.4. Reuses

	2015	2016	2017
Yes	4% (26,241)	2% (8,706)	3% (22,824)
No	96% (591,033)	98% (493,156)	97% (634,705)
Total	**100% (617,274)**	**100% (501,862)**	**100% (657,529)**

Table 3.5: Reuse of animals used for the creation of new genetically altered animal lines

Between 2015 and 2017, the number of reuses for the creation of new genetic lines knew an important variation mainly explained by the uses of zebra fish.

	Yes	No
Mice	<1% (2,120)	100% (488,597)
Rats	0% (0)	100% (9,960)
Rabbits	0% (0)	100% (475)
Pigs	1% (3)	99% (224)
Sheep	0% (0)	100% (17)
Marmoset and tamarins	0% (0)	100% (10)
Other Mammals	0% (0)	100% (61)
Domestic fowl	0% (0)	100% (647)
Xenopus	0% (0)	100% (250)
Zebra fish	14% (20,701)	86% (129,895)
Other Fish	0% (0)	100% (4,569)
Total	**3% (22,824)**	**97% (634,705)**

Table 3.6: Reuses by species for the creation of new genetically altered animal lines in 2017

In 2017, the only species of reused animals were zebra fish, mice and pigs (Table 3.6).

III.3.3. All uses of animals for the maintenance of colonies of established genetically altered animal lines

Directive 2010/63/EU requires Member States to report animals used for the maintenance of colonies for genetically altered animals. This category contains animals required for the maintenance of colonies of genetically altered animals of established lines *with an intended harmful phenotype* and which *have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype* before being killed.

This category also includes genetically altered animals of an established line, irrespective of whether the line is of non-harmful or harmful phenotype, and

- for which the genotype has been confirmed using an invasive method (tissue sampling/ genotyping), which was not carried out for the purposes of marking of the animal, and the animal is killed without further use;
- that are of unsuitable genotype, confirmed using an invasive method, which was not carried out for the purposes of marking of the animal.

Given the complexity of the reporting obligations, errors in the reporting of uses under maintenance of colonies are still being detected. In addition, some Member States apply different reporting rules for their national reporting, which has, in some cases, resulted in incorrect (over-) reporting for EU purposes, whilst at the same time it seems that not all genotyping using invasive methods has been correctly reported by all Member States, resulting in under-reporting for EU purposes.

Consequently, the level of confidence in the numbers reported under the maintenance of colonies at this early stage, is still relatively low, and any year-to-year comparisons are for the time being discouraged. The Commission is working together with Member States to improve the situation. The identification and correction of some of the misunderstandings of the reporting obligations is likely to explain some of the decrease in total numbers noted for the maintenance of colonies between 2015 and 2017.

III.3.3.1. Maintenance of colonies of established genetically altered animal lines by genetic status

In 2017, 642,000 uses were reported under the maintenance of colonies of established genetically altered animal lines. Amongst these uses, 74% were genetically altered without a harmful phenotype, 20% with a harmful phenotype and 6% without genetic alteration (Figure 3.3). This seems to suggest that the majority of uses reported under maintenance of colonies of established genetically altered animal lines concern animals that have been genotyped using an invasive method. Those reported with a harmful phenotype are likely to be a mix of those that were genotyped and those having exhibited the harmful phenotype before being killed.

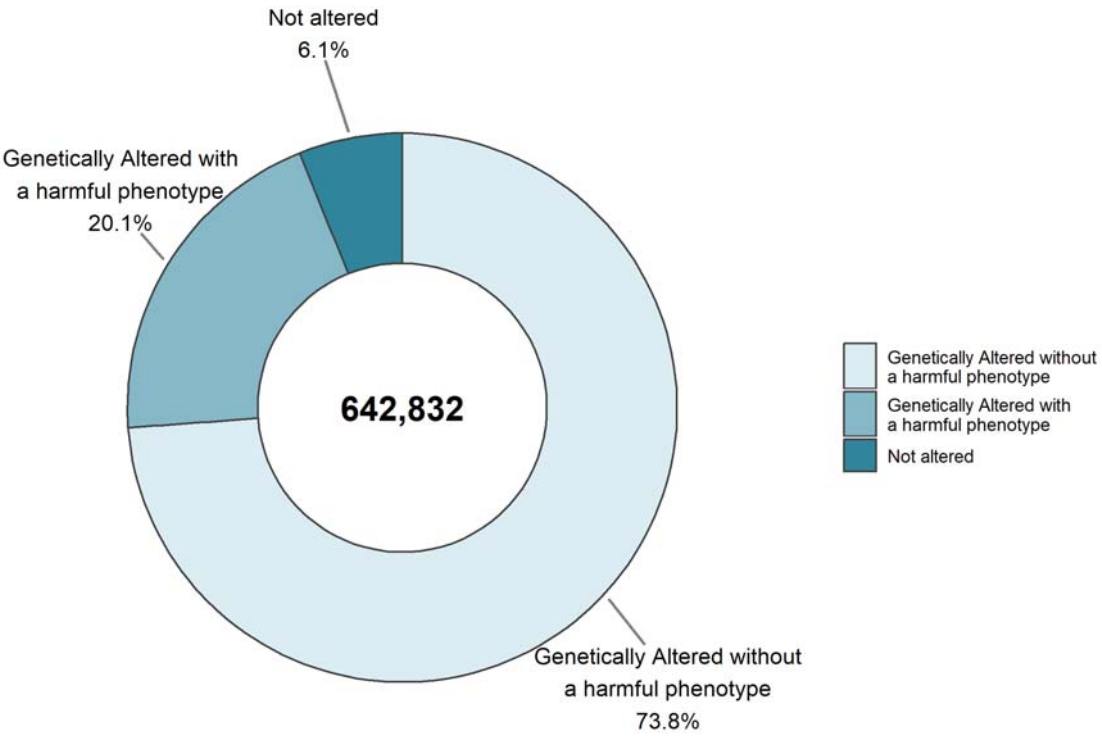

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Figure 3.3: Genetic status of animals used for the maintenance of colonies of established genetically altered animal lines in 2017

III.3.3.2. Maintenance of colonies of established genetically altered animal lines by severity

In 2017, in 79% of the uses the severities remained at mild (and up to mild) level (Table 3.7). Drawing from the previous figure 3.3 in which it was stated that almost 74% percent of animals were of non-harmful phenotype, the severities seem to relate to the effects of tissue sampling (invasive genotyping). For those classed as having a harmful-phenotype, the severities can be linked to the phenotype and invasive tissue sampling. Where animals are found dead with no clear reason, this results in reporting these as 'severe'.

	2015	2016	2017
Non-recovery	1% (5,790)	0% (1,031)	0% (740)
Mild [up to and including]	84% (842,365)	87% (609,140)	79% (510,466)
Moderate	9% (85,781)	7% (51,298)	13% (83,866)
Severe	7% (67,250)	6% (40,040)	7% (47,760)
Total	**100% (1,001,186)**	**100% (701,509)**	**100% (642,832)**

Table 3.7: Uses of animals for the maintenance of colonies of genetically altered animal lines by severity in 2017

III.3.3.2. Maintenance of colonies of established genetically altered animal lines by species

Mice and zebra fish are the most common genetically altered animals used for scientific purposes, and are therefore the main species also used for the maintenance of colonies.

	2015	2016	2017
Mice	910,724	623,988	563,784
Rats	9,003	9,294	6,799
Dogs	7	17	10
Other Mammals	0	4	0
Domestic fowl	322	582	367
Xenopus	188	259	392
Zebra fish	80,632	66,794	70,840
Other Fish	310	571	640
Total	**1,001,186**	**701,509**	**642,832**

Table 3.8: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species

III.3.3.3. Reuses

	2015	2016	2017
Yes	4,193	973	950
No	996,993	700,536	641,882
Total	**1,001,186**	**701,509**	**642,832**

Table 3.9: Reuses of animals for the maintenance of colonies of established genetically altered animal lines

These reuses involved three types of species: zebra fish, xenopus and mice.

	Yes	No
Mice	141	563,643
Rats	0	6,799
Dogs	0	10
Domestic fowl	0	367
Xenopus	197	195
Zebra fish	612	70,228
Other Fish	0	640
Total	**950**	**641,882**

Table 3.10: Reuses by species for the maintenance of colonies of established genetically altered animal lines

III.4. Glossary of terms

Species of animals

The Directive applies to live non-human vertebrate animals, including independently feeding larval forms and foetal forms of mammals as from the last third of their normal development, and live cephalopods.

Larval forms and cephalopods are reported in the statistics when they become capable of independent feeding. Due to the small size of many larval forms of fish and cephalopod species, the count for these animals may be done on the basis of estimation.

Procedure

"Procedure" means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues.

Use and reuse

The “use” of an animal within a project extends from the time the procedure (or first procedure/technique in a series) is applied to it, to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed.

“Reuse” is a term to indicate any subsequent use of an animal, which has already completed a procedure (or series of procedures/techniques) for a particular scientific purpose. Article 16 of the Directive on reuse defines it as a use when a different animal on which no procedure has previously been carried out could also be used. Article 16 also defines the conditions under which an animal may be reused.

Reporting of actual severity experienced by the animals

The impact on animal welfare is reported by assigning an animal’s experience to a ‘severity’ category – "mild", "moderate" or "severe". There is a further category termed "non-recovery" which relates to where animals are placed under general anesthesia before they are used and are killed afterwards before regaining consciousness.

The reported severity reflects the highest degree of pain, suffering, distress or lasting harm observed to be actually experienced by the animal during the course of its use. Further guidance on severity assessment can be found at
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf.

i. **Non-recovery -** Animals which have undergone a procedure that has been performed entirely under general anaesthesia from which the animal has not recovered consciousness shall be reported as Non-recovery.

ii. **Mild (up to and including)** - Animals which have undergone a procedure as a result of which the animals have experienced short-term mild pain, suffering or distress, as well as when there has been no significant impairment of the well-being or general condition of the animals shall be reported as Mild.

This cateogry also includes any animals used in an authorised project, but which have ultimately *not* been observed to have experienced a level of pain, suffering, distress or lasting harm above the minimum threshold (equivalent to that caused by the introduction of a needle in accordance with good veterinary practice) for example untreated control animals ("up to mild"). However, animals required for the maintenance of colonies of genetically altered animals of established lines *with an intended harmful phenotype and which have not exhibited* pain, suffering, distress or lasting harm as a consequence of the harmful genotype are not reported in annual statistics.

iii. **Moderate** - Animals which have undergone a procedure as a result of which the animals have experienced short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that have caused moderate impairment of the well-being or general condition of the animals shall be reported as Moderate.

iv. **Severe** - Animals which have undergone a procedure as a result of which the animals have experienced severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures, that have caused severe impairment of the well-being or general condition of the animals shall be reported as Severe.

In the exceptional circumstances where, under the safeguard clause, the Severe classification is exceeded these animals and their use will be reported under Severe. Should this occur, further explanation on the circumstances of this use is provided in the respective Member State narrative.

Genetically altered animals

For the purposes of statistical reporting, "genetically altered animals" refer to either of the following:

- genetically modified (such as transgenic, knock-out and other forms of genetic alteration) and induced mutant animals (irrespective of the type of mutation);
- animals with spontaneous deleterious mutations maintained for research for that specific genotype.

Genetically altered animals are reported either

a) When used for the creation of a new animal line;
b) When used for the maintenance of an established line with an intended ***and*** exhibited harmful phenotype; This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of intended non-harmful or harmful

phenotype, that have been subject to invasive genotyping (genetic characterisation/tissue sampling);

c) When used in other (scientific) procedures (i.e. not for the creation or the maintenance of a line).

The reporting of genetically altered animals are summarised in the above table.

Creation

All animals *carrying a genetic alteration* are reported during the creation of a new line. Also, those used for superovulation, vasectomy and embryo implantation are reported (these may or may not be genetically altered).

Genetically normal animals (*wild-type offspring*) produced as a result of the creation of a new genetically altered line are not reported, unless these have been subjected to a procedure, for example an invasive method for the sole purposes of genotyping.

Establishment and maintenance of breeding colonies

A new strain or line of genetically altered animals is considered to be "established" when transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed. This marks the transition from "creation" to "breeding".

The welfare assessment determines if the newly established line is expected to have an *intended harmful phenotype (characteristic/trait)* i.e. an effect of genetic alteration that impacts negatively on an animal's health or welfare, such as muscle weakness, diabetes, tumour development.

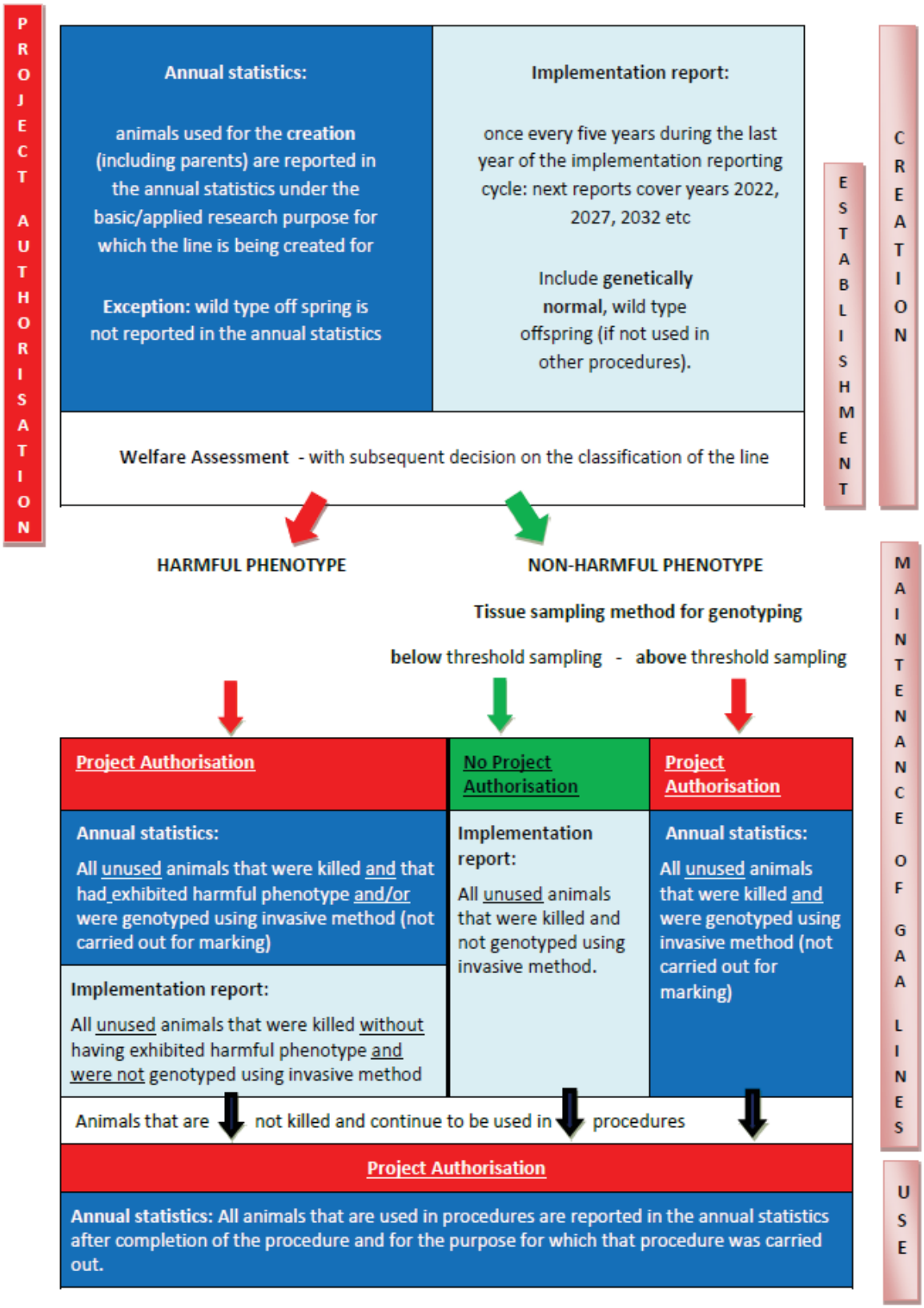
If the welfare assessment concludes that the line is *not* expected to have a harmful phenotype, its breeding falls outside the scope of a procedure and is not reported in the annual statistics.

If the welfare assessment concludes that the line *is* expected to have a harmful phenotype, its breeding falls within the scope of a procedure. If this is the case, and if the animal is not used in other procedures and it has exhibited, before being killed, pain, suffering, distress of lasting harm as a result of the harmful phenotype, it is reported under the category *Maintenance of colonies of established genetically altered animals, not used in other procedures.*

Use in procedures (other than creation or maintenance of a genetically altered line)

All genetically altered animals which are used in procedures (not for the creation or maintenance of a genetically altered line) are reported under their respective purposes they were used for(. These animals may or may not exhibit a harmful phenotype.

Diagram for the reporting of the creation, maintenance and use of genetically altered animals



Main categories of purposes of uses for research, testing, routine production and education (including training)

Basic research

Basic research includes studies of a fundamental nature including physiology. Studies that are designed to add knowledge about normal and abnormal structure, functioning and behaviour of living organisms and environment, this includes fundamental studies in toxicology. Investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

Translational and applied research

Translational and applied research includes animals used for purposes as described in Article 5(b) and (c) of the Directive, that is to say,

"(b) translational or applied research with any of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or

(iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;

(c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;"

This category also includes discovery toxicology and investigations to *prepare* for the regulatory submission and method development. This does not include studies *required* for regulatory submissions.

Regulatory use

Regulatory uses cover the use of animals in procedures with a view to satisfying regulatory requirements, that is to say, for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. It also includes tests carried out in respect of products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because these were deemed unsuitable for the market by the developer and thus fail to reach the end of the development process.

Routine production

Routine production includes the production of antibodies and blood products including polyclonal antisera by established methods.

Protection of the natural environment in the interests of the health or welfare of human beings or animals

This category includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity, and epidemiology studies in wild animals. This excludes any regulatory use of animals for ecotoxicology purposes.

Preservation of species

Studies aimed at conserving species, often those at risk of extinction, for example to investigate improved breeding strategies or preservation of habitats.

Higher education or training

This category covers the use of animals for the purposes of education and also for the acquisition, maintenance or improvement of vocational skills.

Forensic enquiries

Studies to assist the investigation of forensic enquiries.

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PART 2/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

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SECTION B: EU DATA BETWEEN 2015 AND 2017

IV. Detailed EU tables 2015 - 2017

This section presents the basic consolidated tables used for the conclusions at the EU level.

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EU statistical tables 2015

Part 1: Numbers of animals used for research, testing, routine production and educational purposes in the EU

Table 1: Numbers of animals used for the first time by species (2015)

		Number of animals	%
Mammals			
	Rodents		
	Mice	5,711,612	**59.6**
	Rats	1,201,189	**12.5**
	Guinea-Pigs	149,328	**1.6**
	Hamsters (Syrian)	20,195	**0.2**
	Hamsters (Chinese)	30	**0**
	Mongolian gerbil	6,199	**0.1**
	Other rodents	26,088	**0.3**
	Rabbits		
	Rabbits	346,052	**3.6**
	Carnivores		
	Cats	1,975	**0**
	Dogs	14,501	**0.2**
	Ferrets	2,212	**0**
	Other carnivores	3,648	**0**
	Farm animals		
	Horses, donkeys and cross-breeds	3,217	**0**
	Pigs	73,895	**0.8**
	Goats	2,233	**0**
	Sheep	20,106	**0.2**
	Cattle	26,763	**0.3**
	Non-human primates		
	Prosimians	169	**0**
	Marmoset and tamarins	429	**0**
	Squirrel monkey	13	**0**
	Other species of new world monkeys (Ceboidea)	0	**0**
	Cynomolgus monkey	6,221	**0.1**
	Rhesus monkey	211	**0**
	Vervets (Chlorocebus spp.)	56	**0**
	Baboons	37	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	**0**
	Other mammals		
	Other mammals	9,535	**0.1**
Birds			
	Domestic fowl	515,834	**5.4**
	Other birds	119,377	**1.2**
Reptiles			
	Reptiles	2,414	**0**
Amphibians			
	Rana	4,884	**0.1**
	Xenopus	10,837	**0.1**
	Other amphibians	20,190	**0.2**
Fish			
	Zebra fish	338,815	**3.5**
	Other fish	936,252	**9.8**
Cephalopods			
	Cephalopods	15,862	**0.2**
Totals			
	Total	**9,590,379**	**100**
	%	**100**	

Table 2: Place of birth by species (other than non-human primates) (2015)

	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of world	Total	%
Mammals						
Rodents						
Mice	5,466,761	170,399	38,177	36,275	**5,711,612**	**59.6**
Rats	1,185,595	9,656	705	5,233	**1,201,189**	**12.5**
Guinea-Pigs	148,500	828	0	0	**149,328**	**1.6**
Hamsters (Syrian)	19,310	83	7	795	**20,195**	**0.2**
Hamsters (Chinese)	30	0	0	0	**30**	**0**
Mongolian gerbil	5,841	290	0	68	**6,199**	**0.1**
Other rodents	8,501	17,130	57	400	**26,088**	**0.3**
Rabbits						
Rabbits	337,709	5,448	173	2,722	**346,052**	**3.6**
Carnivores						
Cats	1,053	531	0	391	**1,975**	**0**
Dogs	6,109	3,752	52	4,588	**14,501**	**0.2**
Ferrets	1,796	148	0	268	**2,212**	**0**
Other carnivores	1,088	2,556	4	0	**3,648**	**0**
Farm animals						
Horses, donkeys and cross-breeds	700	2,517	0	0	**3,217**	**0**
Pigs	35,355	37,327	1,203	10	**73,895**	**0.8**
Goats	805	1,428	0	0	**2,233**	**0**
Sheep	6,503	13,505	98	0	**20,106**	**0.2**
Cattle	8,677	17,993	93	0	**26,763**	**0.3**
Other mammals						
Other mammals	2,078	5,967	18	1,472	**9,535**	**0.1**
Birds						
Domestic fowl	266,406	244,616	4,800	12	**515,834**	**5.4**
Other birds	19,867	92,967	3,244	3,299	**119,377**	**1.2**
Reptiles						
Reptiles	459	1,557	42	356	**2,414**	**0**
Amphibians						
Rana	3,194	1,540	150	0	**4,884**	**0.1**
Xenopus	7,952	312	0	2,573	**10,837**	**0.1**
Other amphibians	1,816	17,039	247	1,088	**20,190**	**0.2**
Fish						
Zebra fish	320,358	15,458	812	2,187	**338,815**	**3.5**
Other fish	594,363	292,494	44,337	5,058	**936,252**	**9.8**
Cephalopods						
Cephalopods	15,840	22	0	0	**15,862**	**0.2**
Totals						
Total	**8,466,666**	**955,563**	**94,219**	**66,795**	**9,583,243**	**100**
%	**88.3**	**10**	**1**	**0.7**	**100**	

Table 3: Source of non-human primates by species (2015)

	Animals born at a registered breeder within EU	Animals born in rest of Europe	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total	%
Non-human primates								
New World Monkeys								
Prosimians	158	11	0	0	0	0	**169**	**2.4**
Marmoset and tamarins	429	0	0	0	0	0	**429**	**6**
Squirrel monkey	10	0	0	3	0	0	**13**	**0.2**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	**0**	**0**
Old World Monkeys								
Cynomolgus monkey	146	0	2,052	9	3,923	91	**6,221**	**87.2**
Rhesus monkey	175	3	33	0	0	0	**211**	**3**
Vervets (Chlorocebus spp.)	4	0	0	52	0	0	**56**	**0.8**
Baboons	37	0	0	0	0	0	**37**	**0.5**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	**0**	**0**
Totals								
Total	**959**	**14**	**2,085**	**64**	**3,923**	**91**	**7,136**	**100**
%	**13.4**	**0.2**	**29.2**	**0.9**	**55**	**1.3**	**100**	

Table 4: Generation of non-human primates by species (2015)

	F0	F1	F2 or greater	Self-sustaining colony	Total	%
Non-human primates						
New World Monkeys						
Prosimians	0	1	0	168	**169**	**2.4**
Marmoset and tamarins	0	0	102	327	**429**	**6**
Squirrel monkey	0	8	5	0	**13**	**0.2**
Other species of new world monkeys (Ceboidea)	0	0	0	0	**0**	**0**
Old World Monkeys						
Cynomolgus monkey	1	1,737	2,420	2,063	**6,221**	**87.2**
Rhesus monkey	0	22	55	134	**211**	**3**
Vervets (Chlorocebus spp.)	0	4	0	52	**56**	**0.8**
Baboons	0	1	32	4	**37**	**0.5**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	**0**	**0**
Totals						
Total	**1**	**1,773**	**2,614**	**2,748**	**7,136**	**100**
%	**0**	**24.8**	**36.6**	**38.5**	**100**	

Part 2: Details of all uses of animals for research, testing, routine production and educational purposes in the EU

Table 5: Uses of animals by species, main categories of scientific purposes and severities (2015)

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Non-recovery	249,177	121,186	10,856	2	0	380	14,674	4	396,279	6.9
	Mild	1,521,311	551,716	578,720	3,059	3,178	6,338	38,369	36	2,702,727	46.9
Mice	Moderate	1,047,417	663,033	284,691	16,948	200	0	18,851	0	2,031,140	35.2
	Severe	188,709	107,101	326,302	13,673	243	0	630	0	636,658	11.0
	Total	**3,006,614**	**1,443,036**	**1,200,569**	**33,682**	**3,621**	**6,718**	**72,524**	**40**	**5,766,804**	**100.0**
	Non-recovery	50,257	30,045	8,639	76	0	32	22,163	1	111,213	9.1
	Mild	117,925	120,119	365,129	1,162	562	127	13,426	100	618,550	50.8
Rats	Moderate	132,492	118,106	176,306	36	493	0	6,539	0	433,972	35.7
	Severe	28,512	15,030	9,007	176	96	0	12	0	52,833	4.3
	Total	**329,186**	**283,300**	**559,081**	**1,450**	**1,151**	**159**	**42,140**	**101**	**1,216,568**	**100.0**
	Non-recovery	907	16,936	1,218	270	0	0	245	17	19,593	13.0
	Mild	2,351	6,091	61,775	1,115	0	0	1,834	0	73,166	48.7
Guinea-Pigs	Moderate	1,172	2,285	38,110	45	0	0	277	19	41,908	27.9
	Severe	85	702	14,690	0	0	0	0	0	15,477	10.3
	Total	**4,515**	**26,014**	**115,793**	**1,430**	**0**	**0**	**2,356**	**36**	**150,144**	**100.0**
	Non-recovery	525	183	0	0	0	0	17	0	725	3.6
	Mild	246	2,089	5,946	7	0	0	94	0	8,382	41.4
Hamsters (Syrian)	Moderate	929	4,646	1,019	0	0	0	0	0	6,594	32.6
	Severe	77	563	3,725	173	0	0	0	0	4,538	22.4
	Total	**1,777**	**7,481**	**10,690**	**180**	**0**	**0**	**111**	**0**	**20,239**	**100.0**
	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	0	0	30	0	0	0	0	0	30	100.0
Hamsters (Chinese)	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**0**	**0**	**30**	**0**	**0**	**0**	**0**	**0**	**30**	**100.0**
	Non-recovery	268	0	0	0	0	0	26	0	294	4.5
	Mild	644	1,570	1,489	167	0	0	23	0	3,893	59.0
Mongolian gerbil	Moderate	523	949	110	19	0	0	30	0	1,631	24.7
	Severe	112	667	6	0	0	0	0	0	785	11.9
	Total	**1,547**	**3,186**	**1,605**	**186**	**0**	**0**	**79**	**0**	**6,603**	**100.0**
	Non-recovery	559	0	0	0	0	42	83	0	684	2.5
	Mild	5,646	1,977	8,354	38	647	113	175	0	16,950	63.1
Other rodents	Moderate	8,010	404	82	0	0	160	2	0	8,658	32.2
	Severe	81	509	1	0	0	0	0	0	591	2.2
	Total	**14,296**	**2,890**	**8,437**	**38**	**647**	**315**	**260**	**0**	**26,883**	**100.0**
	Non-recovery	5,793	2,785	3,124	0	0	0	952	0	12,654	3.5
	Mild	5,867	5,401	75,619	165,138	233	0	837	0	253,095	70.1
Rabbits	Moderate	7,310	6,991	23,119	48,056	0	0	279	0	85,755	23.7
	Severe	2,926	871	1,159	4,738	4	0	0	0	9,698	2.7
	Total	**21,896**	**16,048**	**103,021**	**217,932**	**237**	**0**	**2,068**	**0**	**361,202**	**100.0**
	Non-recovery	68	0	1	0	0	0	0	0	69	2.2
	Mild	635	565	987	0	0	0	48	0	2,235	70.2
Cats	Moderate	100	325	159	18	0	0	1	0	603	18.9
	Severe	0	225	53	0	0	0	0	0	278	8.7
	Total	**803**	**1,115**	**1,200**	**18**	**0**	**0**	**49**	**0**	**3,185**	**100.0**
	Non-recovery	14	219	328	2	6	0	10	0	579	2.7
	Mild	1,264	6,302	7,335	237	6	0	521	0	15,665	72.1
Dogs	Moderate	56	1,466	3,382	0	0	0	14	0	4,918	22.6
	Severe	21	365	191	0	0	0	0	0	577	2.7
	Total	**1,355**	**8,352**	**11,236**	**239**	**12**	**0**	**545**	**0**	**21,739**	**100.0**
	Non-recovery	111	0	0	0	0	0	14	0	125	5.3
	Mild	61	745	680	6	0	0	70	0	1,562	66.4
Ferrets	Moderate	172	295	151	0	0	0	17	0	635	27.0
	Severe	0	22	8	0	0	0	0	0	30	1.3
	Total	**344**	**1,062**	**839**	**6**	**0**	**0**	**101**	**0**	**2,352**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Other carnivores	Non-recovery	5	0	0	2	0	0	0	0	7	0.2
	Mild	1,583	696	220	0	170	62	0	0	2,731	73.3
	Moderate	169	176	622	0	0	0	0	0	967	26.0
	Severe	9	10	0	0	0	0	0	0	19	0.5
	Total	**1,766**	**882**	**842**	**2**	**170**	**62**	**0**	**0**	**3,724**	**100.0**
Horses, donkeys and cross-breeds	Non-recovery	78	35	0	0	0	34	24	0	171	1.4
	Mild	2,418	890	141	7,669	1	0	265	0	11,384	94.3
	Moderate	100	292	12	107	0	0	0	0	511	4.2
	Severe	0	0	0	2	0	0	0	0	2	0.0
	Total	**2,596**	**1,217**	**153**	**7,778**	**1**	**34**	**289**	**0**	**12,068**	**100.0**
Pigs	Non-recovery	5,366	2,719	9	21	0	0	5,962	0	14,077	18.2
	Mild	14,887	15,664	12,225	255	780	3	2,549	0	46,363	59.9
	Moderate	4,217	7,474	2,456	15	8	0	964	0	15,134	19.6
	Severe	429	1,168	229	0	0	0	0	0	1,826	2.4
	Total	**24,899**	**27,025**	**14,919**	**291**	**788**	**3**	**9,475**	**0**	**77,400**	**100.0**
Goats	Non-recovery	0	46	0	0	0	0	6	0	52	2.0
	Mild	829	948	115	22	0	0	184	0	2,098	79.4
	Moderate	85	366	6	5	10	0	8	0	480	18.2
	Severe	8	3	0	0	0	0	0	0	11	0.4
	Total	**922**	**1,363**	**121**	**27**	**10**	**0**	**198**	**0**	**2,641**	**100.0**
Sheep	Non-recovery	96	212	16	0	0	0	571	0	895	1.4
	Mild	6,412	6,717	1,892	40,923	370	62	756	121	57,253	91.1
	Moderate	1,535	2,018	73	136	2	0	149	0	3,913	6.2
	Severe	398	407	0	0	0	0	0	0	805	1.3
	Total	**8,441**	**9,354**	**1,981**	**41,059**	**372**	**62**	**1,476**	**121**	**62,866**	**100.0**
Cattle	Non-recovery	111	32	0	0	0	0	8	0	151	0.4
	Mild	14,047	8,885	3,489	138	715	0	3,246	6	30,526	84.0
	Moderate	1,610	1,629	479	15	11	0	1,599	0	5,343	14.7
	Severe	23	293	12	0	0	0	9	0	337	0.9
	Total	**15,791**	**10,839**	**3,980**	**153**	**726**	**0**	**4,862**	**6**	**36,357**	**100.0**
Prosimians	Non-recovery	2	0	0	0	0	0	0	0	2	0.8
	Mild	189	0	0	0	0	0	0	0	189	73.0
	Moderate	65	1	0	0	0	0	0	0	66	25.5
	Severe	2	0	0	0	0	0	0	0	2	0.8
	Total	**258**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**259**	**100.0**
Marmoset and tamarins	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	147	24	124	84	0	0	6	0	385	62.7
	Moderate	108	57	38	0	0	0	0	0	203	33.1
	Severe	18	8	0	0	0	0	0	0	26	4.2
	Total	**273**	**89**	**162**	**84**	**0**	**0**	**6**	**0**	**614**	**100.0**
Squirrel monkey	Non-recovery	4	0	0	0	0	0	0	0	4	30.8
	Mild	2	0	0	0	0	0	0	0	2	15.4
	Moderate	7	0	0	0	0	0	0	0	7	53.8
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**13**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**13**	**100.0**
Other species of new world monkeys (Ceboidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	24	0	0	0	0	0	0	0	24	100.0
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**24**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**100.0**
Cynomolgus monkey	Non-recovery	15	74	8	10	0	0	0	0	107	1.1
	Mild	30	531	3,513	2,053	0	0	23	0	6,150	65.4
	Moderate	95	460	2,336	0	0	0	0	0	2,891	30.8
	Severe	0	132	118	1	0	0	0	0	251	2.7
	Total	**140**	**1,197**	**5,975**	**2,064**	**0**	**0**	**23**	**0**	**9,399**	**100.0**
Rhesus monkey	Non-recovery	21	1	0	0	0	0	0	0	22	4.8
	Mild	81	109	54	32	0	0	5	0	281	61.9
	Moderate	113	38	0	0	0	0	0	0	151	33.3
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**215**	**148**	**54**	**32**	**0**	**0**	**5**	**0**	**454**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Vervets (Chlorocebus spp.)	Non-recovery	0	39	0	0	0	0	0	0	39	69.6
	Mild	0	13	0	0	0	0	0	0	13	23.2
	Moderate	0	4	0	0	0	0	0	0	4	7.1
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**0**	**56**	**0**	**0**	**0**	**0**	**0**	**0**	**56**	**100.0**
Baboons	Non-recovery	0	2	0	0	0	0	0	0	2	4.8
	Mild	1	0	0	0	0	0	0	0	1	2.4
	Moderate	11	18	0	0	0	0	0	0	29	69.0
	Severe	0	10	0	0	0	0	0	0	10	23.8
	Total	**12**	**30**	**0**	**0**	**0**	**0**	**0**	**0**	**42**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	8	1	0	0	0	0	0	0	9	100.0
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**100.0**
Other mammals	Non-recovery	997	86	0	0	0	0	0	0	1,083	9.7
	Mild	6,445	1,303	125	34	544	205	73	0	8,729	78.0
	Moderate	990	345	15	0	0	0	0	0	1,350	12.1
	Severe	14	6	0	12	0	0	0	0	32	0.3
	Total	**8,446**	**1,740**	**140**	**46**	**544**	**205**	**73**	**0**	**11,194**	**100.0**
Domestic fowl	Non-recovery	8,840	3,226	120	379	0	0	607	0	13,172	2.5
	Mild	53,827	60,665	138,520	91,027	2,485	939	6,029	0	353,492	67.8
	Moderate	84,815	15,538	24,207	15,283	34	0	526	0	140,403	26.9
	Severe	914	7,268	5,614	231	58	0	0	0	14,085	2.7
	Total	**148,396**	**86,697**	**168,461**	**106,920**	**2,577**	**939**	**7,162**	**0**	**521,152**	**100.0**
Other birds	Non-recovery	1,400	20	80	0	0	6	6	0	1,512	1.2
	Mild	44,392	13,725	5,186	521	2,740	573	602	11	67,750	55.7
	Moderate	6,112	3,899	429	41,031	0	45	18	0	51,534	42.4
	Severe	88	160	599	0	1	0	0	0	848	0.7
	Total	**51,992**	**17,804**	**6,294**	**41,552**	**2,741**	**624**	**626**	**11**	**121,644**	**100.0**
Reptiles	Non-recovery	505	0	0	0	0	0	0	0	505	13.2
	Mild	2,274	0	0	300	93	0	33	0	2,700	70.5
	Moderate	581	0	0	0	0	46	0	0	627	16.4
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**3,360**	**0**	**0**	**300**	**93**	**46**	**33**	**0**	**3,832**	**100.0**
Rana	Non-recovery	25	0	0	0	0	0	206	0	231	4.7
	Mild	85	0	0	0	0	0	789	0	874	17.9
	Moderate	4	0	132	0	600	0	1,865	0	2,601	53.3
	Severe	1,178	0	0	0	0	0	0	0	1,178	24.1
	Total	**1,292**	**0**	**132**	**0**	**600**	**0**	**2,860**	**0**	**4,884**	**100.0**
Xenopus	Non-recovery	528	0	0	0	0	0	188	0	716	3.8
	Mild	13,844	703	719	0	8	0	57	0	15,331	80.7
	Moderate	1,310	551	0	0	840	0	0	0	2,701	14.2
	Severe	241	0	1	0	0	0	0	0	242	1.3
	Total	**15,923**	**1,254**	**720**	**0**	**848**	**0**	**245**	**0**	**18,990**	**100.0**
Other amphibians	Non-recovery	1,262	0	0	0	5	0	49	0	1,316	6.4
	Mild	3,966	57	0	0	6,692	3,881	200	0	14,796	72.4
	Moderate	2,560	7	60	0	0	12	2	0	2,641	12.9
	Severe	1,476	0	0	0	205	0	0	0	1,681	8.2
	Total	**9,264**	**64**	**60**	**0**	**6,902**	**3,893**	**251**	**0**	**20,434**	**100.0**
Zebra fish	Non-recovery	7,702	585	635	0	21	0	124	0	9,067	2.6
	Mild	200,713	28,169	20,063	0	3,996	0	1,426	0	254,367	74.1
	Moderate	26,004	22,065	15,495	0	200	0	89	0	63,853	18.6
	Severe	4,172	4,931	6,872	0	3	0	0	0	15,978	4.7
	Total	**238,591**	**55,750**	**43,065**	**0**	**4,220**	**0**	**1,639**	**0**	**343,265**	**100.0**
Other fish	Non-recovery	15,185	3,694	1,922	0	10,565	3,999	1,303	0	36,668	3.9
	Mild	516,527	63,729	71,130	25	61,392	18,759	11,442	0	743,004	79.1
	Moderate	48,780	40,111	5,524	0	2,899	2,252	191	0	99,757	10.6
	Severe	18,371	19,884	18,216	0	3,718	0	20	0	60,209	6.4
	Total	**598,863**	**127,418**	**96,792**	**25**	**78,574**	**25,010**	**12,956**	**0**	**939,638**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Cephalopods	Non-recovery	0	8	0	0	0	0	12	0	20	0.1
	Mild	2	15,840	0	0	0	0	0	0	15,842	99.9
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**2**	**15,848**	**0**	**0**	**0**	**0**	**12**	**0**	**15,862**	**100.0**
All Species	**Non-recovery**	**349,821**	**182,133**	**26,956**	**762**	**10,597**	**4,493**	**47,250**	**22**	**622,034**	**6.4**
	Mild	**2,538,683**	**915,244**	**1,363,580**	**314,012**	**84,612**	**31,062**	**83,082**	**274**	**5,330,549**	**54.5**
	Moderate	**1,377,452**	**893,549**	**579,013**	**121,714**	**5,297**	**2,515**	**31,421**	**19**	**3,010,980**	**30.8**
	Severe	**247,864**	**160,335**	**386,803**	**19,006**	**4,328**	**0**	**671**	**0**	**819,007**	**8.4**
	Total	**4,513,820**	**2,151,261**	**2,356,352**	**455,494**	**104,834**	**38,070**	**162,424**	**315**	**9,782,570**	**100.0**

Table 5.1: Uses of animals in all sub-categories of research and testing by severities (2015)

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Basic research						
Oncology	16,863	205,653	241,475	52,413	**516,404**	**5.3**
Cardiovascular Blood and Lymphatic System	39,624	156,509	127,681	14,792	**338,606**	**3.5**
Nervous System	103,055	411,549	289,393	53,816	**857,813**	**8.8**
Respiratory System	4,852	30,596	46,781	3,549	**85,778**	**0.9**
Gastrointestinal System including Liver	36,535	95,497	67,130	8,871	**208,033**	**2.1**
Musculoskeletal System	6,569	52,664	29,437	4,000	**92,670**	**0.9**
Immune System	53,310	434,346	245,774	70,922	**804,352**	**8.2**
Urogenital/Reproductive System	11,677	96,984	25,900	3,396	**137,957**	**1.4**
Sensory Organs (skin, eyes and ears)	8,790	46,750	24,472	6,140	**86,152**	**0.9**
Endocrine System/Metabolism	27,929	118,434	60,363	2,402	**209,128**	**2.1**
Multisystemic	12,780	211,491	60,786	12,548	**297,605**	**3**
Ethology / Animal Behaviour /Animal Biology	7,084	534,729	57,298	6,128	**605,239**	**6.2**
Other basic research	20,753	143,481	100,962	8,887	**274,083**	**2.8**
Translational and applied research						
Human Cancer	4,050	138,664	320,931	28,675	**492,320**	**5**
Human Infectious Disorders	16,479	116,281	107,722	41,720	**282,202**	**2.9**
Human Cardiovascular Disorders	11,671	23,742	20,640	6,110	**62,163**	**0.6**
Human Nervous and Mental Disorders	18,038	182,111	127,563	18,187	**345,899**	**3.5**
Human Respiratory Disorders	6,321	29,296	28,519	2,248	**66,384**	**0.7**
Human Gastrointestinal Disorders including Liver	2,072	13,139	14,729	2,270	**32,210**	**0.3**
Human Musculoskeletal Disorders	1,323	12,085	15,687	2,179	**31,274**	**0.3**
Human Immune Disorders	6,168	36,602	31,252	3,228	**77,250**	**0.8**
Human Urogenital/Reproductive Disorders	1,460	5,618	9,769	1,058	**17,905**	**0.2**
Human Sensory Organ Disorders (skin, eyes and ears)	2,543	24,547	18,001	1,295	**46,386**	**0.5**
Human Endocrine/Metabolism Disorders	6,910	54,770	59,587	2,546	**123,813**	**1.3**
Other Human Disorders	75,126	15,772	13,396	1,479	**105,773**	**1.1**
Animal Diseases and Disorders	20,537	110,959	69,339	22,978	**223,813**	**2.3**
Animal Welfare	999	70,921	6,422	173	**78,515**	**0.8**
Diagnosis of diseases	3,560	36,920	23,984	20,499	**84,963**	**0.9**
Plant diseases	0	455	24	1	**480**	**0**
Non-regulatory toxicology and ecotoxicology	4,876	43,362	25,984	5,689	**79,911**	**0.8**
Regulatory use						
Quality control (incl batch safety and potency testing)						
Batch safety testing	0	192,119	26,350	10,348	**228,817**	**2.3**
Pyrogenicity testing	923	28,448	17,178	4	**46,553**	**0.5**
Batch potency testing	8,757	407,504	310,422	305,552	**1,032,235**	**10.6**
Other quality controls	264	21,932	1,325	1,410	**24,931**	**0.3**
Toxicity and other safety testing including pharmacology						
Acute and sub-acute toxicity testing methods						
LD50, LC50	4,688	29,893	6,651	17,079	**58,311**	**0.6**
Other lethal methods	1,364	753	1,219	494	**3,830**	**0**
Non lethal methods	412	18,621	10,784	2,303	**32,120**	**0.3**
Skin irritation/corrosion	249	3,603	880	41	**4,773**	**0**
Skin sensitisation	3,218	42,305	3,482	544	**49,549**	**0.5**
Eye irritation/corrosion	269	523	681	45	**1,518**	**0**
Repeated dose toxicity						
up to 28 days	1	45,957	25,616	2,118	**73,692**	**0.8**
29 - 90 days	0	20,121	7,224	678	**28,023**	**0.3**
> 90 days	884	9,690	7,010	611	**18,195**	**0.2**
Carcinogenicity	239	11,691	11,143	950	**24,023**	**0.2**
Genotoxicity	135	10,224	1,665	381	**12,405**	**0.1**
Reproductive toxicity	586	80,724	14,188	1,428	**96,926**	**1**
Developmental toxicity	724	99,384	11,244	1,674	**113,026**	**1.2**
Neurotoxicity	6	1,944	4,728	3,122	**9,800**	**0.1**
Kinetics	224	42,423	20,853	1,022	**64,522**	**0.7**
Pharmaco-dynamics (incl safety pharmacology)	1,073	65,901	37,813	5,977	**110,764**	**1.1**
Phototoxicity	0	468	122	6	**596**	**0**
Ecotoxicity						
Acute toxicity	2,557	43,678	2,958	10,901	**60,094**	**0.6**
Chronic toxicity	0	13,956	4,000	2,205	**20,161**	**0.2**
Reproductive ecotoxicity	0	3,637	0	16	**3,653**	**0**
Endocrine activity	0	2,050	7,538	322	**9,910**	**0.1**
Bioaccumulation	0	2,058	886	6	**2,950**	**0**
Other ecotoxicity	0	8,195	21	161	**8,377**	**0.1**
Safety testing in food and feed area	0	24,702	90	10,931	**35,723**	**0.4**
Target animal safety	0	11,791	3,103	224	**15,118**	**0.2**
Other toxicity/safety testing	141	11,383	3,686	318	**15,528**	**0.2**
Other efficacy and tolerance testing						
Other efficacy and tolerance testing	242	107,902	36,153	5,932	**150,229**	**1.5**
Routine production						
Blood based products	762	178,344	90,831	1,456	**271,393**	**2.8**
Monoclonal antibody by mouse ascites method	0	2,027	11,633	13,673	**27,333**	**0.3**
Other product types	0	133,641	19,250	3,877	**156,768**	**1.6**
Other						

		Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
	Protection of the natural environment in the interests of the health or welfare of human beings or animals	10,597	84,612	5,297	4,328	**104,834**	**1.1**
	Preservation of species	4,493	31,062	2,515	0	**38,070**	**0.4**
	Higher education or training for the acquisition, maintenance or improvement of vocational skills	47,250	83,082	31,421	671	**162,424**	**1.7**
	Forensic enquiries	22	274	19	0	**315**	**0**
Total		**622,034**	**5,330,549**	**3,010,980**	**819,007**	**9,782,570**	**100**
%		**6.4**	**54.5**	**30.8**	**8.4**	**100**	

Table 6: Basic research related uses by species and type of research (2015)

	Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals															
Rodents															
Mice	481,130	264,604	619,288	64,378	104,835	65,104	730,529	92,982	68,536	140,699	211,768	23,914	138,847	**3,006,614**	**66.6**
Rats	8,219	38,373	157,662	17,464	12,094	8,302	12,199	12,845	6,200	19,790	12,405	12,477	11,156	**329,186**	**7.3**
Guinea-Pigs	72	396	350	1,664	247	0	222	37	856	0	354	80	237	**4,515**	**0.1**
Hamsters (Syrian)	466	4	275	0	75	0	169	0	0	520	4	28	236	**1,777**	**0**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Mongolian gerbil	0	0	841	0	104	0	74	0	285	0	0	38	205	**1,547**	**0**
Other rodents	226	0	267	0	30	0	1,203	67	87	535	331	3,945	7,605	**14,296**	**0.3**
Rabbits															
Rabbits	238	2,149	285	1,184	328	739	1,083	640	838	5,122	943	2,987	5,360	**21,896**	**0.5**
Carnivores															
Cats	40	109	81	0	62	31	10	14	61	135	177	55	28	**803**	**0**
Dogs	16	54	180	4	98	339	4	75	35	42	270	156	82	**1,355**	**0**
Ferrets	0	0	244	18	0	0	0	0	20	0	0	6	56	**344**	**0**
Other carnivores	0	0	0	0	0	0	0	330	0	180	9	1,237	10	**1,766**	**0**
Farm animals															
Horses, donkeys and cross-breeds	0	29	0	45	101	158	322	422	631	318	53	310	207	**2,596**	**0.1**
Pigs	179	1,796	531	556	7,094	430	1,418	845	241	1,195	1,265	7,016	2,333	**24,899**	**0.6**
Goats	0	22	2	0	55	0	39	138	0	30	53	259	324	**922**	**0**
Sheep	31	548	202	177	508	291	265	379	0	183	447	2,749	2,661	**8,441**	**0.2**
Cattle	16	239	52	41	934	0	965	3,113	0	1,398	2,341	6,014	678	**15,791**	**0.3**
Non-human primates															
Prosimians	0	0	59	0	0	0	0	0	0	138	0	61	0	**258**	**0**
Marmoset and tamarins	0	0	87	42	0	38	0	54	0	0	52	0	0	**273**	**0**
Squirrel monkey	0	0	13	0	0	0	0	0	0	0	0	0	0	**13**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	24	0	**24**	**0**
Cynomolgus monkey	4	0	101	0	0	6	15	0	0	5	1	4	4	**140**	**0**
Rhesus monkey	0	61	121	0	0	0	18	0	0	4	0	0	11	**215**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Baboons	0	0	9	0	0	0	3	0	0	0	0	0	0	**12**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	8	0	**8**	**0**
Other mammals															
Other mammals	0	2	200	0	10	726	154	57	9	14	5	7,097	172	**8,446**	**0.2**
Birds															
Domestic fowl	1,026	700	2,711	20	24,691	31	4,326	908	211	4,673	7,116	29,257	72,726	**148,396**	**3.3**
Other birds	24	593	470	0	780	52	1,897	132	14	446	4,060	38,279	5,245	**51,992**	**1.2**
Reptiles															
Reptiles	0	45	332	30	0	0	0	0	0	0	4	2,896	53	**3,360**	**0.1**
Amphibians															
Rana	800	0	0	0	0	0	0	0	10	0	0	482	0	**1,292**	**0**
Xenopus	437	371	2,990	0	328	45	0	2,021	719	664	858	284	7,206	**15,923**	**0.4**
Other amphibians	0	27	19	0	0	751	0	14	202	0	0	5,626	2,625	**9,264**	**0.2**
Fish															
Zebra fish	20,341	28,026	67,207	54	922	15,578	24,086	15,808	7,057	11,823	29,073	6,051	12,565	**238,591**	**5.3**
Other fish	3,139	458	3,234	101	54,737	49	25,351	7,076	140	21,214	26,016	453,898	3,450	**598,863**	**13.3**
Cephalopods															
Cephalopods	0	0	0	0	0	0	0	0	0	0	0	1	1	**2**	**0**
Totals															
Total	**516,404**	**338,606**	**857,813**	**85,778**	**208,033**	**92,670**	**804,352**	**137,957**	**86,152**	**209,128**	**297,605**	**605,239**	**274,083**	**4,513,820**	**100**
%	**11.4**	**7.5**	**19**	**1.9**	**4.6**	**2.1**	**17.8**	**3.1**	**1.9**	**4.6**	**6.6**	**13.4**	**6.1**	**100**	

Table 7.1: Translational and applied research related uses by species and type of research (Part 1) (2015)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders	Human Urogenital/Reproductive Disorders
Mammals									
Rodents									
Mice	480,841	239,021	41,262	214,488	35,801	24,619	21,550	70,732	11,394
Rats	7,583	9,986	14,778	112,839	23,188	6,515	6,763	5,785	3,451
Guinea-Pigs	2	930	586	607	5,836	55	280	121	53
Hamsters (Syrian)	390	5,109	134	65	0	0	0	0	4
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0
Mongolian gerbil	216	1,089	0	75	28	0	0	0	0
Other rodents	0	2,101	0	494	0	0	0	80	0
Rabbits									
Rabbits	1,283	1,164	796	143	875	124	1,062	146	18
Carnivores									
Cats	0	0	0	0	0	38	0	0	0
Dogs	54	36	97	747	98	29	86	43	6
Ferrets	0	885	0	0	0	64	0	0	0
Other carnivores	0	4	0	0	0	0	0	0	0
Farm animals									
Horses, donkeys and cross-breeds	0	92	0	0	0	0	25	5	0
Pigs	250	108	2,728	203	417	704	110	274	391
Goats	11	0	18	5	0	0	111	0	7
Sheep	24	1,781	525	207	38	5	784	0	211
Cattle	0	113	39	0	46	0	0	0	16
Non-human primates									
Prosimians	0	0	0	1	0	0	0	0	0
Marmoset and tamarins	0	4	0	38	0	0	0	4	0
Squirrel monkey	0	0	0	0	0	0	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	3	479	38	129	57	57	5	49	1
Rhesus monkey	3	127	0	12	0	0	0	0	2
Vervets (Chlorocebus spp.)	0	4	0	0	0	0	0	0	0
Baboons	0	0	6	0	0	0	0	0	6
Other species of old world monkeys (Cercopithecoidea)	0	1	0	0	0	0	0	0	0
Other mammals									
Other mammals	34	487	6	15	0	0	0	6	21
Birds									
Domestic fowl	509	97	0	0	0	0	0	2	0
Other birds	0	6,502	0	0	0	0	0	3	0
Reptiles									
Reptiles	0	0	0	0	0	0	0	0	0
Amphibians									
Rana	0	0	0	0	0	0	0	0	0
Xenopus	0	0	44	25	0	0	0	0	0
Other amphibians	0	0	0	18	0	0	0	0	0
Fish									
Zebra fish	1,113	12,082	1,106	15,788	0	0	498	0	2,324
Other fish	4	0	0	0	0	0	0	0	0
Cephalopods									
Cephalopods	0	0	0	0	0	0	0	0	0
Totals									
Total	**492,320**	**282,202**	**62,163**	**345,899**	**66,384**	**32,210**	**31,274**	**77,250**	**17,905**
%	**22.9**	**13.1**	**2.9**	**16.1**	**3.1**	**1.5**	**1.5**	**3.6**	**0.8**

Table 7.2: Translational and applied research related uses by species and type of research (Part 2) (2015)

	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	38,408	79,739	73,176	44,132	4,092	46,755	6	17,020	**1,443,036**	**67.1**
Rats	6,095	41,142	15,021	1,549	723	4,665	419	22,798	**283,300**	**13.2**
Guinea-Pigs	403	18	13,705	1,934	243	1,080	0	161	**26,014**	**1.2**
Hamsters (Syrian)	0	682	218	790	0	78	0	11	**7,481**	**0.3**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	**0**	**0**
Mongolian gerbil	12	0	0	1,704	0	0	0	62	**3,186**	**0.1**
Other rodents	0	0	0	145	0	0	0	70	**2,890**	**0.1**
Rabbits										
Rabbits	1,006	115	1,315	5,968	10	862	44	1,117	**16,048**	**0.7**
Carnivores										
Cats	0	0	0	1,028	8	36	0	5	**1,115**	**0.1**
Dogs	28	257	291	5,265	19	84	0	1,212	**8,352**	**0.4**
Ferrets	0	0	0	40	52	21	0	0	**1,062**	**0**
Other carnivores	0	0	0	346	532	0	0	0	**882**	**0**
Farm animals										
Horses, donkeys and cross-breeds	0	0	0	731	264	100	0	0	**1,217**	**0.1**
Pigs	253	1,395	529	15,412	3,489	136	11	615	**27,025**	**1.3**
Goats	0	0	2	1,151	51	7	0	0	**1,363**	**0.1**
Sheep	10	0	2	4,508	332	895	0	32	**9,354**	**0.4**
Cattle	0	0	264	8,016	2,156	175	0	14	**10,839**	**0.5**
Non-human primates										
Prosimians	0	0	0	0	0	0	0	0	**1**	**0**
Marmoset and tamarins	0	14	12	0	0	0	0	17	**89**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	**0**	**0**
Cynomolgus monkey	32	55	1	0	0	0	0	291	**1,197**	**0.1**
Rhesus monkey	0	4	0	0	0	0	0	0	**148**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	52	**56**	**0**
Baboons	0	0	0	0	0	0	0	18	**30**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	**1**	**0**
Other mammals										
Other mammals	0	17	0	490	45	619	0	0	**1,740**	**0.1**
Birds										
Domestic fowl	0	0	271	63,761	19,857	1,825	0	375	**86,697**	**4**
Other birds	0	0	165	7,706	492	2,936	0	0	**17,804**	**0.8**
Reptiles										
Reptiles	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians										
Rana	0	0	0	0	0	0	0	0	**0**	**0**
Xenopus	12	0	0	0	0	0	0	1,173	**1,254**	**0.1**
Other amphibians	0	0	15	24	7	0	0	0	**64**	**0**
Fish										
Zebra fish	127	375	786	888	0	0	0	20,663	**55,750**	**2.6**
Other fish	0	0	0	58,217	30,303	24,689	0	14,205	**127,418**	**5.9**
Cephalopods										
Cephalopods	0	0	0	8	15,840	0	0	0	**15,848**	**0.7**
Totals										
Total	**46,386**	**123,813**	**105,773**	**223,813**	**78,515**	**84,963**	**480**	**79,911**	**2,151,261**	**100**
%	**2.2**	**5.8**	**4.9**	**10.4**	**3.6**	**3.9**	**0**	**3.7**	**100**	

Table 8: Regulatory uses by species and type of use (2015)

		Quality				Toxicity	Other		
		Quality: Batch safety testing	Quality: Pyrogenicity testing	Quality: Batch potency testing	Quality: Other quality controls	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing	Total	%
Mammals									
	Rodents								
	Mice	131,742	10	715,180	17,685	257,936	78,016	**1,200,569**	**51**
	Rats	14,935	0	147,981	1,573	388,116	6,476	**559,081**	**23.7**
	Guinea-Pigs	20,617	0	62,455	1,202	30,923	596	**115,793**	**4.9**
	Hamsters (Syrian)	2,025	0	5,326	352	1,259	1,728	**10,690**	**0.5**
	Hamsters (Chinese)	0	0	0	0	30	0	**30**	**0**
	Mongolian gerbil	0	0	0	0	1,581	24	**1,605**	**0.1**
	Other rodents	67	0	0	0	8,370	0	**8,437**	**0.4**
	Rabbits								
	Rabbits	3,375	46,543	19,762	235	30,692	2,414	**103,021**	**4.4**
	Carnivores								
	Cats	145	0	103	0	723	229	**1,200**	**0.1**
	Dogs	285	0	17	0	9,877	1,057	**11,236**	**0.5**
	Ferrets	621	0	0	0	171	47	**839**	**0**
	Other carnivores	556	0	0	0	142	144	**842**	**0**
	Farm animals								
	Horses, donkeys and cross-breeds	9	0	4	0	47	93	**153**	**0**
	Pigs	2,621	0	2,177	109	4,285	5,727	**14,919**	**0.6**
	Goats	6	0	48	0	67	0	**121**	**0**
	Sheep	608	0	567	21	683	102	**1,981**	**0.1**
	Cattle	297	0	1,584	6	769	1,324	**3,980**	**0.2**
	Non-human primates								
	Prosimians	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	0	0	162	0	**162**	**0**
	Squirrel monkey	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	18	0	0	0	5,954	3	**5,975**	**0.3**
	Rhesus monkey	0	0	0	0	23	31	**54**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	**0**	**0**
	Other mammals								
	Other mammals	0	0	0	0	77	63	**140**	**0**
Birds									
	Domestic fowl	48,806	0	72,451	3,046	16,511	27,647	**168,461**	**7.1**
	Other birds	1,884	0	547	180	2,585	1,098	**6,294**	**0.3**
Reptiles									
	Reptiles	0	0	0	0	0	0	**0**	**0**
Amphibians									
	Rana	0	0	0	0	132	0	**132**	**0**
	Xenopus	0	0	0	0	720	0	**720**	**0**
	Other amphibians	0	0	0	0	60	0	**60**	**0**
Fish									
	Zebra fish	0	0	0	86	42,979	0	**43,065**	**1.8**
	Other fish	200	0	4,033	436	68,713	23,410	**96,792**	**4.1**
Cephalopods									
	Cephalopods	0	0	0	0	0	0	**0**	**0**
Totals									
	Total	**228,817**	**46,553**	**1,032,235**	**24,931**	**873,587**	**150,229**	**2,356,352**	**100**
	%	**9.7**	**2**	**43.8**	**1.1**	**37.1**	**6.4**	**100**	

Table 9.1: Toxicity and other safety testing including pharmacology by species and type of use (Part 1) (2015)

	Acute						Repeated Dose						
	LD50, LC50	Other lethal methods	Non lethal methods	Skin irritation / corrosion	Skin sensitisation	Eye irritation / corrosion	up to 28 days	29 - 90 days	> 90 days	Carcinogenicity	Genotoxicity	Developmental toxicity	Safety testing in food and feed area
Mammals													
Rodents													
Mice	39,713	1,671	13,492	0	21,683	0	22,683	3,722	2,159	9,083	6,165	644	33,105
Rats	6,638	1,168	12,846	400	69	49	44,025	21,197	12,227	14,940	6,148	104,091	0
Guinea-Pigs	342	0	1,373	19	27,653	22	0	0	0	0	0	0	0
Hamsters (Syrian)	0	0	334	139	7	0	395	0	200	0	4	0	0
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	30	0	0
Mongolian gerbil	0	0	0	0	0	0	0	0	0	0	0	0	0
Other rodents	0	0	0	0	0	0	0	0	0	0	0	0	0
Rabbits													
Rabbits	0	0	1,165	4,182	129	1,447	1,310	740	224	0	58	6,961	32
Carnivores													
Cats	0	0	0	0	0	0	0	9	0	0	0	0	0
Dogs	0	0	671	0	0	0	2,993	1,211	1,431	0	0	14	38
Ferrets	0	0	0	0	0	0	146	0	0	0	0	0	0
Other carnivores	58	0	0	0	0	0	0	0	0	0	0	0	0
Farm animals													
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	0	0	0	0
Pigs	0	0	147	33	8	0	716	376	369	0	0	0	91
Goats	0	0	0	0	0	0	0	0	0	0	0	0	0
Sheep	0	0	0	0	0	0	0	0	0	0	0	0	344
Cattle	0	0	0	0	0	0	0	0	0	0	0	0	176
Non-human primates													
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0
Marmoset and tamarins	0	0	0	0	0	0	0	6	36	0	0	0	0
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	0	0	128	0	0	0	1,421	762	1,549	0	0	113	0
Rhesus monkey	0	0	0	0	0	0	3	0	0	0	0	0	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
Other mammals													
Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	0
Birds													
Domestic fowl	3,570	0	0	0	0	0	0	0	0	0	0	0	1,505
Other birds	80	0	40	0	0	0	0	0	0	0	0	0	0
Reptiles													
Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0
Amphibians													
Rana	0	0	0	0	0	0	0	0	0	0	0	0	0
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish													
Zebra fish	2,101	991	1,579	0	0	0	0	0	0	0	0	800	0
Other fish	5,809	0	345	0	0	0	0	0	0	0	0	403	432
Cephalopods													
Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals													
Total	**58,311**	**3,830**	**32,120**	**4,773**	**49,549**	**1,518**	**73,692**	**28,023**	**18,195**	**24,023**	**12,405**	**113,026**	**35,723**
%	**6.7**	**0.4**	**3.7**	**0.5**	**5.7**	**0.2**	**8.5**	**3.2**	**2.1**	**2.8**	**1.4**	**13**	**4.1**

Table 9.2: Toxicity and other safety testing including pharmacology by species and type of use (Part 2) (2015)

							EcoToxicity								
		Target animal safety	Neurotoxicity	Kinetics	Pharmaco - dynamics (incl safety pharmacology)	Phototoxicity	Acute toxicity	Chronic toxicity	Reproductive toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Other toxicity / safety testing	Total	%
Mammals															
	Rodents														
	Mice	632	484	29,729	60,090	420	6,495	81	160	0	0	0	5,725	**257,936**	**29.7**
	Rats	60	916	27,815	42,105	112	1,864	896	85,462	0	58	0	5,030	**388,116**	**44.6**
	Guinea-Pigs	0	0	102	1,111	64	137	0	0	0	0	0	100	**30,923**	**3.6**
	Hamsters (Syrian)	0	0	23	100	0	0	0	0	0	0	0	57	**1,259**	**0.1**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	**30**	**0**
	Mongolian gerbil	0	0	0	1,581	0	0	0	0	0	0	0	0	**1,581**	**0.2**
	Other rodents	314	0	0	0	0	0	0	0	0	0	5,201	2,855	**8,370**	**1**
	Rabbits														
	Rabbits	38	0	838	2,097	0	27	0	11,104	0	0	0	340	**30,692**	**3.5**
	Carnivores														
	Cats	155	0	437	78	0	0	0	0	0	18	0	26	**723**	**0.1**
	Dogs	173	0	2,066	942	0	0	0	0	0	0	0	338	**9,877**	**1.1**
	Ferrets	0	0	0	25	0	0	0	0	0	0	0	0	**171**	**0**
	Other carnivores	84	0	0	0	0	0	0	0	0	0	0	0	**142**	**0**
	Farm animals														
	Horses, donkeys and cross-breeds	28	0	19	0	0	0	0	0	0	0	0	0	**47**	**0**
	Pigs	871	0	1,072	352	0	0	0	9	0	0	6	235	**4,285**	**0.5**
	Goats	0	0	66	0	0	0	0	0	0	0	0	1	**67**	**0**
	Sheep	20	0	242	21	0	0	0	0	0	0	0	56	**683**	**0.1**
	Cattle	23	0	355	20	0	0	0	0	0	0	0	195	**769**	**0.1**
	Non-human primates														
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	37	22	0	0	0	0	0	0	0	61	**162**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	0	1,013	298	0	0	0	191	0	0	0	479	**5,954**	**0.7**
	Rhesus monkey	0	0	20	0	0	0	0	0	0	0	0	0	**23**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals														
	Other mammals	77	0	0	0	0	0	0	0	0	0	0	0	**77**	**0**
Birds															
	Domestic fowl	10,781	0	610	0	0	15	0	0	0	0	0	30	**16,511**	**1.9**
	Other birds	312	0	78	0	0	1,125	0	0	0	0	154	0	**1,789**	**0.2**
Reptiles															
	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians															
	Rana	0	0	0	0	0	132	0	0	0	0	0	0	**132**	**0**
	Xenopus	0	0	0	0	0	0	0	0	720	0	0	0	**720**	**0.1**
	Other amphibians	0	0	0	0	0	0	60	0	0	0	0	0	**60**	**0**
Fish															
	Zebra fish	120	8,400	0	1,410	0	7,246	8,362	0	8,210	591	812	0	**40,622**	**4.7**
	Other fish	1,430	0	0	512	0	43,053	10,762	0	980	2,283	2,204	0	**68,213**	**7.8**
Cephalopods															
	Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals															
	Total	**15,118**	**9,800**	**64,522**	**110,764**	**596**	**60,094**	**20,161**	**96,926**	**9,910**	**2,950**	**8,377**	**15,528**	**869,934**	**100**
	%	**1.7**	**1.1**	**7.4**	**12.7**	**0.1**	**6.9**	**2.3**	**11.1**	**1.1**	**0.3**	**1**	**1.8**	**100**	

Table 10: Regulatory uses by species and type of legislation (2015)

		Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Other legislation	Total	%
Mammals												
	Rodents											
	Mice	988,107	124,591	16,001	13,014	10,086	1,966	41,099	3,683	2,022	**1,200,569**	**51**
	Rats	349,497	12,869	3,976	152,321	31,060	1,488	4,564	223	3,083	**559,081**	**23.7**
	Guinea-Pigs	73,760	16,106	21,660	2,432	1,412	105	38	0	280	**115,793**	**4.9**
	Hamsters (Syrian)	1,212	8,866	591	10	0	0	0	0	11	**10,690**	**0.5**
	Hamsters (Chinese)	0	0	0	30	0	0	0	0	0	**30**	**0**
	Mongolian gerbil	35	1,570	0	0	0	0	0	0	0	**1,605**	**0.1**
	Other rodents	67	0	0	0	8,370	0	0	0	0	**8,437**	**0.4**
	Rabbits											
	Rabbits	71,027	14,746	4,527	9,792	1,390	86	35	4	1,414	**103,021**	**4.4**
	Carnivores											
	Cats	58	1,142	0	0	0	0	0	0	0	**1,200**	**0.1**
	Dogs	8,843	1,906	32	60	158	0	0	12	225	**11,236**	**0.5**
	Ferrets	792	47	0	0	0	0	0	0	0	**839**	**0**
	Other carnivores	0	818	0	0	0	0	0	0	24	**842**	**0**
	Farm animals											
	Horses, donkeys and cross-breeds	8	121	0	0	0	0	0	0	24	**153**	**0**
	Pigs	3,339	10,169	297	0	1	0	98	967	48	**14,919**	**0.6**
	Goats	52	51	0	0	18	0	0	0	0	**121**	**0**
	Sheep	13	1,385	172	0	0	0	338	16	57	**1,981**	**0.1**
	Cattle	0	3,303	0	0	123	0	0	406	148	**3,980**	**0.2**
	Non-human primates											
	Prosimians	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	162	0	0	0	0	0	0	0	0	**162**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	5,962	0	0	0	0	0	0	0	13	**5,975**	**0.3**
	Rhesus monkey	54	0	0	0	0	0	0	0	0	**54**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals											
	Other mammals	0	140	0	0	0	0	0	0	0	**140**	**0**
Birds												
	Domestic fowl	1,547	157,170	0	0	525	0	160	9,059	0	**168,461**	**7.1**
	Other birds	80	3,082	0	24	2,091	0	57	960	0	**6,294**	**0.3**
Reptiles												
	Reptiles	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians												
	Rana	0	0	0	0	132	0	0	0	0	**132**	**0**
	Xenopus	0	0	0	0	0	0	0	0	720	**720**	**0**
	Other amphibians	0	0	0	0	60	0	0	0	0	**60**	**0**
Fish												
	Zebra fish	7,946	2,511	0	7,122	4,442	1,109	0	1,512	18,423	**43,065**	**1.8**
	Other fish	5,562	7,978	14	11,145	12,216	142	953	23,410	35,372	**96,792**	**4.1**
Cephalopods												
	Cephalopods	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals												
	Total	**1,518,123**	**368,571**	**47,270**	**195,950**	**72,084**	**4,896**	**47,342**	**40,252**	**61,864**	**2,356,352**	**100**
	%	**64.4**	**15.6**	**2**	**8.3**	**3.1**	**0.2**	**2**	**1.7**	**2.6**	**100**	

Table 11: Regulatory uses by species and origin of regulatory requirement (2015)

	Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total	%
Mammals					
Rodents					
Mice	1,128,543	21,105	50,921	**1,200,569**	**51**
Rats	548,222	1,121	9,738	**559,081**	**23.7**
Guinea-Pigs	105,812	0	9,981	**115,793**	**4.9**
Hamsters (Syrian)	10,353	157	180	**10,690**	**0.5**
Hamsters (Chinese)	30	0	0	**30**	**0**
Mongolian gerbil	1,605	0	0	**1,605**	**0.1**
Other rodents	8,437	0	0	**8,437**	**0.4**
Rabbits					
Rabbits	90,220	15	12,786	**103,021**	**4.4**
Carnivores					
Cats	1,198	0	2	**1,200**	**0.1**
Dogs	11,183	13	40	**11,236**	**0.5**
Ferrets	839	0	0	**839**	**0**
Other carnivores	818	24	0	**842**	**0**
Farm animals					
Horses, donkeys and cross-breeds	153	0	0	**153**	**0**
Pigs	13,607	69	1,243	**14,919**	**0.6**
Goats	121	0	0	**121**	**0**
Sheep	1,974	1	6	**1,981**	**0.1**
Cattle	3,966	2	12	**3,980**	**0.2**
Non-human primates					
Prosimians	0	0	0	**0**	**0**
Marmoset and tamarins	162	0	0	**162**	**0**
Squirrel monkey	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
Cynomolgus monkey	5,963	0	12	**5,975**	**0.3**
Rhesus monkey	54	0	0	**54**	**0**
Vervets (Chlorocebus spp.)	0	0	0	**0**	**0**
Baboons	0	0	0	**0**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
Other mammals					
Other mammals	140	0	0	**140**	**0**
Birds					
Domestic fowl	162,369	341	5,751	**168,461**	**7.1**
Other birds	6,072	206	16	**6,294**	**0.3**
Reptiles					
Reptiles	0	0	0	**0**	**0**
Amphibians					
Rana	132	0	0	**132**	**0**
Xenopus	720	0	0	**720**	**0**
Other amphibians	60	0	0	**60**	**0**
Fish					
Zebra fish	39,955	3,110	0	**43,065**	**1.8**
Other fish	79,909	15,410	1,473	**96,792**	**4.1**
Cephalopods					
Cephalopods	0	0	0	**0**	**0**
Totals					
Total	**2,222,617**	**41,574**	**92,161**	**2,356,352**	**100**
%	**94.3**	**1.8**	**3.9**	**100**	

Table 12: Routine production uses by species and product type (2015)

	Blood based products	Other product types	Monoclonal antibody by mouse ascites method	Total	%
Mammals					
Rodents					
Mice	2,955	3,660	27,067	**33,682**	**7.4**
Rats	1,161	263	26	**1,450**	**0.3**
Guinea-Pigs	1,397	33	0	**1,430**	**0.3**
Hamsters (Syrian)	180	0	0	**180**	**0**
Hamsters (Chinese)	0	0	0	**0**	**0**
Mongolian gerbil	19	167	0	**186**	**0**
Other rodents	38	0	0	**38**	**0**
Rabbits					
Rabbits	174,320	43,372	240	**217,932**	**47.8**
Carnivores					
Cats	0	18	0	**18**	**0**
Dogs	239	0	0	**239**	**0.1**
Ferrets	6	0	0	**6**	**0**
Other carnivores	2	0	0	**2**	**0**
Farm animals					
Horses, donkeys and cross-breeds	7,760	18	0	**7,778**	**1.7**
Pigs	34	257	0	**291**	**0.1**
Goats	27	0	0	**27**	**0**
Sheep	39,517	1,542	0	**41,059**	**9**
Cattle	8	145	0	**153**	**0**
Non-human primates					
Prosimians	0	0	0	**0**	**0**
Marmoset and tamarins	84	0	0	**84**	**0**
Squirrel monkey	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
Cynomolgus monkey	2,036	28	0	**2,064**	**0.5**
Rhesus monkey	32	0	0	**32**	**0**
Vervets (Chlorocebus spp.)	0	0	0	**0**	**0**
Baboons	0	0	0	**0**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
Other mammals					
Other mammals	31	15	0	**46**	**0**
Birds					
Domestic fowl	497	106,423	0	**106,920**	**23.5**
Other birds	41,050	502	0	**41,552**	**9.1**
Reptiles					
Reptiles	0	300	0	**300**	**0.1**
Amphibians					
Rana	0	0	0	**0**	**0**
Xenopus	0	0	0	**0**	**0**
Other amphibians	0	0	0	**0**	**0**
Fish					
Zebra fish	0	0	0	**0**	**0**
Other fish	0	25	0	**25**	**0**
Cephalopods					
Cephalopods	0	0	0	**0**	**0**
Totals					
Total	**271,393**	**156,768**	**27,333**	**455,494**	**100**
%	**59.6**	**34.4**	**6**	**100**	

Table 13: Reuses of animals by species and main categories of scientific purposes in research, testing routine production and education (2015)

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Yes	16,924	11,745	19,717	72	2	1,840	4,892	0	55,192	1.0
	No	2,989,690	1,431,291	1,180,852	33,610	3,619	4,878	67,632	40	5,711,612	99.0
	Total	**3,006,614**	**1,443,036**	**1,200,569**	**33,682**	**3,621**	**6,718**	**72,524**	**40**	**5,766,804**	**100.0**
Rats	Yes	3,592	5,596	3,347	169	0	0	2,645	30	15,379	1.3
	No	325,594	277,704	555,734	1,281	1,151	159	39,495	71	1,201,189	98.7
	Total	**329,186**	**283,300**	**559,081**	**1,450**	**1,151**	**159**	**42,140**	**101**	**1,216,568**	**100.0**
Guinea-Pigs	Yes	19	71	469	28	0	0	229	0	816	0.5
	No	4,496	25,943	115,324	1,402	0	0	2,127	36	149,328	99.5
	Total	**4,515**	**26,014**	**115,793**	**1,430**	**0**	**0**	**2,356**	**36**	**150,144**	**100.0**
Hamsters (Syrian)	Yes	28	0	0	0	0	0	16	0	44	0.2
	No	1,749	7,481	10,690	180	0	0	95	0	20,195	99.8
	Total	**1,777**	**7,481**	**10,690**	**180**	**0**	**0**	**111**	**0**	**20,239**	**100.0**
Hamsters (Chinese)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	0	0	30	0	0	0	0	0	30	100.0
	Total	**0**	**0**	**30**	**0**	**0**	**0**	**0**	**0**	**30**	**100.0**
Mongolian gerbil	Yes	145	259	0	0	0	0	0	0	404	6.1
	No	1,402	2,927	1,605	186	0	0	79	0	6,199	93.9
	Total	**1,547**	**3,186**	**1,605**	**186**	**0**	**0**	**79**	**0**	**6,603**	**100.0**
Other rodents	Yes	757	0	0	0	22	0	16	0	795	3.0
	No	13,539	2,890	8,437	38	625	315	244	0	26,088	97.0
	Total	**14,296**	**2,890**	**8,437**	**38**	**647**	**315**	**260**	**0**	**26,883**	**100.0**
Rabbits	Yes	441	895	12,477	1,004	12	0	321	0	15,150	4.2
	No	21,455	15,153	90,544	216,928	225	0	1,747	0	346,052	95.8
	Total	**21,896**	**16,048**	**103,021**	**217,932**	**237**	**0**	**2,068**	**0**	**361,202**	**100.0**
Cats	Yes	282	389	492	0	0	0	47	0	1,210	38.0
	No	521	726	708	18	0	0	2	0	1,975	62.0
	Total	**803**	**1,115**	**1,200**	**18**	**0**	**0**	**49**	**0**	**3,185**	**100.0**
Dogs	Yes	460	3,163	2,971	231	6	0	407	0	7,238	33.3
	No	895	5,189	8,265	8	6	0	138	0	14,501	66.7
	Total	**1,355**	**8,352**	**11,236**	**239**	**12**	**0**	**545**	**0**	**21,739**	**100.0**
Ferrets	Yes	15	46	0	0	0	0	79	0	140	6.0
	No	329	1,016	839	6	0	0	22	0	2,212	94.0
	Total	**344**	**1,062**	**839**	**6**	**0**	**0**	**101**	**0**	**2,352**	**100.0**
Other carnivores	Yes	36	0	24	2	0	14	0	0	76	2.0
	No	1,730	882	818	0	170	48	0	0	3,648	98.0
	Total	**1,766**	**882**	**842**	**2**	**170**	**62**	**0**	**0**	**3,724**	**100.0**
Horses, donkeys and cross-breeds	Yes	555	370	46	7,679	1	34	166	0	8,851	73.3
	No	2,041	847	107	99	0	0	123	0	3,217	26.7
	Total	**2,596**	**1,217**	**153**	**7,778**	**1**	**34**	**289**	**0**	**12,068**	**100.0**
Pigs	Yes	658	1,314	507	1	8	3	1,014	0	3,505	4.5
	No	24,241	25,711	14,412	290	780	0	8,461	0	73,895	95.5
	Total	**24,899**	**27,025**	**14,919**	**291**	**788**	**3**	**9,475**	**0**	**77,400**	**100.0**
Goats	Yes	235	8	0	3	0	0	162	0	408	15.4
	No	687	1,355	121	24	10	0	36	0	2,233	84.6
	Total	**922**	**1,363**	**121**	**27**	**10**	**0**	**198**	**0**	**2,641**	**100.0**
Sheep	Yes	1,446	1,344	264	39,249	53	62	342	0	42,760	68.0
	No	6,995	8,010	1,717	1,810	319	0	1,134	121	20,106	32.0
	Total	**8,441**	**9,354**	**1,981**	**41,059**	**372**	**62**	**1,476**	**121**	**62,866**	**100.0**
Cattle	Yes	4,128	1,309	592	2	17	0	3,546	0	9,594	26.4
	No	11,663	9,530	3,388	151	709	0	1,316	6	26,763	73.6
	Total	**15,791**	**10,839**	**3,980**	**153**	**726**	**0**	**4,862**	**6**	**36,357**	**100.0**
Prosimians	Yes	90	0	0	0	0	0	0	0	90	34.7
	No	168	1	0	0	0	0	0	0	169	65.3

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Total	**258**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**259**	**100.0**
Marmoset and tamarins	Yes	26	9	60	84	0	0	6	0	185	30.1
	No	247	80	102	0	0	0	0	0	429	69.9
	Total	**273**	**89**	**162**	**84**	**0**	**0**	**6**	**0**	**614**	**100.0**
Squirrel monkey	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	13	0	0	0	0	0	0	0	13	100.0
	Total	**13**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**13**	**100.0**
Other species of new world monkeys (Ceboidea)	Yes	24	0	0	0	0	0	0	0	24	100.0
	No	0	0	0	0	0	0	0	0	0	0.0
	Total	**24**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**100.0**
Cynomolgus monkey	Yes	53	434	1,498	1,170	0	0	23	0	3,178	33.8
	No	87	763	4,477	894	0	0	0	0	6,221	66.2
	Total	**140**	**1,197**	**5,975**	**2,064**	**0**	**0**	**23**	**0**	**9,399**	**100.0**
Rhesus monkey	Yes	125	30	51	32	0	0	5	0	243	53.5
	No	90	118	3	0	0	0	0	0	211	46.5
	Total	**215**	**148**	**54**	**32**	**0**	**0**	**5**	**0**	**454**	**100.0**
Vervets (Chlorocebus spp.)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	0	56	0	0	0	0	0	0	56	100.0
	Total	**0**	**56**	**0**	**0**	**0**	**0**	**0**	**0**	**56**	**100.0**
Baboons	Yes	3	2	0	0	0	0	0	0	5	11.9
	No	9	28	0	0	0	0	0	0	37	88.1
	Total	**12**	**30**	**0**	**0**	**0**	**0**	**0**	**0**	**42**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Yes	8	1	0	0	0	0	0	0	9	100.0
	No	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**100.0**
Other mammals	Yes	1,206	453	0	0	0	0	0	0	1,659	14.8
	No	7,240	1,287	140	46	544	205	73	0	9,535	85.2
	Total	**8,446**	**1,740**	**140**	**46**	**544**	**205**	**73**	**0**	**11,194**	**100.0**
Domestic fowl	Yes	688	812	2,030	173	253	0	1,362	0	5,318	1.0
	No	147,708	85,885	166,431	106,747	2,324	939	5,800	0	515,834	99.0
	Total	**148,396**	**86,697**	**168,461**	**106,920**	**2,577**	**939**	**7,162**	**0**	**521,152**	**100.0**
Other birds	Yes	1,213	354	236	0	4	0	460	0	2,267	1.9
	No	50,779	17,450	6,058	41,552	2,737	624	166	11	119,377	98.1
	Total	**51,992**	**17,804**	**6,294**	**41,552**	**2,741**	**624**	**626**	**11**	**121,644**	**100.0**
Reptiles	Yes	1,099	0	0	300	0	0	19	0	1,418	37.0
	No	2,261	0	0	0	93	46	14	0	2,414	63.0
	Total	**3,360**	**0**	**0**	**300**	**93**	**46**	**33**	**0**	**3,832**	**100.0**
Rana	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	1,292	0	132	0	600	0	2,860	0	4,884	100.0
	Total	**1,292**	**0**	**132**	**0**	**600**	**0**	**2,860**	**0**	**4,884**	**100.0**
Xenopus	Yes	7,443	694	0	0	0	0	16	0	8,153	42.9
	No	8,480	560	720	0	848	0	229	0	10,837	57.1
	Total	**15,923**	**1,254**	**720**	**0**	**848**	**0**	**245**	**0**	**18,990**	**100.0**
Other amphibians	Yes	115	9	0	0	120	0	0	0	244	1.2
	No	9,149	55	60	0	6,782	3,893	251	0	20,190	98.8
	Total	**9,264**	**64**	**60**	**0**	**6,902**	**3,893**	**251**	**0**	**20,434**	**100.0**
Zebra fish	Yes	4,450	0	0	0	0	0	0	0	4,450	1.3
	No	234,141	55,750	43,065	0	4,220	0	1,639	0	338,815	98.7
	Total	**238,591**	**55,750**	**43,065**	**0**	**4,220**	**0**	**1,639**	**0**	**343,265**	**100.0**
Other fish	Yes	3,337	0	0	0	0	0	49	0	3,386	0.4
	No	595,526	127,418	96,792	25	78,574	25,010	12,907	0	936,252	99.6
	Total	**598,863**	**127,418**	**96,792**	**25**	**78,574**	**25,010**	**12,956**	**0**	**939,638**	**100.0**
Cephalopods	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	**2**	**15,848**	**0**	**0**	**0**	**0**	**12**	**0**	**15,862**	**100.0**
	Total	**2**	**15,848**	**0**	**0**	**0**	**0**	**12**	**0**	**15,862**	**100.0**
All Species	**Yes**	**49,601**	**29,307**	**44,781**	**50,199**	**498**	**1,953**	**15,822**	**30**	**192,191**	**2.0**
	No	**4,464,219**	**2,121,954**	**2,311,571**	**405,295**	**104,336**	**36,117**	**146,602**	**285**	**9,590,379**	**98.0**
	Total	**4,513,820**	**2,151,261**	**2,356,352**	**455,494**	**104,834**	**38,070**	**162,424**	**315**	**9,782,570**	**100.0**

Table 14: Genetic status of animals used by species and main categories of scientific purposes (2015)

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Not altered	1,341,777	991,245	1,152,221	33,666	3,621	583	66,939	4	3,590,056	62.3
	Non harmful	1,411,193	331,031	46,407	16	0	6,063	5,059	0	1,799,769	31.2
	Harmful	253,644	120,760	1,941	0	0	72	526	36	376,979	6.5
	Total	**3,006,614**	**1,443,036**	**1,200,569**	**33,682**	**3,621**	**6,718**	**72,524**	**40**	**5,766,804**	**100.0**
Rats	Not altered	310,741	274,782	555,923	1,450	1,151	159	41,984	101	1,186,291	97.5
	Non harmful	14,917	3,755	3,024	0	0	0	120	0	21,816	1.8
	Harmful	3,528	4,763	134	0	0	0	36	0	8,461	0.7
	Total	**329,186**	**283,300**	**559,081**	**1,450**	**1,151**	**159**	**42,140**	**101**	**1,216,568**	**100.0**
Guinea-Pigs	Not altered	4,515	25,923	115,793	1,430	0	0	2,356	36	150,053	99.9
	Non harmful	0	91	0	0	0	0	0	0	91	0.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**4,515**	**26,014**	**115,793**	**1,430**	**0**	**0**	**2,356**	**36**	**150,144**	**100.0**
Hamsters (Syrian)	Not altered	1,777	7,481	10,690	180	0	0	111	0	20,239	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,777**	**7,481**	**10,690**	**180**	**0**	**0**	**111**	**0**	**20,239**	**100.0**
Hamsters (Chinese)	Not altered	0	0	30	0	0	0	0	0	30	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**0**	**0**	**30**	**0**	**0**	**0**	**0**	**0**	**30**	**100.0**
Mongolian gerbil	Not altered	1,547	3,186	1,605	186	0	0	79	0	6,603	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,547**	**3,186**	**1,605**	**186**	**0**	**0**	**79**	**0**	**6,603**	**100.0**
Other rodents	Not altered	14,296	2,890	8,437	38	647	315	260	0	26,883	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**14,296**	**2,890**	**8,437**	**38**	**647**	**315**	**260**	**0**	**26,883**	**100.0**
Rabbits	Not altered	21,851	15,968	103,021	180,133	237	0	2,067	0	323,277	89.5
	Non harmful	22	34	0	37,799	0	0	0	0	37,855	10.5
	Harmful	23	46	0	0	0	0	1	0	70	0.0
	Total	**21,896**	**16,048**	**103,021**	**217,932**	**237**	**0**	**2,068**	**0**	**361,202**	**100.0**
Cats	Not altered	803	1,115	1,200	18	0	0	49	0	3,185	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**803**	**1,115**	**1,200**	**18**	**0**	**0**	**49**	**0**	**3,185**	**100.0**
Dogs	Not altered	1,338	8,350	11,236	239	12	0	545	0	21,720	99.9
	Non harmful	8	0	0	0	0	0	0	0	8	0.0
	Harmful	9	2	0	0	0	0	0	0	11	0.1
	Total	**1,355**	**8,352**	**11,236**	**239**	**12**	**0**	**545**	**0**	**21,739**	**100.0**
Ferrets	Not altered	344	1,062	839	6	0	0	101	0	2,352	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**344**	**1,062**	**839**	**6**	**0**	**0**	**101**	**0**	**2,352**	**100.0**
Other carnivores	Not altered	1,766	882	842	2	170	62	0	0	3,724	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,766**	**882**	**842**	**2**	**170**	**62**	**0**	**0**	**3,724**	**100.0**
Horses, donkeys and cross-breeds	Not altered	2,596	1,217	153	7,778	1	34	289	0	12,068	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**2,596**	**1,217**	**153**	**7,778**	**1**	**34**	**289**	**0**	**12,068**	**100.0**

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Pigs	Not altered	24,821	26,759	14,919	291	788	3	9,475	0	77,056	99.6
	Non harmful	48	135	0	0	0	0	0	0	183	0.2
	Harmful	30	131	0	0	0	0	0	0	161	0.2
	Total	**24,899**	**27,025**	**14,919**	**291**	**788**	**3**	**9,475**	**0**	**77,400**	**100.0**
Goats	Not altered	922	1,363	121	27	10	0	198	0	2,641	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**922**	**1,363**	**121**	**27**	**10**	**0**	**198**	**0**	**2,641**	**100.0**
Sheep	Not altered	8,434	9,354	1,981	41,059	372	62	1,476	121	62,859	100.0
	Non harmful	7	0	0	0	0	0	0	0	7	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**8,441**	**9,354**	**1,981**	**41,059**	**372**	**62**	**1,476**	**121**	**62,866**	**100.0**
Cattle	Not altered	15,790	10,839	3,980	153	726	0	4,862	6	36,356	100.0
	Non harmful	1	0	0	0	0	0	0	0	1	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**15,791**	**10,839**	**3,980**	**153**	**726**	**0**	**4,862**	**6**	**36,357**	**100.0**
Prosimians	Not altered	258	1	0	0	0	0	0	0	259	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**258**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**259**	**100.0**
Marmoset and tamarins	Not altered	273	89	162	84	0	0	6	0	614	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**273**	**89**	**162**	**84**	**0**	**0**	**6**	**0**	**614**	**100.0**
Squirrel monkey	Not altered	13	0	0	0	0	0	0	0	13	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**13**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**13**	**100.0**
Other species of new world monkeys (Ceboidea)	Not altered	24	0	0	0	0	0	0	0	24	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**24**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**100.0**
Cynomolgus monkey	Not altered	140	1,197	5,975	2,064	0	0	23	0	9,399	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**140**	**1,197**	**5,975**	**2,064**	**0**	**0**	**23**	**0**	**9,399**	**100.0**
Rhesus monkey	Not altered	215	148	54	32	0	0	5	0	454	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**215**	**148**	**54**	**32**	**0**	**0**	**5**	**0**	**454**	**100.0**
Vervets (Chlorocebus spp.)	Not altered	0	56	0	0	0	0	0	0	56	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**0**	**56**	**0**	**0**	**0**	**0**	**0**	**0**	**56**	**100.0**
Baboons	Not altered	12	30	0	0	0	0	0	0	42	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**12**	**30**	**0**	**0**	**0**	**0**	**0**	**0**	**42**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Not altered	8	1	0	0	0	0	0	0	9	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**100.0**
Other mammals	Not altered	8,446	1,740	140	46	544	205	73	0	11,194	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**8,446**	**1,740**	**140**	**46**	**544**	**205**	**73**	**0**	**11,194**	**100.0**
Domestic fowl	Not altered	148,143	86,678	168,461	106,920	2,577	939	7,162	0	520,880	99.9
	Non harmful	139	19	0	0	0	0	0	0	158	0.0
	Harmful	114	0	0	0	0	0	0	0	114	0.0
	Total	**148,396**	**86,697**	**168,461**	**106,920**	**2,577**	**939**	**7,162**	**0**	**521,152**	**100.0**

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Other birds	Not altered	51,992	17,804	6,294	41,552	2,741	624	626	11	121,644	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**51,992**	**17,804**	**6,294**	**41,552**	**2,741**	**624**	**626**	**11**	**121,644**	**100.0**
Reptiles	Not altered	3,360	0	0	300	93	46	33	0	3,832	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**3,360**	**0**	**0**	**300**	**93**	**46**	**33**	**0**	**3,832**	**100.0**
Rana	Not altered	1,292	0	132	0	600	0	2,860	0	4,884	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,292**	**0**	**132**	**0**	**600**	**0**	**2,860**	**0**	**4,884**	**100.0**
Xenopus	Not altered	14,326	1,163	720	0	848	0	245	0	17,302	91.1
	Non harmful	1,597	91	0	0	0	0	0	0	1,688	8.9
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**15,923**	**1,254**	**720**	**0**	**848**	**0**	**245**	**0**	**18,990**	**100.0**
Other amphibians	Not altered	9,143	64	60	0	6,902	3,893	251	0	20,313	99.4
	Non harmful	121	0	0	0	0	0	0	0	121	0.6
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**9,264**	**64**	**60**	**0**	**6,902**	**3,893**	**251**	**0**	**20,434**	**100.0**
Zebra fish	Not altered	92,424	24,740	42,465	0	1,758	0	1,381	0	162,768	47.4
	Non harmful	135,171	30,883	600	0	2,462	0	258	0	169,374	49.3
	Harmful	10,996	127	0	0	0	0	0	0	11,123	3.2
	Total	**238,591**	**55,750**	**43,065**	**0**	**4,220**	**0**	**1,639**	**0**	**343,265**	**100.0**
Other fish	Not altered	595,637	122,491	96,792	25	78,574	25,010	12,956	0	931,485	99.1
	Non harmful	2,620	4,927	0	0	0	0	0	0	7,547	0.8
	Harmful	606	0	0	0	0	0	0	0	606	0.1
	Total	**598,863**	**127,418**	**96,792**	**25**	**78,574**	**25,010**	**12,956**	**0**	**939,638**	**100.0**
Cephalopods	Not altered	2	15,848	0	0	0	0	12	0	15,862	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**2**	**15,848**	**0**	**0**	**0**	**0**	**12**	**0**	**15,862**	**100.0**
All Species	**Harmful**	**268,950**	**125,829**	**2,075**	**0**	**0**	**72**	**563**	**36**	**397,525**	**4.1**
	Non harmful	**1,565,844**	**370,966**	**50,031**	**37,815**	**2,462**	**6,063**	**5,437**	**0**	**2,038,618**	**20.8**
	Not altered	**2,679,026**	**1,654,466**	**2,304,246**	**417,679**	**102,372**	**31,935**	**156,424**	**279**	**7,346,427**	**75.1**
	Total	**4,513,820**	**2,151,261**	**2,356,352**	**455,494**	**104,834**	**38,070**	**162,424**	**315**	**9,782,570**	**100.0**

Part 3: Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

Table 15: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2015)

	Severity	Basic research	Translational and applied research	Total	%
Mice	Non-recovery	12,455	3,643	16,098	3.4
	Mild	382,665	13,727	396,392	83.0
	Moderate	52,476	9,094	61,570	12.9
	Severe	2,949	774	3,723	0.8
	Total	**450,545**	**27,238**	**477,783**	**100.0**
Rats	Non-recovery	146	0	146	3.3
	Mild	1,363	438	1,801	41.1
	Moderate	1,895	264	2,159	49.3
	Severe	275	0	275	6.3
	Total	**3,679**	**702**	**4,381**	**100.0**
Rabbits	Non-recovery	90	0	90	33.1
	Mild	0	0	0	0.0
	Moderate	101	81	182	66.9
	Severe	0	0	0	0.0
	Total	**191**	**81**	**272**	**100.0**
Pigs	Non-recovery	0	14	14	4.0
	Mild	138	12	150	42.9
	Moderate	166	0	166	47.4
	Severe	20	0	20	5.7
	Total	**324**	**26**	**350**	**100.0**
Sheep	Non-recovery	0	0	0	0.0
	Mild	15	0	15	48.4
	Moderate	16	0	16	51.6
	Severe	0	0	0	0.0
	Total	**31**	**0**	**31**	**100.0**
Other mammals	Non-recovery	0	0	0	0.0
	Mild	0	0	0	0.0
	Moderate	4	0	4	100.0
	Severe	0	0	0	0.0
	Total	**4**	**0**	**4**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0.0
	Mild	177	102	279	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**177**	**102**	**279**	**100.0**
Xenopus	Non-recovery	0	0	0	0.0
	Mild	6,976	0	6,976	96.1
	Moderate	283	0	283	3.9
	Severe	0	0	0	0.0
	Total	**7,259**	**0**	**7,259**	**100.0**
Zebra fish	Non-recovery	657	0	657	0.5
	Mild	104,439	1,512	105,951	85.2
	Moderate	12,584	130	12,714	10.2
	Severe	4,724	313	5,037	4.1
	Total	**122,404**	**1,955**	**124,359**	**100.0**
Other fish	Non-recovery	26	0	26	1.0
	Mild	2,516	0	2,516	98.4
	Moderate	14	0	14	0.5
	Severe	0	0	0	0.0
	Total	**2,556**	**0**	**2,556**	**100.0**
All Species	**Non-recovery**	**13,374**	**3,657**	**17,031**	**2.8**
	Mild	**498,289**	**15,791**	**514,080**	**83.3**
	Moderate	**67,539**	**9,569**	**77,108**	**12.5**
	Severe	**7,968**	**1,087**	**9,055**	**1.5**
	Total	**587,170**	**30,104**	**617,274**	**100.0**

Table 16: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2015)

	Reuse	Basic research	Translational and applied research	Total	%
Mice	Yes	1,864	151	2,015	0.4
	No	448,681	27,087	475,768	99.6
	Total	**450,545**	**27,238**	**477,783**	**100.0**
Rats	Yes	0	0	0	0.0
	No	3,679	702	4,381	100.0
	Total	**3,679**	**702**	**4,381**	**100.0**
Rabbits	Yes	0	0	0	0.0
	No	191	81	272	100.0
	Total	**191**	**81**	**272**	**100.0**
Pigs	Yes	5	0	5	1.4
	No	319	26	345	98.6
	Total	**324**	**26**	**350**	**100.0**
Sheep	Yes	0	0	0	0.0
	No	31	0	31	100.0
	Total	**31**	**0**	**31**	**100.0**
Other mammals	Yes	0	0	0	0.0
	No	4	0	4	100.0
	Total	**4**	**0**	**4**	**100.0**
Domestic fowl	Yes	0	0	0	0.0
	No	177	102	279	100.0
	Total	**177**	**102**	**279**	**100.0**
Xenopus	Yes	5	0	5	0.1
	No	7,254	0	7,254	99.9
	Total	**7,259**	**0**	**7,259**	**100.0**
Zebra fish	Yes	24,216	0	24,216	19.5
	No	98,188	1,955	100,143	80.5
	Total	**122,404**	**1,955**	**124,359**	**100.0**
Other fish	Yes	0	0	0	0.0
	No	2,556	0	2,556	100.0
	Total	**2,556**	**0**	**2,556**	**100.0**
All Species	**Yes**	**26,090**	**151**	**26,241**	**4.3**
	No	**561,080**	**29,953**	**591,033**	**95.7**
	Total	**587,170**	**30,104**	**617,274**	**100.0**

Table 17: Uses of animals for the creation of new genetically altered animal lines in basic research by species and type of research (2015)

	Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals															
Rodents															
Mice	59,475	11,835	34,962	17,196	7,257	4,114	29,805	16,561	6,702	13,612	137,627	266	111,133	**450,545**	**76.7**
Rats	133	133	700	0	72	0	100	0	43	0	1,702	0	796	**3,679**	**0.6**
Guinea-Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Other rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Rabbits															
Rabbits	0	59	0	0	0	62	0	70	0	0	0	0	0	**191**	**0**
Farm animals															
Pigs	0	0	4	40	0	0	95	0	0	6	179	0	0	**324**	**0.1**
Sheep	0	0	0	0	8	5	0	2	0	0	16	0	0	**31**	**0**
Non-human primates															
Marmoset and tamarins	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Other mammals															
Other mammals	0	0	0	0	0	0	0	4	0	0	0	0	0	**4**	**0**
Birds															
Domestic fowl	0	0	0	0	0	0	0	60	0	0	117	0	0	**177**	**0**
Amphibians															
Xenopus	0	541	0	0	0	0	0	0	0	0	6,200	0	518	**7,259**	**1.2**
Fish															
Zebra fish	3,139	19,911	20,531	0	380	15,988	3,598	2,069	549	2,879	39,075	1,800	12,485	**122,404**	**20.8**
Other fish	0	0	26	0	0	248	0	0	1,565	0	701	0	16	**2,556**	**0.4**
Totals															
Total	**62,747**	**32,479**	**56,223**	**17,236**	**7,717**	**20,417**	**33,598**	**18,766**	**8,859**	**16,497**	**185,617**	**2,066**	**124,948**	**587,170**	**100**
%	**10.7**	**5.5**	**9.6**	**2.9**	**1.3**	**3.5**	**5.7**	**3.2**	**1.5**	**2.8**	**31.6**	**0.4**	**21.3**	**100**	

Table 18.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species and type of research (Part 1) (2015)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders
Mammals								
Rodents								
Mice	15,348	396	4,887	2,301	263	574	304	836
Rats	44	0	0	264	0	0	44	0
Guinea-Pigs	0	0	0	0	0	0	0	0
Other rodents	0	0	0	0	0	0	0	0
Rabbits								
Rabbits	0	0	0	0	0	0	0	0
Farm animals								
Pigs	0	0	0	4	0	0	5	0
Sheep	0	0	0	0	0	0	0	0
Non-human primates								
Marmoset and tamarins	0	0	0	0	0	0	0	0
Other mammals								
Other mammals	0	0	0	0	0	0	0	0
Birds								
Domestic fowl	0	0	0	0	0	0	0	0
Amphibians								
Xenopus	0	0	0	0	0	0	0	0
Fish								
Zebra fish	0	1,256	0	0	0	0	0	0
Other fish	0	0	0	0	0	0	0	0
Totals								
Total	**15,392**	**1,652**	**4,887**	**2,569**	**263**	**574**	**353**	**836**
%	**51.5**	**5.5**	**16.4**	**8.6**	**0.9**	**1.9**	**1.2**	**2.8**

Table 18.2: Uses of animals for the creation of new genetically altered animal lines in basic translational and applied research by species and type of research (Part 2) (2015)

	Human Urogenital/Reproductive Disorders	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	262	377	815	84	577	0	157	57	**27,238**	**90.5**
Rats	0	0	0	0	167	111	72	0	**702**	**2.3**
Guinea-Pigs	0	0	0	0	0	0	0	0	**0**	**0**
Other rodents	0	0	0	0	0	0	0	0	**0**	**0**
Rabbits										
Rabbits	0	0	0	0	81	0	0	0	**81**	**0.3**
Farm animals										
Pigs	0	0	17	0	0	0	0	0	**26**	**0.1**
Sheep	0	0	0	0	0	0	0	0	**0**	**0**
Non-human primates										
Marmoset and tamarins	0	0	0	0	0	0	0	0	**0**	**0**
Other mammals										
Other mammals	0	0	0	0	0	0	0	0	**0**	**0**
Birds										
Domestic fowl	0	0	0	11	91	0	0	0	**102**	**0.3**
Amphibians										
Xenopus	0	0	0	0	0	0	0	0	**0**	**0**
Fish										
Zebra fish	0	695	0	4	0	0	0	0	**1,955**	**6.5**
Other fish	0	0	0	0	0	0	0	0	**0**	**0**
Totals										
Total	**262**	**1,072**	**832**	**99**	**916**	**111**	**229**	**57**	**30,104**	**100**
%	**0.9**	**3.6**	**2.8**	**0.3**	**3**	**0.4**	**0.8**	**0.2**	**100**	

Table 19: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, severity and genetic status (2015)

	Severity	Genetically altered with a harmful phenotype	Genetically altered without a harmful phenotype	Not genetically altered	Total	%
Mice	Non-recovery	49	700	105	854	0.1
	Mild	291,597	430,173	52,600	774,370	85.0
	Moderate	45,136	32,800	3,843	81,779	9.0
	Severe	29,156	24,346	219	53,721	5.9
	Total	**365,938**	**488,019**	**56,767**	**910,724**	**100.0**
Rats	Non-recovery	0	104	0	104	1.2
	Mild	4,916	2,035	507	7,458	82.8
	Moderate	203	253	0	456	5.1
	Severe	842	134	9	985	10.9
	Total	**5,961**	**2,526**	**516**	**9,003**	**100.0**
Dogs	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	0	0	0	0	0.0
	Severe	7	0	0	7	100.0
	Total	**7**	**0**	**0**	**7**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0	0.0
	Mild	0	231	0	231	71.7
	Moderate	58	0	0	58	18.0
	Severe	33	0	0	33	10.2
	Total	**91**	**231**	**0**	**322**	**100.0**
Xenopus	Non-recovery	0	0	0	0	0.0
	Mild	0	56	0	56	29.8
	Moderate	0	91	0	91	48.4
	Severe	0	41	0	41	21.8
	Total	**0**	**188**	**0**	**188**	**100.0**
Zebra fish	Non-recovery	0	4,679	153	4,832	6.0
	Mild	3,065	52,585	4,600	60,250	74.7
	Moderate	567	2,426	94	3,087	3.8
	Severe	199	11,896	368	12,463	15.5
	Total	**3,831**	**71,586**	**5,215**	**80,632**	**100.0**
Other fish	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	32	278	0	310	100.0
	Severe	0	0	0	0	0.0
	Total	**32**	**278**	**0**	**310**	**100.0**
All Species	**Non-recovery**	**49**	**5,483**	**258**	**5,790**	**0.6**
	Mild	**299,578**	**485,080**	**57,707**	**842,365**	**84.1**
	Moderate	**45,996**	**35,848**	**3,937**	**85,781**	**8.6**
	Severe	**30,237**	**36,417**	**596**	**67,250**	**6.7**
	Total	**375,860**	**562,828**	**62,498**	**1,001,186**	**100.0**

Table 20: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and genetic status (2015)

	Reuse	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	%
Mice	Yes	0	0	0	0	0.0
	No	56,767	488,019	365,938	910,724	100.0
	Total	**56,767**	**488,019**	**365,938**	**910,724**	**100.0**
Rats	Yes	0	0	0	0	0.0
	No	516	2,526	5,961	9,003	100.0
	Total	**516**	**2,526**	**5,961**	**9,003**	**100.0**
Dogs	Yes	0	0	0	0	0.0
	No	0	0	7	7	100.0
	Total	**0**	**0**	**7**	**7**	**100.0**
Domestic fowl	Yes	0	0	0	0	0.0
	No	0	231	91	322	100.0
	Total	**0**	**231**	**91**	**322**	**100.0**
Xenopus	Yes	0	188	0	188	100.0
	No	0	0	0	0	0.0
	Total	**0**	**188**	**0**	**188**	**100.0**
Zebra fish	Yes	1,750	2,217	38	4,005	5.0
	No	3,465	69,369	3,793	76,627	95.0
	Total	**5,215**	**71,586**	**3,831**	**80,632**	**100.0**
Other fish	Yes	0	0	0	0	0.0
	No	0	278	32	310	100.0
	Total	**0**	**278**	**32**	**310**	**100.0**
All Species	**Yes**	**1,750**	**2,405**	**38**	**4,193**	**0.4**
	No	**60,748**	**560,423**	**375,822**	**996,993**	**99.6**
	Total	**62,498**	**562,828**	**375,860**	**1,001,186**	**100.0**

EU statistical tables 2016

Part 1: Numbers of animals used for research, testing, routine production and educational purposes in the EU

Table 1: Numbers of animals used for the first time by species (2016)

		Number of animals	%
Mammals			
	Rodents		
	Mice	5,989,413	**61**
	Rats	1,173,135	**11.9**
	Guinea-Pigs	150,985	**1.5**
	Hamsters (Syrian)	18,614	**0.2**
	Hamsters (Chinese)	519	**0**
	Mongolian gerbil	5,645	**0.1**
	Other rodents	13,712	**0.1**
	Rabbits		
	Rabbits	350,405	**3.6**
	Carnivores		
	Cats	1,951	**0**
	Dogs	15,691	**0.2**
	Ferrets	1,530	**0**
	Other carnivores	1,444	**0**
	Farm animals		
	Horses, donkeys and cross-breeds	3,474	**0**
	Pigs	80,029	**0.8**
	Goats	1,365	**0**
	Sheep	21,240	**0.2**
	Cattle	22,782	**0.2**
	Non-human primates		
	Prosimians	44	**0**
	Marmoset and tamarins	285	**0**
	Squirrel monkey	8	**0**
	Other species of new world monkeys (Ceboidea)	0	**0**
	Cynomolgus monkey	6,503	**0.1**
	Rhesus monkey	318	**0**
	Vervets (Chlorocebus spp.)	19	**0**
	Baboons	62	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	**0**
	Other mammals		
	Other mammals	3,637	**0**
Birds			
	Domestic fowl	500,920	**5.1**
	Other birds	94,804	**1**
Reptiles			
	Reptiles	3,240	**0**
Amphibians			
	Rana	4,482	**0**
	Xenopus	18,511	**0.2**
	Other amphibians	19,558	**0.2**
Fish			
	Zebra fish	513,011	**5.2**
	Other fish	791,726	**8.1**
Cephalopods			
	Cephalopods	8,884	**0.1**
Totals			
	Total	**9,817,946**	**100**
	%	**100**	

Table 2: Place of birth by species (other than non-human primates) (2016)

	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of world	Total	%
Mammals						
Rodents						
Mice	5,740,868	191,446	20,197	36,902	**5,989,413**	**61**
Rats	1,147,202	17,123	3,641	5,169	**1,173,135**	**12**
Guinea-Pigs	149,831	1,076	0	78	**150,985**	**1.5**
Hamsters (Syrian)	18,055	77	0	482	**18,614**	**0.2**
Hamsters (Chinese)	519	0	0	0	**519**	**0**
Mongolian gerbil	5,367	255	6	17	**5,645**	**0.1**
Other rodents	1,749	11,733	104	126	**13,712**	**0.1**
Rabbits						
Rabbits	341,786	6,283	210	2,126	**350,405**	**3.6**
Carnivores						
Cats	897	694	5	355	**1,951**	**0**
Dogs	5,527	5,424	33	4,707	**15,691**	**0.2**
Ferrets	1,298	82	6	144	**1,530**	**0**
Other carnivores	423	961	23	37	**1,444**	**0**
Farm animals						
Horses, donkeys and cross-breeds	576	2,894	2	2	**3,474**	**0**
Pigs	40,755	39,257	17	0	**80,029**	**0.8**
Goats	591	646	128	0	**1,365**	**0**
Sheep	8,311	12,872	57	0	**21,240**	**0.2**
Cattle	8,541	14,140	101	0	**22,782**	**0.2**
Other mammals						
Other mammals	623	2,823	187	4	**3,637**	**0**
Birds						
Domestic fowl	366,599	134,321	0	0	**500,920**	**5.1**
Other birds	27,337	60,933	5,168	1,366	**94,804**	**1**
Reptiles						
Reptiles	1,239	1,650	82	269	**3,240**	**0**
Amphibians						
Rana	2,466	2,016	0	0	**4,482**	**0**
Xenopus	16,096	708	177	1,530	**18,511**	**0.2**
Other amphibians	2,478	15,523	1,363	194	**19,558**	**0.2**
Fish						
Zebra fish	488,212	23,535	0	1,264	**513,011**	**5.2**
Other fish	489,106	226,656	50,712	25,252	**791,726**	**8.1**
Cephalopods						
Cephalopods	8,400	484	0	0	**8,884**	**0.1**
Totals						
Total	**8,874,852**	**773,612**	**82,219**	**80,024**	**9,810,707**	**100**
%	**90.5**	**7.9**	**0.8**	**0.8**	**100**	

Table 3: Source of non-human primates by species (2016)

	Animals born at a registered breeder within EU	Animals born in rest of Europe	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total	%
Non-human primates								
New World Monkeys								
Prosimians	44	0	0	0	0	0	**44**	**0.6**
Marmoset and tamarins	285	0	0	0	0	0	**285**	**3.9**
Squirrel monkey	2	0	0	6	0	0	**8**	**0.1**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	**0**	**0**
Old World Monkeys								
Cynomolgus monkey	97	2	2,045	0	4,340	19	**6,503**	**89.8**
Rhesus monkey	159	0	143	0	16	0	**318**	**4.4**
Vervets (Chlorocebus spp.)	0	0	0	6	13	0	**19**	**0.3**
Baboons	57	0	0	0	5	0	**62**	**0.9**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	**0**	**0**
Totals								
Total	**644**	**2**	**2,188**	**12**	**4,374**	**19**	**7,239**	**100**
%	**8.9**	**0**	**30.2**	**0.2**	**60.4**	**0.3**	**100**	

Table 4: Generation of non-human primates by species (2016)

	F0	F1	F2 or greater	Self-sustaining colony	Total	%
Non-human primates						
New World Monkeys						
Prosimians	0	0	7	37	**44**	**0.6**
Marmoset and tamarins	0	0	19	266	**285**	**3.9**
Squirrel monkey	0	6	2	0	**8**	**0.1**
Other species of new world monkeys (Ceboidea)	0	0	0	0	**0**	**0**
Old World Monkeys						
Cynomolgus monkey	1	1,451	3,210	1,841	**6,503**	**89.8**
Rhesus monkey	0	47	144	127	**318**	**4.4**
Vervets (Chlorocebus spp.)	0	2	17	0	**19**	**0.3**
Baboons	4	22	36	0	**62**	**0.9**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	**0**	**0**
Totals						
Total	**5**	**1,528**	**3,435**	**2,271**	**7,239**	**100**
%	**0.1**	**21.1**	**47.5**	**31.4**	**100**	

Part 2: Details of all uses of animals for research, testing, routine production and educational purposes in the EU

Table 5: Uses of animals by species, main categories of scientific purposes and severities (2016)

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Non-recovery	308,547	48,480	3,808	78	591	718	14,214	4	376,440	6.2
	Mild	1,571,423	575,186	554,409	1,859	771	13,676	46,507	128	2,763,959	45.7
Mice	Moderate	1,160,958	679,490	247,412	22,432	839	0	15,063	0	2,126,194	35.2
	Severe	232,177	204,637	312,304	27,703	51	16	466	0	777,354	12.9
	Total	**3,273,105**	**1,507,793**	**1,117,933**	**52,072**	**2,252**	**14,410**	**76,250**	**132**	**6,043,947**	**100.0**
	Non-recovery	64,754	22,406	11,851	71	0	65	24,369	1	123,517	10.4
	Mild	96,936	115,346	361,982	1,421	552	159	14,475	30	590,901	49.6
Rats	Moderate	135,599	99,351	166,458	167	1,084	0	4,588	23	407,270	34.2
	Severe	37,560	14,766	13,402	483	2,895	0	16	0	69,122	5.8
	Total	**334,849**	**251,869**	**553,693**	**2,142**	**4,531**	**224**	**43,448**	**54**	**1,190,810**	**100.0**
	Non-recovery	18,286	1,388	1,704	242	0	0	371	0	21,991	14.5
	Mild	3,616	4,381	64,014	440	0	0	1,207	0	73,658	48.6
Guinea-Pigs	Moderate	1,568	2,918	32,523	89	0	0	285	0	37,383	24.6
	Severe	38	548	18,077	12	0	0	0	0	18,675	12.3
	Total	**23,508**	**9,235**	**116,318**	**783**	**0**	**0**	**1,863**	**0**	**151,707**	**100.0**
	Non-recovery	127	10	0	0	0	0	11	0	148	0.8
	Mild	431	2,988	6,719	11	0	0	204	0	10,353	55.4
Hamsters (Syrian)	Moderate	1,988	1,095	554	0	0	0	4	0	3,641	19.5
	Severe	307	589	3,396	238	0	0	0	0	4,530	24.3
	Total	**2,853**	**4,682**	**10,669**	**249**	**0**	**0**	**219**	**0**	**18,672**	**100.0**
	Non-recovery	0	0	0	0	0	0	2	0	2	0.4
	Mild	0	287	91	0	0	0	0	0	378	72.8
Hamsters (Chinese)	Moderate	0	0	138	0	0	0	0	0	138	26.6
	Severe	0	0	1	0	0	0	0	0	1	0.2
	Total	**0**	**287**	**230**	**0**	**0**	**0**	**2**	**0**	**519**	**100.0**
	Non-recovery	308	6	0	0	0	0	33	0	347	5.7
	Mild	467	715	1,952	167	0	0	42	0	3,343	55.1
Mongolian gerbil	Moderate	784	1,285	8	31	0	0	10	0	2,118	34.9
	Severe	2	261	1	0	0	0	0	0	264	4.3
	Total	**1,561**	**2,267**	**1,961**	**198**	**0**	**0**	**85**	**0**	**6,072**	**100.0**
	Non-recovery	489	37	0	0	0	0	2	0	528	3.8
	Mild	8,134	383	3,184	0	316	38	17	0	12,072	85.9
Other rodents	Moderate	995	55	50	0	128	0	0	0	1,228	8.7
	Severe	35	84	100	0	0	2	0	0	221	1.6
	Total	**9,653**	**559**	**3,334**	**0**	**444**	**40**	**19**	**0**	**14,049**	**100.0**
	Non-recovery	2,793	2,917	7,884	0	0	0	848	0	14,442	4.0
	Mild	16,076	4,054	53,617	132,741	174	0	1,019	0	207,681	57.0
Rabbits	Moderate	5,550	6,446	27,776	50,850	22	0	230	0	90,874	25.0
	Severe	2,539	2,029	1,633	44,934	0	0	0	0	51,135	14.0
	Total	**26,958**	**15,446**	**90,910**	**228,525**	**196**	**0**	**2,097**	**0**	**364,132**	**100.0**
	Non-recovery	27	0	0	0	0	0	0	0	27	0.7
	Mild	733	1,116	819	27	0	0	214	0	2,909	78.7
Cats	Moderate	45	406	171	0	0	0	0	0	622	16.8
	Severe	0	97	40	0	0	0	0	0	137	3.7
	Total	**805**	**1,619**	**1,030**	**27**	**0**	**0**	**214**	**0**	**3,695**	**100.0**
	Non-recovery	64	138	447	2	0	0	1	0	652	2.8
	Mild	1,472	7,764	7,427	141	0	0	372	0	17,176	73.2
Dogs	Moderate	254	1,272	3,666	29	0	0	30	0	5,251	22.4
	Severe	0	80	293	0	0	0	0	0	373	1.6
	Total	**1,790**	**9,254**	**11,833**	**172**	**0**	**0**	**403**	**0**	**23,452**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Ferrets	Non-recovery	96	2	11	0	0	0	8	0	117	7.3
	Mild	38	407	410	14	0	0	54	0	923	57.3
	Moderate	55	300	40	0	0	0	2	0	397	24.7
	Severe	7	166	0	0	0	0	0	0	173	10.7
	Total	**196**	**875**	**461**	**14**	**0**	**0**	**64**	**0**	**1,610**	**100.0**
Other carnivores	Non-recovery	0	0	0	3	0	0	0	0	3	0.2
	Mild	282	294	195	0	68	47	0	0	886	48.2
	Moderate	500	38	336	0	1	4	0	0	879	47.8
	Severe	15	53	0	0	0	1	0	0	69	3.8
	Total	**797**	**385**	**531**	**3**	**69**	**52**	**0**	**0**	**1,837**	**100.0**
Horses, donkeys and cross-breeds	Non-recovery	0	26	0	0	0	0	23	0	49	0.4
	Mild	2,278	1,650	218	8,070	2	20	258	0	12,496	95.2
	Moderate	127	237	68	110	10	0	20	0	572	4.4
	Severe	0	0	0	7	0	0	0	0	7	0.1
	Total	**2,405**	**1,913**	**286**	**8,187**	**12**	**20**	**301**	**0**	**13,124**	**100.0**
Pigs	Non-recovery	4,128	1,826	40	70	0	0	7,491	0	13,555	16.3
	Mild	10,209	20,186	10,138	162	447	0	1,505	62	42,709	51.3
	Moderate	4,299	13,493	3,477	5	75	0	2,323	0	23,672	28.5
	Severe	511	2,470	265	8	0	0	0	0	3,254	3.9
	Total	**19,147**	**37,975**	**13,920**	**245**	**522**	**0**	**11,319**	**62**	**83,190**	**100.0**
Goats	Non-recovery	0	165	0	0	0	0	7	0	172	7.8
	Mild	998	96	72	76	30	0	145	0	1,417	63.9
	Moderate	239	268	14	0	20	0	64	0	605	27.3
	Severe	16	3	4	0	0	0	0	0	23	1.0
	Total	**1,253**	**532**	**90**	**76**	**50**	**0**	**216**	**0**	**2,217**	**100.0**
Sheep	Non-recovery	118	441	53	0	0	0	630	0	1,242	1.8
	Mild	6,779	7,096	1,530	44,966	2	0	613	90	61,076	90.0
	Moderate	2,164	2,078	240	145	27	0	154	0	4,808	7.1
	Severe	192	450	112	0	12	0	0	2	768	1.1
	Total	**9,253**	**10,065**	**1,935**	**45,111**	**41**	**0**	**1,397**	**92**	**67,894**	**100.0**
Cattle	Non-recovery	15	0	0	0	0	0	23	0	38	0.1
	Mild	9,118	9,994	2,531	134	1,992	28	3,995	25	27,817	83.5
	Moderate	850	1,529	527	15	34	0	2,189	0	5,144	15.4
	Severe	57	208	26	0	7	0	6	0	304	0.9
	Total	**10,040**	**11,731**	**3,084**	**149**	**2,033**	**28**	**6,213**	**25**	**33,303**	**100.0**
Prosimians	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	117	0	0	0	0	0	0	0	117	99.2
	Moderate	0	1	0	0	0	0	0	0	1	0.8
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**117**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**118**	**100.0**
Marmoset and tamarins	Non-recovery	32	0	0	0	0	0	0	0	32	8.5
	Mild	73	48	0	16	0	0	1	0	138	36.7
	Moderate	136	41	18	0	0	0	0	0	195	51.9
	Severe	2	9	0	0	0	0	0	0	11	2.9
	Total	**243**	**98**	**18**	**16**	**0**	**0**	**1**	**0**	**376**	**100.0**
Squirrel monkey	Non-recovery	7	0	0	0	0	0	0	0	7	87.5
	Mild	0	0	0	0	0	0	0	0	0	0.0
	Moderate	1	0	0	0	0	0	0	0	1	12.5
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Cynomolgus monkey	Non-recovery	26	9	12	4	0	0	17	0	68	0.7
	Mild	424	680	3,108	1,018	0	0	19	0	5,249	56.6
	Moderate	111	524	3,167	0	0	0	9	0	3,811	41.1
	Severe	0	7	146	0	0	0	0	0	153	1.6
	Total	**561**	**1,220**	**6,433**	**1,022**	**0**	**0**	**45**	**0**	**9,281**	**100.0**
Rhesus monkey	Non-recovery	11	0	0	0	0	0	0	0	11	1.9
	Mild	104	92	54	3	0	0	5	0	258	45.6
	Moderate	138	116	42	0	0	0	0	0	296	52.3
	Severe	1	0	0	0	0	0	0	0	1	0.2
	Total	**254**	**208**	**96**	**3**	**0**	**0**	**5**	**0**	**566**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Vervets Chlorocebus spp	Non-recovery	0	0	0	13	0	0	0	0	13	31.7
	Mild	6	18	0	0	0	0	0	0	24	58.5
	Moderate	0	4	0	0	0	0	0	0	4	9.8
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**6**	**22**	**0**	**13**	**0**	**0**	**0**	**0**	**41**	**100.0**
Baboons	Non-recovery	2	0	0	0	0	0	0	0	2	2.0
	Mild	46	3	0	0	0	0	0	0	49	49.0
	Moderate	15	22	0	0	0	0	0	0	37	37.0
	Severe	8	4	0	0	0	0	0	0	12	12.0
	Total	**71**	**29**	**0**	**0**	**0**	**0**	**0**	**0**	**100**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	8	18	0	0	0	0	0	0	26	100.0
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**18**	**0**	**0**	**0**	**0**	**0**	**0**	**26**	**100.0**
Other mammals	Non-recovery	99	10	0	0	0	0	0	0	109	2.8
	Mild	2,121	157	0	12	182	259	84	0	2,815	72.1
	Moderate	925	28	0	9	0	0	3	0	965	24.7
	Severe	1	0	8	8	0	0	0	0	17	0.4
	Total	**3,146**	**195**	**8**	**29**	**182**	**259**	**87**	**0**	**3,906**	**100.0**
Domestic fowl	Non-recovery	5,165	1,024	120	377	0	0	317	0	7,003	1.4
	Mild	82,586	77,224	123,546	90,123	3,012	709	2,155	536	379,891	74.9
	Moderate	47,122	21,681	21,456	15,158	0	0	838	0	106,255	20.9
	Severe	2,298	6,624	4,660	211	269	0	200	0	14,262	2.8
	Total	**137,171**	**106,553**	**149,782**	**105,869**	**3,281**	**709**	**3,510**	**536**	**507,411**	**100.0**
Other birds	Non-recovery	946	50	0	0	0	0	109	0	1,105	1.1
	Mild	51,121	14,527	7,251	354	1,527	839	516	14	76,149	78.2
	Moderate	8,091	610	514	9,875	20	16	90	0	19,216	19.7
	Severe	53	359	527	0	0	0	0	0	939	1.0
	Total	**60,211**	**15,546**	**8,292**	**10,229**	**1,547**	**855**	**715**	**14**	**97,409**	**100.0**
Reptiles	Non-recovery	246	0	0	0	0	0	0	0	246	2.9
	Mild	6,017	0	0	300	65	0	27	0	6,409	74.7
	Moderate	1,831	16	0	0	0	0	0	0	1,847	21.5
	Severe	73	0	0	0	0	0	0	0	73	0.9
	Total	**8,167**	**16**	**0**	**300**	**65**	**0**	**27**	**0**	**8,575**	**100.0**
Rana	Non-recovery	0	0	0	0	850	0	1,056	0	1,906	42.5
	Mild	51	0	0	0	0	0	220	0	271	6.0
	Moderate	0	0	0	0	600	0	1,000	0	1,600	35.7
	Severe	625	0	80	0	0	0	0	0	705	15.7
	Total	**676**	**0**	**80**	**0**	**1,450**	**0**	**2,276**	**0**	**4,482**	**100.0**
Xenopus	Non-recovery	456	0	0	0	0	0	102	0	558	2.0
	Mild	23,594	1,296	0	0	8	0	25	0	24,923	89.3
	Moderate	955	285	0	0	600	0	4	0	1,844	6.6
	Severe	374	0	205	0	0	0	0	0	579	2.1
	Total	**25,379**	**1,581**	**205**	**0**	**608**	**0**	**131**	**0**	**27,904**	**100.0**
Other amphibians	Non-recovery	151	0	0	0	557	0	117	0	825	4.1
	Mild	3,076	3,219	72	0	1,733	6,202	164	0	14,466	72.6
	Moderate	3,714	0	0	0	0	69	0	0	3,783	19.0
	Severe	688	19	0	0	0	146	0	0	853	4.3
	Total	**7,629**	**3,238**	**72**	**0**	**2,290**	**6,417**	**281**	**0**	**19,927**	**100.0**
Zebra fish	Non-recovery	12,794	993	400	0	140	0	328	0	14,655	2.8
	Mild	308,999	19,907	15,700	0	566	127	1,067	0	346,366	66.8
	Moderate	65,328	61,458	11,207	0	144	0	0	0	138,137	26.6
	Severe	4,082	4,373	10,771	0	5	0	0	0	19,231	3.7
	Total	**391,203**	**86,731**	**38,078**	**0**	**855**	**127**	**1,395**	**0**	**518,389**	**100.0**
Other fish	Non-recovery	27,864	5,489	1,505	0	3,027	2,074	1,035	0	40,994	5.1
	Mild	389,915	28,218	51,364	0	20,153	43,240	10,686	0	543,576	67.9
	Moderate	39,875	41,798	4,719	0	22,303	3,395	176	0	112,266	14.0
	Severe	17,504	48,069	25,962	0	12,492	2	0	0	104,029	13.0
	Total	**475,158**	**123,574**	**83,550**	**0**	**57,975**	**48,711**	**11,897**	**0**	**800,865**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Cephalopods	Non-recovery	0	29	0	0	0	0	15	0	44	0.5
	Mild	352	8,488	0	0	0	0	0	0	8,840	99.5
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**352**	**8,517**	**0**	**0**	**0**	**0**	**15**	**0**	**8,884**	**100.0**
All Species	**Non-recovery**	**447,551**	**85,446**	**27,835**	**860**	**5,165**	**2,857**	**51,129**	**5**	**620,848**	**6.2**
	Mild	**2,597,600**	**905,838**	**1,270,403**	**282,055**	**31,600**	**65,344**	**85,596**	**885**	**5,239,321**	**52.2**
	Moderate	**1,484,217**	**936,845**	**524,581**	**98,915**	**25,907**	**3,484**	**27,082**	**23**	**3,101,054**	**30.9**
	Severe	**299,165**	**285,905**	**392,013**	**73,604**	**15,731**	**167**	**688**	**2**	**1,067,275**	**10.6**
	Total	**4,828,533**	**2,214,034**	**2,214,832**	**455,434**	**78,403**	**71,852**	**164,495**	**915**	**10,028,498**	**100.0**

Table 5.1: Uses of animals in all sub-categories of research and testing by severities (2016)

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Basic research						
Oncology	18,053	221,369	276,394	56,301	**572,117**	**5.7**
Cardiovascular Blood and Lymphatic System	44,899	157,648	128,554	20,535	**351,636**	**3.5**
Nervous System	100,504	422,312	345,194	72,443	**940,453**	**9.4**
Respiratory System	5,961	32,168	34,551	2,897	**75,577**	**0.8**
Gastrointestinal System including Liver	23,199	69,479	51,109	9,964	**153,751**	**1.5**
Musculoskeletal System	2,729	51,884	33,571	5,203	**93,387**	**0.9**
Immune System	46,007	410,447	239,413	57,429	**753,296**	**7.5**
Urogenital/Reproductive System	14,288	69,827	23,952	4,227	**112,294**	**1.1**
Sensory Organs (skin, eyes and ears)	6,715	39,853	23,183	2,809	**72,560**	**0.7**
Endocrine System/Metabolism	30,750	172,010	82,806	16,161	**301,727**	**3**
Multisystemic	25,389	300,429	86,195	11,214	**423,227**	**4.2**
Ethology / Animal Behaviour /Animal Biology	8,762	458,325	87,390	9,565	**564,042**	**5.6**
Other basic research	120,295	191,849	71,905	30,417	**414,466**	**4.1**
Translational and applied research						
Human Cancer	3,991	192,456	304,964	36,850	**538,261**	**5.4**
Human Infectious Disorders	6,570	108,222	132,578	35,728	**283,098**	**2.8**
Human Cardiovascular Disorders	12,029	21,025	26,146	5,305	**64,505**	**0.6**
Human Nervous and Mental Disorders	16,522	150,818	119,040	20,707	**307,087**	**3.1**
Human Respiratory Disorders	4,012	30,615	27,559	3,671	**65,857**	**0.7**
Human Gastrointestinal Disorders including Liver	3,041	16,688	18,545	5,413	**43,687**	**0.4**
Human Musculoskeletal Disorders	444	14,179	18,390	3,129	**36,142**	**0.4**
Human Immune Disorders	3,952	25,683	37,496	4,424	**71,555**	**0.7**
Human Urogenital/Reproductive Disorders	1,318	5,748	5,382	231	**12,679**	**0.1**
Human Sensory Organ Disorders (skin, eyes and ears)	2,185	27,707	22,294	791	**52,977**	**0.5**
Human Endocrine/Metabolism Disorders	5,868	58,661	40,233	2,942	**107,704**	**1.1**
Other Human Disorders	7,978	8,268	17,307	4,975	**38,528**	**0.4**
Animal Diseases and Disorders	7,019	115,958	72,702	64,307	**259,986**	**2.6**
Animal Welfare	1,681	57,019	14,321	733	**73,754**	**0.7**
Diagnosis of diseases	4,627	22,664	51,776	91,671	**170,738**	**1.7**
Plant diseases	0	42	84	0	**126**	**0**
Non-regulatory toxicology and ecotoxicology	4,209	50,085	28,028	5,028	**87,350**	**0.9**
Regulatory use						
Quality control (incl batch safety and potency testing)						
Batch safety testing	2	127,240	15,546	9,655	**152,443**	**1.5**
Pyrogenicity testing	606	16,985	21,840	3	**39,434**	**0.4**
Batch potency testing	9,518	395,222	247,356	292,917	**945,013**	**9.4**
Other quality controls	300	63,430	11,096	6,454	**81,280**	**0.8**
Toxicity and other safety testing including pharmacology						
Acute and sub-acute toxicity testing methods						
LD50, LC50	1,885	29,619	9,252	22,396	**63,152**	**0.6**
Other lethal methods	0	513	2,595	2,050	**5,158**	**0.1**
Non lethal methods	2,508	16,542	10,952	1,404	**31,406**	**0.3**
Skin irritation/corrosion	175	2,501	536	10	**3,222**	**0**
Skin sensitisation	3,588	43,284	3,782	991	**51,645**	**0.5**
Eye irritation/corrosion	131	516	364	64	**1,075**	**0**
Repeated dose toxicity						
up to 28 days	0	34,908	18,760	1,655	**55,323**	**0.6**
29 - 90 days	96	21,041	12,439	982	**34,558**	**0.3**
> 90 days	3,187	11,816	6,439	397	**21,839**	**0.2**
Carcinogenicity	20	2,506	2,629	173	**5,328**	**0.1**
Genotoxicity	156	7,407	1,741	293	**9,597**	**0.1**
Reproductive toxicity	342	78,858	17,144	6,471	**102,815**	**1**
Developmental toxicity	1,401	82,578	26,871	6,585	**117,435**	**1.2**
Neurotoxicity	3	1,799	1,138	126	**3,066**	**0**
Kinetics	10	39,085	21,178	644	**60,917**	**0.6**
Pharmaco-dynamics (incl safety pharmacology)	1,109	68,601	40,924	3,574	**114,208**	**1.1**
Phototoxicity	33	340	94	2	**469**	**0**
Ecotoxicity						
Acute toxicity	2,305	31,655	2,510	10,111	**46,581**	**0.5**
Chronic toxicity	0	13,568	6,472	3,195	**23,235**	**0.2**
Reproductive ecotoxicity	0	2,583	1,486	6	**4,075**	**0**
Endocrine activity	0	7,597	0	172	**7,769**	**0.1**
Bioaccumulation	0	3,111	1,147	0	**4,258**	**0**
Other ecotoxicity	0	1,685	341	235	**2,261**	**0**
Safety testing in food and feed area	0	25,786	528	13,996	**40,310**	**0.4**
Target animal safety	0	11,698	287	37	**12,022**	**0.1**
Other toxicity/safety testing	171	5,328	3,520	940	**9,959**	**0.1**
Other efficacy and tolerance testing						
Other efficacy and tolerance testing	289	122,601	35,614	6,475	**164,979**	**1.6**
Routine production						
Blood based products	646	160,868	60,197	38,517	**260,228**	**2.6**
Monoclonal antibody by mouse ascites method	0	814	20,475	27,645	**48,934**	**0.5**
Other product types	214	120,373	18,243	7,442	**146,272**	**1.5**
Other						

		Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
	Protection of the natural environment in the interests of the health or welfare of human beings or animals	5,165	31,600	25,907	15,731	**78,403**	**0.8**
	Preservation of species	2,857	65,344	3,484	167	**71,852**	**0.7**
	Higher education or training for the acquisition, maintenance or improvement of vocational skills	51,129	85,596	27,082	688	**164,495**	**1.6**
	Forensic enquiries	5	885	23	2	**915**	**0**
Total		**620,848**	**5,239,321**	**3,101,054**	**1,067,275**	**10,028,498**	**100**
%		**6.2**	**52.2**	**30.9**	**10.6**	**100**	

Table 6: Basic research related uses by species and type of research (2016)

		Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals																
	Rodents															
	Mice	530,789	262,594	630,425	59,649	107,302	75,232	685,471	83,617	57,134	177,404	322,640	25,055	255,793	**3,273,105**	**67.8**
	Rats	5,544	37,296	163,296	11,429	14,249	5,692	7,346	7,907	6,426	19,442	12,915	17,038	26,269	**334,849**	**6.9**
	Guinea-Pigs	26	286	364	1,308	213	77	1,971	4	549	487	136	116	17,971	**23,508**	**0.5**
	Hamsters (Syrian)	230	183	296	0	113	0	107	26	0	45	282	25	1,546	**2,853**	**0.1**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Mongolian gerbil	0	0	536	0	14	17	124	0	541	0	0	0	329	**1,561**	**0**
	Other rodents	81	0	408	74	27	20	989	74	105	364	374	6,331	806	**9,653**	**0.2**
	Rabbits															
	Rabbits	177	1,399	546	1,408	289	801	2,913	505	456	260	553	9,850	7,801	**26,958**	**0.6**
	Carnivores															
	Cats	0	24	71	4	156	76	32	14	14	58	230	89	37	**805**	**0**
	Dogs	0	81	85	2	252	364	157	57	9	15	242	44	482	**1,790**	**0**
	Ferrets	0	0	145	15	8	0	0	0	6	0	14	8	0	**196**	**0**
	Other carnivores	0	0	0	0	30	0	323	6	0	0	11	419	8	**797**	**0**
	Farm animals															
	Horses, donkeys and cross-breeds	0	81	0	315	30	147	250	486	3	645	0	291	157	**2,405**	**0**
	Pigs	258	1,708	358	434	5,691	421	1,793	308	77	844	753	5,068	1,434	**19,147**	**0.4**
	Goats	0	44	9	0	184	0	37	77	0	47	62	749	44	**1,253**	**0**
	Sheep	20	518	108	149	903	271	291	650	2	262	501	2,156	3,422	**9,253**	**0.2**
	Cattle	0	202	5	95	500	3	620	307	0	1,868	1,852	3,650	938	**10,040**	**0.2**
	Non-human primates															
	Prosimians	0	0	21	0	0	0	0	0	9	0	0	87	0	**117**	**0**
	Marmoset and tamarins	1	0	71	60	0	0	0	0	0	23	88	0	0	**243**	**0**
	Squirrel monkey	0	0	8	0	0	0	0	0	0	0	0	0	0	**8**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	0	150	0	0	0	6	0	0	0	28	0	377	**561**	**0**
	Rhesus monkey	0	54	146	0	0	0	0	0	0	0	32	0	22	**254**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	6	**6**	**0**
	Baboons	0	3	4	0	0	2	26	0	0	0	2	34	0	**71**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	8	0	**8**	**0**
	Other mammals															
	Other mammals	0	0	155	0	12	0	17	136	35	26	34	2,489	242	**3,146**	**0.1**
Birds																
	Domestic fowl	0	86	4,002	0	16,244	92	6,401	16	479	3,293	4,687	76,657	25,214	**137,171**	**2.8**
	Other birds	0	459	441	0	160	40	900	55	31	521	54	47,231	10,319	**60,211**	**1.2**
Reptiles																
	Reptiles	0	43	268	0	0	0	73	0	3	0	39	7,331	410	**8,167**	**0.2**
Amphibians																
	Rana	0	0	400	0	0	0	0	0	22	0	0	231	23	**676**	**0**
	Xenopus	1,456	398	4,532	0	0	254	8	2,492	195	4,051	2,037	3,504	6,452	**25,379**	**0.5**
	Other amphibians	0	0	0	0	0	470	10	410	22	0	0	3,760	2,957	**7,629**	**0.2**
Fish																
	Zebra fish	31,513	45,789	132,591	419	424	9,015	22,605	14,017	5,946	74,203	24,291	14,640	15,750	**391,203**	**8.1**
	Other fish	2,022	388	1,012	216	6,950	393	20,826	1,118	496	17,869	51,370	336,841	35,657	**475,158**	**9.8**
Cephalopods																
	Cephalopods	0	0	0	0	0	0	0	12	0	0	0	340	0	**352**	**0**
Totals																
	Total	**572,117**	**351,636**	**940,453**	**75,577**	**153,751**	**93,387**	**753,296**	**112,294**	**72,560**	**301,727**	**423,227**	**564,042**	**414,466**	**4,828,533**	**100**
	%	**11.8**	**7.3**	**19.5**	**1.6**	**3.2**	**1.9**	**15.6**	**2.3**	**1.5**	**6.2**	**8.8**	**11.7**	**8.6**	**100**	

Table 7.1: Translational and applied research related uses by species and type of research (Part 1) (2016)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders	Human Urogenital/Reproductive Disorders
Mammals									
Rodents									
Mice	528,247	214,815	44,272	195,670	40,621	34,274	24,367	65,790	9,270
Rats	6,413	4,236	15,489	101,259	20,944	8,318	8,653	4,763	2,419
Guinea-Pigs	148	1,111	444	430	3,392	42	8	152	106
Hamsters (Syrian)	387	2,325	32	47	0	0	0	0	36
Hamsters (Chinese)	0	287	0	0	0	0	0	0	0
Mongolian gerbil	0	1,406	0	88	0	0	0	0	0
Other rodents	0	312	0	0	71	0	0	0	0
Rabbits									
Rabbits	1,985	847	937	100	311	247	1,082	239	31
Carnivores									
Cats	0	0	0	0	0	0	0	0	0
Dogs	45	32	87	416	21	45	91	85	4
Ferrets	0	689	0	0	4	98	0	2	0
Other carnivores	0	0	0	0	0	0	0	0	0
Farm animals									
Horses, donkeys and cross-breeds	0	8	0	0	0	0	8	6	0
Pigs	175	379	2,594	220	342	416	216	220	507
Goats	6	15	18	4	0	0	43	0	1
Sheep	26	157	520	115	0	7	710	47	238
Cattle	0	75	4	0	40	0	0	0	0
Non-human primates									
Prosimians	0	0	0	1	0	0	0	0	0
Marmoset and tamarins	8	0	0	24	0	0	0	16	2
Squirrel monkey	0	0	0	0	0	0	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	14	397	31	106	10	0	21	64	58
Rhesus monkey	0	168	0	11	0	0	0	0	3
Vervets (Chlorocebus spp.)	0	22	0	0	0	0	0	0	0
Baboons	0	22	3	0	0	0	0	0	4
Other species of old world monkeys (Cercopithecoidea)	0	18	0	0	0	0	0	0	0
Other mammals									
Other mammals	58	9	10	8	3	0	0	0	0
Birds									
Domestic fowl	404	325	0	0	90	240	0	10	0
Other birds	0	6,166	0	0	8	0	0	0	0
Reptiles									
Reptiles	0	0	0	0	0	0	0	0	0
Amphibians									
Rana	0	0	0	0	0	0	0	0	0
Xenopus	0	0	0	25	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0
Fish									
Zebra fish	345	49,277	64	8,544	0	0	943	161	0
Other fish	0	0	0	19	0	0	0	0	0
Cephalopods									
Cephalopods	0	0	0	0	0	0	0	0	0
Totals									
Total	**538,261**	**283,098**	**64,505**	**307,087**	**65,857**	**43,687**	**36,142**	**71,555**	**12,679**
%	**24.3**	**12.8**	**2.9**	**13.9**	**3**	**2**	**1.6**	**3.2**	**0.6**

Table 7.2: Translational and applied research related uses by species and type of research (Part 2) (2016)

	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	43,784	70,396	24,306	30,301	1,135	157,985	28	22,532	**1,507,793**	**68.1**
Rats	6,709	34,075	12,093	1,842	412	3,967	56	20,221	**251,869**	**11.4**
Guinea-Pigs	438	0	186	993	0	1,411	0	374	**9,235**	**0.4**
Hamsters (Syrian)	0	698	0	1,036	0	9	0	112	**4,682**	**0.2**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	**287**	**0**
Mongolian gerbil	0	0	0	773	0	0	0	0	**2,267**	**0.1**
Other rodents	0	0	0	86	0	0	0	90	**559**	**0**
Rabbits										
Rabbits	1,436	158	309	6,398	319	632	42	373	**15,446**	**0.7**
Carnivores										
Cats	0	0	0	1,486	34	96	0	3	**1,619**	**0.1**
Dogs	17	154	13	6,216	47	94	0	1,887	**9,254**	**0.4**
Ferrets	0	0	0	81	0	1	0	0	**875**	**0**
Other carnivores	0	0	0	218	167	0	0	0	**385**	**0**
Farm animals										
Horses, donkeys and cross-breeds	0	0	0	1,535	227	129	0	0	**1,913**	**0.1**
Pigs	476	1,589	245	17,018	12,824	507	0	247	**37,975**	**1.7**
Goats	0	0	0	219	169	55	0	2	**532**	**0**
Sheep	4	49	55	5,854	1,365	861	0	57	**10,065**	**0.5**
Cattle	0	290	0	8,981	2,118	209	0	14	**11,731**	**0.5**
Non-human primates										
Prosimians	0	0	0	0	0	0	0	0	**1**	**0**
Marmoset and tamarins	0	0	24	0	0	0	0	24	**98**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	**0**	**0**
Cynomolgus monkey	61	17	38	0	0	0	0	403	**1,220**	**0.1**
Rhesus monkey	24	2	0	0	0	0	0	0	**208**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	**22**	**0**
Baboons	0	0	0	0	0	0	0	0	**29**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	**18**	**0**
Other mammals										
Other mammals	0	0	8	82	0	17	0	0	**195**	**0**
Birds										
Domestic fowl	28	0	0	72,941	30,251	2,149	0	115	**106,553**	**4.8**
Other birds	0	0	0	6,671	2,447	86	0	168	**15,546**	**0.7**
Reptiles										
Reptiles	0	0	0	16	0	0	0	0	**16**	**0**
Amphibians										
Rana	0	0	0	0	0	0	0	0	**0**	**0**
Xenopus	0	117	0	19	0	0	0	1,420	**1,581**	**0.1**
Other amphibians	0	0	24	79	0	0	0	3,135	**3,238**	**0.1**
Fish										
Zebra fish	0	120	1,227	648	99	0	0	25,303	**86,731**	**3.9**
Other fish	0	39	0	96,464	13,740	2,530	0	10,782	**123,574**	**5.6**
Cephalopods										
Cephalopods	0	0	0	29	8,400	0	0	88	**8,517**	**0.4**
Totals										
Total	**52,977**	**107,704**	**38,528**	**259,986**	**73,754**	**170,738**	**126**	**87,350**	**2,214,034**	**100**
%	**2.4**	**4.9**	**1.7**	**11.7**	**3.3**	**7.7**	**0**	**3.9**	**100**	

Table 8: Regulatory uses by species and type of use (2016)

		Quality				Toxicity	Other		
		Quality: Batch safety testing	Quality: Pyrogenicity testing	Quality: Batch potency testing	Quality: Other quality controls	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing	Total	%
Mammals									
	Rodents								
	Mice	96,993	1,050	633,305	50,300	242,767	93,518	**1,117,933**	**50.5**
	Rats	11,666	0	151,394	1,603	381,032	7,998	**553,693**	**25**
	Guinea-Pigs	16,574	0	63,566	2,160	33,808	210	**116,318**	**5.3**
	Hamsters (Syrian)	14	0	5,889	2,959	1,017	790	**10,669**	**0.5**
	Hamsters (Chinese)	0	0	0	0	230	0	**230**	**0**
	Mongolian gerbil	0	0	0	0	1,930	31	**1,961**	**0.1**
	Other rodents	0	0	0	0	3,304	30	**3,334**	**0.2**
	Rabbits								
	Rabbits	2,078	38,384	19,144	3,143	23,831	4,330	**90,910**	**4.1**
	Carnivores								
	Cats	65	0	40	98	485	342	**1,030**	**0**
	Dogs	148	0	87	403	10,071	1,124	**11,833**	**0.5**
	Ferrets	277	0	127	0	17	40	**461**	**0**
	Other carnivores	223	0	155	0	33	120	**531**	**0**
	Farm animals								
	Horses, donkeys and cross-breeds	10	0	50	0	126	100	**286**	**0**
	Pigs	1,891	0	2,291	867	4,543	4,328	**13,920**	**0.6**
	Goats	8	0	48	0	18	16	**90**	**0**
	Sheep	321	0	723	237	261	393	**1,935**	**0.1**
	Cattle	193	0	1,120	87	596	1,088	**3,084**	**0.1**
	Non-human primates								
	Prosimians	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	0	0	18	0	**18**	**0**
	Squirrel monkey	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	0	0	0	6,364	69	**6,433**	**0.3**
	Rhesus monkey	0	0	0	0	90	6	**96**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	**0**	**0**
	Other mammals								
	Other mammals	0	0	0	0	8	0	**8**	**0**
Birds									
	Domestic fowl	21,675	0	63,791	17,622	12,476	34,218	**149,782**	**6.8**
	Other birds	229	0	368	885	4,694	2,116	**8,292**	**0.4**
Reptiles									
	Reptiles	0	0	0	0	0	0	**0**	**0**
Amphibians									
	Rana	0	0	0	0	80	0	**80**	**0**
	Xenopus	0	0	0	0	205	0	**205**	**0**
	Other amphibians	0	0	0	0	72	0	**72**	**0**
Fish									
	Zebra fish	0	0	0	188	37,890	0	**38,078**	**1.7**
	Other fish	78	0	2,915	728	65,717	14,112	**83,550**	**3.8**
Cephalopods									
	Cephalopods	0	0	0	0	0	0	**0**	**0**
Totals									
	Total	**152,443**	**39,434**	**945,013**	**81,280**	**831,683**	**164,979**	**2,214,832**	**100**
	%	**6.9**	**1.8**	**42.7**	**3.7**	**37.6**	**7.4**	**100**	

Table 9.1: Toxicity and other safety testing including pharmacology by species and type of use (Part 1) (2016)

	Acute						Repeated Dose						
	LD50, LC50	Other lethal methods	Non lethal methods	Skin irritation / corrosion	Skin sensitisation	Eye irritation / corrosion	up to 28 days	29 - 90 days	> 90 days	Carcinogenicity	Genotoxicity	Developmental toxicity	Safety testing in food and feed area
Mammals													
Rodents													
Mice	36,392	1,325	10,112	0	19,931	0	13,164	7,260	2,270	1,793	4,420	164	37,378
Rats	5,384	1,060	16,785	163	0	0	36,800	22,595	15,417	3,535	5,148	101,403	0
Guinea-Pigs	10	0	634	0	31,638	21	4	0	108	0	0	0	0
Hamsters (Syrian)	0	0	472	215	15	0	59	56	80	0	29	0	0
Hamsters (Chinese)	0	0	0	0	0	0	0	230	0	0	0	0	0
Mongolian gerbil	0	0	0	0	0	0	0	0	0	0	0	0	0
Other rodents	70	0	0	0	0	0	0	0	0	0	0	0	0
Rabbits													
Rabbits	12	0	701	2,832	54	1,054	730	927	352	0	0	9,678	9
Carnivores													
Cats	0	0	0	0	0	0	0	0	12	0	0	0	0
Dogs	0	0	534	0	0	0	2,465	1,371	1,802	0	0	0	0
Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0
Other carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0
Farm animals													
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	0	0	0	0
Pigs	0	0	111	12	7	0	681	523	242	0	0	0	148
Goats	0	0	0	0	0	0	0	0	0	0	0	0	0
Sheep	0	0	0	0	0	0	0	0	0	0	0	0	148
Cattle	0	0	0	0	0	0	0	0	0	0	0	0	26
Non-human primates													
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0
Marmoset and tamarins	0	0	0	0	0	0	9	0	0	0	0	0	0
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	11	0	409	0	0	0	1,399	1,572	1,522	0	0	0	0
Rhesus monkey	0	0	0	0	0	0	12	24	34	0	0	0	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
Other mammals													
Other mammals	8	0	0	0	0	0	0	0	0	0	0	0	0
Birds													
Domestic fowl	3,960	0	0	0	0	0	0	0	0	0	0	0	1,747
Other birds	272	0	159	0	0	0	0	0	0	0	0	0	854
Reptiles													
Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0
Amphibians													
Rana	0	0	0	0	0	0	0	0	0	0	0	0	0
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish													
Zebra fish	1,502	2,773	624	0	0	0	0	0	0	0	0	6,190	0
Other fish	15,531	0	865	0	0	0	0	0	0	0	0	0	0
Cephalopods													
Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals													
Total	**63,152**	**5,158**	**31,406**	**3,222**	**51,645**	**1,075**	**55,323**	**34,558**	**21,839**	**5,328**	**9,597**	**117,435**	**40,310**
%	**7.6**	**0.6**	**3.8**	**0.4**	**6.2**	**0.1**	**6.7**	**4.2**	**2.6**	**0.6**	**1.2**	**14.2**	**4.9**

Table 9.2: Toxicity and other safety testing including pharmacology by species and type of use (Part 2) (2016)

							EcoToxicity								
		Target animal safety	Neurotoxicity	Kinetics	Pharmaco - dynamics (incl safety pharmacology)	Phototoxicity	Acute toxicity	Chronic toxicity	Reproductive toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Other toxicity / safety testing	Total	%
Mammals															
	Rodents														
	Mice	188	246	29,209	64,776	403	8,236	254	939	0	0	0	4,307	**242,767**	**29.3**
	Rats	0	396	25,246	42,834	0	1,810	819	97,247	0	0	0	4,390	**381,032**	**46**
	Guinea-Pigs	0	0	70	1,039	66	186	0	0	0	0	0	32	**33,808**	**4.1**
	Hamsters (Syrian)	0	0	4	81	0	0	0	0	0	0	0	6	**1,017**	**0.1**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	**230**	**0**
	Mongolian gerbil	0	0	0	1,930	0	0	0	0	0	0	0	0	**1,930**	**0.2**
	Other rodents	3,054	0	0	0	0	0	0	0	0	0	180	0	**3,304**	**0.4**
	Rabbits														
	Rabbits	76	0	746	1,835	0	9	5	4,598	0	24	0	180	**23,822**	**2.9**
	Carnivores														
	Cats	83	0	378	12	0	0	0	0	0	0	0	0	**485**	**0.1**
	Dogs	158	0	2,274	977	0	0	0	0	0	0	0	490	**10,071**	**1.2**
	Ferrets	0	0	0	6	0	0	0	0	0	0	0	11	**17**	**0**
	Other carnivores	33	0	0	0	0	0	0	0	0	0	0	0	**33**	**0**
	Farm animals														
	Horses, donkeys and cross-breeds	8	0	90	0	0	0	0	0	0	0	28	0	**126**	**0**
	Pigs	973	0	1,197	480	0	0	0	0	0	0	48	121	**4,543**	**0.5**
	Goats	0	0	16	0	0	0	0	0	0	0	0	2	**18**	**0**
	Sheep	0	0	88	0	0	0	0	0	0	18	0	7	**261**	**0**
	Cattle	125	0	315	15	0	0	0	0	0	0	0	115	**596**	**0.1**
	Non-human primates														
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	9	0	0	0	0	0	0	0	0	0	**18**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	18	983	223	0	0	0	31	0	0	0	196	**6,364**	**0.8**
	Rhesus monkey	0	0	20	0	0	0	0	0	0	0	0	0	**90**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals														
	Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	**8**	**0**
Birds															
	Domestic fowl	6,404	0	263	0	0	0	0	0	0	0	0	102	**12,476**	**1.5**
	Other birds	274	0	9	0	0	607	158	0	0	0	0	0	**2,333**	**0.3**
Reptiles															
	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians															
	Rana	0	0	0	0	0	80	0	0	0	0	0	0	**80**	**0**
	Xenopus	0	0	0	0	0	205	0	0	0	0	0	0	**205**	**0**
	Other amphibians	0	0	0	0	0	72	0	0	0	0	0	0	**72**	**0**
Fish															
	Zebra fish	0	2,406	0	0	0	6,337	9,414	0	6,080	526	573	0	**36,425**	**4.4**
	Other fish	646	0	0	0	0	29,039	12,585	0	1,689	3,690	1,432	0	**65,477**	**7.9**
Cephalopods															
	Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals															
	Total	**12,022**	**3,066**	**60,917**	**114,208**	**469**	**46,581**	**23,235**	**102,815**	**7,769**	**4,258**	**2,261**	**9,959**	**827,608**	**100**
	%	**1.5**	**0.4**	**7.4**	**13.8**	**0.1**	**5.6**	**2.8**	**12.4**	**0.9**	**0.5**	**0.3**	**1.2**	**100**	

Table 10: Regulatory uses by species and type of legislation (2016)

		Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Other legislation	Total	%
Mammals												
	Rodents											
	Mice	910,195	129,381	15,234	14,994	4,307	1,609	40,150	1,488	575	**1,117,933**	**50.5**
	Rats	343,737	12,431	2,867	164,098	21,405	3,860	3,250	444	1,601	**553,693**	**25**
	Guinea-Pigs	70,801	16,028	25,208	3,029	1,085	85	0	0	82	**116,318**	**5.3**
	Hamsters (Syrian)	905	9,058	706	0	0	0	0	0	0	**10,669**	**0.5**
	Hamsters (Chinese)	230	0	0	0	0	0	0	0	0	**230**	**0**
	Mongolian gerbil	0	1,961	0	0	0	0	0	0	0	**1,961**	**0.1**
	Other rodents	0	0	0	0	3,234	70	0	0	30	**3,334**	**0.2**
	Rabbits											
	Rabbits	65,163	14,701	3,073	5,710	954	68	9	0	1,232	**90,910**	**4.1**
	Carnivores											
	Cats	50	980	0	0	0	0	0	0	0	**1,030**	**0**
	Dogs	8,839	2,316	22	106	206	0	0	0	344	**11,833**	**0.5**
	Ferrets	450	0	0	0	0	0	0	0	11	**461**	**0**
	Other carnivores	0	518	0	0	0	0	0	0	13	**531**	**0**
	Farm animals											
	Horses, donkeys and cross-breeds	49	237	0	0	0	0	0	0	0	**286**	**0**
	Pigs	3,215	9,233	210	44	0	0	16	1,073	129	**13,920**	**0.6**
	Goats	50	24	0	0	16	0	0	0	0	**90**	**0**
	Sheep	42	1,673	90	0	0	0	110	17	3	**1,935**	**0.1**
	Cattle	0	2,914	0	0	18	0	0	50	102	**3,084**	**0.1**
	Non-human primates											
	Prosimians	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	18	0	0	0	0	0	0	0	0	**18**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	6,433	0	0	0	0	0	0	0	0	**6,433**	**0.3**
	Rhesus monkey	96	0	0	0	0	0	0	0	0	**96**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals											
	Other mammals	0	0	0	0	0	8	0	0	0	**8**	**0**
Birds												
	Domestic fowl	1,904	124,752	0	0	230	0	20	20,100	2,776	**149,782**	**6.8**
	Other birds	0	3,555	0	0	3,623	0	0	1,114	0	**8,292**	**0.4**
Reptiles												
	Reptiles	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians												
	Rana	0	0	0	0	80	0	0	0	0	**80**	**0**
	Xenopus	0	0	0	0	205	0	0	0	0	**205**	**0**
	Other amphibians	0	0	0	0	72	0	0	0	0	**72**	**0**
Fish												
	Zebra fish	1,880	872	1,040	12,977	14,474	805	0	0	6,030	**38,078**	**1.7**
	Other fish	8,399	6,420	494	13,814	11,593	583	0	12,300	29,947	**83,550**	**3.8**
Cephalopods												
	Cephalopods	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals												
	Total	**1,422,456**	**337,054**	**48,944**	**214,772**	**61,502**	**7,088**	**43,555**	**36,586**	**42,875**	**2,214,832**	**100**
	%	**64.2**	**15.2**	**2.2**	**9.7**	**2.8**	**0.3**	**2**	**1.7**	**1.9**	**100**	

Table 11: Regulatory uses by species and origin of regulatory requirement (2016)

		Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total	%
Mammals						
	Rodents					
	Mice	1,032,534	16,404	68,995	**1,117,933**	**50.5**
	Rats	546,510	1,111	6,072	**553,693**	**25**
	Guinea-Pigs	109,983	62	6,273	**116,318**	**5.3**
	Hamsters (Syrian)	10,663	0	6	**10,669**	**0.5**
	Hamsters (Chinese)	230	0	0	**230**	**0**
	Mongolian gerbil	1,961	0	0	**1,961**	**0.1**
	Other rodents	3,304	30	0	**3,334**	**0.2**
	Rabbits					
	Rabbits	68,514	139	22,257	**90,910**	**4.1**
	Carnivores					
	Cats	1,024	0	6	**1,030**	**0**
	Dogs	11,737	19	77	**11,833**	**0.5**
	Ferrets	461	0	0	**461**	**0**
	Other carnivores	493	13	25	**531**	**0**
	Farm animals					
	Horses, donkeys and cross-breeds	284	0	2	**286**	**0**
	Pigs	12,315	2	1,603	**13,920**	**0.6**
	Goats	90	0	0	**90**	**0**
	Sheep	1,928	3	4	**1,935**	**0.1**
	Cattle	2,963	91	30	**3,084**	**0.1**
	Non-human primates					
	Prosimians	0	0	0	**0**	**0**
	Marmoset and tamarins	18	0	0	**18**	**0**
	Squirrel monkey	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
	Cynomolgus monkey	6,411	0	22	**6,433**	**0.3**
	Rhesus monkey	96	0	0	**96**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	**0**	**0**
	Baboons	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
	Other mammals					
	Other mammals	8	0	0	**8**	**0**
Birds						
	Domestic fowl	144,335	130	5,317	**149,782**	**6.8**
	Other birds	8,276	0	16	**8,292**	**0.4**
Reptiles						
	Reptiles	0	0	0	**0**	**0**
Amphibians						
	Rana	80	0	0	**80**	**0**
	Xenopus	205	0	0	**205**	**0**
	Other amphibians	72	0	0	**72**	**0**
Fish						
	Zebra fish	36,518	1,560	0	**38,078**	**1.7**
	Other fish	57,540	25,867	143	**83,550**	**3.8**
Cephalopods						
	Cephalopods	0	0	0	**0**	**0**
Totals						
	Total	**2,058,553**	**45,431**	**110,848**	**2,214,832**	**100**
	%	**92.9**	**2.1**	**5**	**100**	

Table 12: Routine production uses by species and product type (2016)

	Blood based products	Other product types	Monoclonal antibody by mouse ascites method	Total	%
Mammals					
Rodents					
Mice	1,192	2,591	48,289	**52,072**	**11.4**
Rats	1,684	442	16	**2,142**	**0.5**
Guinea-Pigs	772	11	0	**783**	**0.2**
Hamsters (Syrian)	238	11	0	**249**	**0.1**
Hamsters (Chinese)	0	0	0	**0**	**0**
Mongolian gerbil	0	198	0	**198**	**0**
Other rodents	0	0	0	**0**	**0**
Rabbits					
Rabbits	191,190	36,706	629	**228,525**	**50.2**
Carnivores					
Cats	6	21	0	**27**	**0**
Dogs	170	2	0	**172**	**0**
Ferrets	14	0	0	**14**	**0**
Other carnivores	3	0	0	**3**	**0**
Farm animals					
Horses, donkeys and cross-breeds	8,187	0	0	**8,187**	**1.8**
Pigs	20	225	0	**245**	**0.1**
Goats	61	15	0	**76**	**0**
Sheep	44,014	1,097	0	**45,111**	**9.9**
Cattle	123	26	0	**149**	**0**
Non-human primates					
Prosimians	0	0	0	**0**	**0**
Marmoset and tamarins	16	0	0	**16**	**0**
Squirrel monkey	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
Cynomolgus monkey	958	64	0	**1,022**	**0.2**
Rhesus monkey	0	3	0	**3**	**0**
Vervets (Chlorocebus spp.)	0	13	0	**13**	**0**
Baboons	0	0	0	**0**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
Other mammals					
Other mammals	10	19	0	**29**	**0**
Birds					
Domestic fowl	1,655	104,214	0	**105,869**	**23.2**
Other birds	9,915	314	0	**10,229**	**2.2**
Reptiles					
Reptiles	0	300	0	**300**	**0.1**
Amphibians					
Rana	0	0	0	**0**	**0**
Xenopus	0	0	0	**0**	**0**
Other amphibians	0	0	0	**0**	**0**
Fish					
Zebra fish	0	0	0	**0**	**0**
Other fish	0	0	0	**0**	**0**
Cephalopods					
Cephalopods	0	0	0	**0**	**0**
Totals					
Total	**260,228**	**146,272**	**48,934**	**455,434**	**100**
%	**57.1**	**32.1**	**10.7**	**100**	

Table 13: Reuses of animals by species and main categories of scientific purposes in research, testing routine production and education (2016)

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Yes	14,006	8,806	26,148	180	0	0	5,394	0	54,534	0.9
	No	3,259,099	1,498,987	1,091,785	51,892	2,252	14,410	70,856	132	5,989,413	99.1
	Total	**3,273,105**	**1,507,793**	**1,117,933**	**52,072**	**2,252**	**14,410**	**76,250**	**132**	**6,043,947**	**100.0**
Rats	Yes	6,462	4,959	3,250	138	0	0	2,826	40	17,675	1.5
	No	328,387	246,910	550,443	2,004	4,531	224	40,622	14	1,173,135	98.5
	Total	**334,849**	**251,869**	**553,693**	**2,142**	**4,531**	**224**	**43,448**	**54**	**1,190,810**	**100.0**
Guinea-Pigs	Yes	31	50	518	5	0	0	118	0	722	0.5
	No	23,477	9,185	115,800	778	0	0	1,745	0	150,985	99.5
	Total	**23,508**	**9,235**	**116,318**	**783**	**0**	**0**	**1,863**	**0**	**151,707**	**100.0**
Hamsters (Syrian)	Yes	25	4	6	11	0	0	12	0	58	0.3
	No	2,828	4,678	10,663	238	0	0	207	0	18,614	99.7
	Total	**2,853**	**4,682**	**10,669**	**249**	**0**	**0**	**219**	**0**	**18,672**	**100.0**
Hamsters (Chinese)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	0	287	230	0	0	0	2	0	519	100.0
	Total	**0**	**287**	**230**	**0**	**0**	**0**	**2**	**0**	**519**	**100.0**
Mongolian gerbil	Yes	30	397	0	0	0	0	0	0	427	7.0
	No	1,531	1,870	1,961	198	0	0	85	0	5,645	93.0
	Total	**1,561**	**2,267**	**1,961**	**198**	**0**	**0**	**85**	**0**	**6,072**	**100.0**
Other rodents	Yes	337	0	0	0	0	0	0	0	337	2.4
	No	9,316	559	3,334	0	444	40	19	0	13,712	97.6
	Total	**9,653**	**559**	**3,334**	**0**	**444**	**40**	**19**	**0**	**14,049**	**100.0**
Rabbits	Yes	133	278	12,022	932	5	0	357	0	13,727	3.8
	No	26,825	15,168	78,888	227,593	191	0	1,740	0	350,405	96.2
	Total	**26,958**	**15,446**	**90,910**	**228,525**	**196**	**0**	**2,097**	**0**	**364,132**	**100.0**
Cats	Yes	426	703	403	6	0	0	206	0	1,744	47.2
	No	379	916	627	21	0	0	8	0	1,951	52.8
	Total	**805**	**1,619**	**1,030**	**27**	**0**	**0**	**214**	**0**	**3,695**	**100.0**
Dogs	Yes	881	2,985	3,436	143	0	0	316	0	7,761	33.1
	No	909	6,269	8,397	29	0	0	87	0	15,691	66.9
	Total	**1,790**	**9,254**	**11,833**	**172**	**0**	**0**	**403**	**0**	**23,452**	**100.0**
Ferrets	Yes	2	24	0	0	0	0	54	0	80	5.0
	No	194	851	461	14	0	0	10	0	1,530	95.0
	Total	**196**	**875**	**461**	**14**	**0**	**0**	**64**	**0**	**1,610**	**100.0**
Other carnivores	Yes	346	4	40	3	0	0	0	0	393	21.4
	No	451	381	491	0	69	52	0	0	1,444	78.6
	Total	**797**	**385**	**531**	**3**	**69**	**52**	**0**	**0**	**1,837**	**100.0**
Horses, donkeys and cross-breeds	Yes	1,131	247	26	8,077	2	0	167	0	9,650	73.5
	No	1,274	1,666	260	110	10	20	134	0	3,474	26.5
	Total	**2,405**	**1,913**	**286**	**8,187**	**12**	**20**	**301**	**0**	**13,124**	**100.0**
Pigs	Yes	347	1,168	606	0	75	0	965	0	3,161	3.8
	No	18,800	36,807	13,314	245	447	0	10,354	62	80,029	96.2
	Total	**19,147**	**37,975**	**13,920**	**245**	**522**	**0**	**11,319**	**62**	**83,190**	**100.0**
Goats	Yes	766	5	0	6	30	0	45	0	852	38.4
	No	487	527	90	70	20	0	171	0	1,365	61.6
	Total	**1,253**	**532**	**90**	**76**	**50**	**0**	**216**	**0**	**2,217**	**100.0**
Sheep	Yes	3,576	316	246	42,277	0	0	239	0	46,654	68.7
	No	5,677	9,749	1,689	2,834	41	0	1,158	92	21,240	31.3
	Total	**9,253**	**10,065**	**1,935**	**45,111**	**41**	**0**	**1,397**	**92**	**67,894**	**100.0**
Cattle	Yes	2,600	2,645	336	19	1,653	0	3,268	0	10,521	31.6
	No	7,440	9,086	2,748	130	380	28	2,945	25	22,782	68.4
	Total	**10,040**	**11,731**	**3,084**	**149**	**2,033**	**28**	**6,213**	**25**	**33,303**	**100.0**
Prosimians	Yes	74	0	0	0	0	0	0	0	74	62.7
	No	43	1	0	0	0	0	0	0	44	37.3

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Total	**117**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**118**	**100.0**
Marmoset and tamarins	Yes	40	26	9	16	0	0	0	0	91	24.2
	No	203	72	9	0	0	0	1	0	285	75.8
	Total	**243**	**98**	**18**	**16**	**0**	**0**	**1**	**0**	**376**	**100.0**
Squirrel monkey	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	8	0	0	0	0	0	0	0	8	100.0
	Total	**8**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Cynomolgus monkey	Yes	42	671	1,054	968	0	0	43	0	2,778	29.9
	No	519	549	5,379	54	0	0	2	0	6,503	70.1
	Total	**561**	**1,220**	**6,433**	**1,022**	**0**	**0**	**45**	**0**	**9,281**	**100.0**
Rhesus monkey	Yes	128	87	26	3	0	0	4	0	248	43.8
	No	126	121	70	0	0	0	1	0	318	56.2
	Total	**254**	**208**	**96**	**3**	**0**	**0**	**5**	**0**	**566**	**100.0**
Vervets Chlorocebus spp	Yes	0	22	0	0	0	0	0	0	22	53.7
	No	6	0	0	13	0	0	0	0	19	46.3
	Total	**6**	**22**	**0**	**13**	**0**	**0**	**0**	**0**	**41**	**100.0**
Baboons	Yes	20	18	0	0	0	0	0	0	38	38.0
	No	51	11	0	0	0	0	0	0	62	62.0
	Total	**71**	**29**	**0**	**0**	**0**	**0**	**0**	**0**	**100**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Yes	8	18	0	0	0	0	0	0	26	100.0
	No	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**18**	**0**	**0**	**0**	**0**	**0**	**0**	**26**	**100.0**
Other mammals	Yes	211	50	0	0	5	0	3	0	269	6.9
	No	2,935	145	8	29	177	259	84	0	3,637	93.1
	Total	**3,146**	**195**	**8**	**29**	**182**	**259**	**87**	**0**	**3,906**	**100.0**
Domestic fowl	Yes	2,670	494	2,284	63	0	0	980	0	6,491	1.3
	No	134,501	106,059	147,498	105,806	3,281	709	2,530	536	500,920	98.7
	Total	**137,171**	**106,553**	**149,782**	**105,869**	**3,281**	**709**	**3,510**	**536**	**507,411**	**100.0**
Other birds	Yes	1,763	185	140	0	108	0	409	0	2,605	2.7
	No	58,448	15,361	8,152	10,229	1,439	855	306	14	94,804	97.3
	Total	**60,211**	**15,546**	**8,292**	**10,229**	**1,547**	**855**	**715**	**14**	**97,409**	**100.0**
Reptiles	Yes	5,026	0	0	300	0	0	9	0	5,335	62.2
	No	3,141	16	0	0	65	0	18	0	3,240	37.8
	Total	**8,167**	**16**	**0**	**300**	**65**	**0**	**27**	**0**	**8,575**	**100.0**
Rana	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	676	0	80	0	1,450	0	2,276	0	4,482	100.0
	Total	**676**	**0**	**80**	**0**	**1,450**	**0**	**2,276**	**0**	**4,482**	**100.0**
Xenopus	Yes	8,786	585	0	0	0	0	22	0	9,393	33.7
	No	16,593	996	205	0	608	0	109	0	18,511	66.3
	Total	**25,379**	**1,581**	**205**	**0**	**608**	**0**	**131**	**0**	**27,904**	**100.0**
Other amphibians	Yes	106	24	0	0	239	0	0	0	369	1.9
	No	7,523	3,214	72	0	2,051	6,417	281	0	19,558	98.1
	Total	**7,629**	**3,238**	**72**	**0**	**2,290**	**6,417**	**281**	**0**	**19,927**	**100.0**
Zebra fish	Yes	5,244	0	134	0	0	0	0	0	5,378	1.0
	No	385,959	86,731	37,944	0	855	127	1,395	0	513,011	99.0
	Total	**391,203**	**86,731**	**38,078**	**0**	**855**	**127**	**1,395**	**0**	**518,389**	**100.0**
Other fish	Yes	8,948	50	92	0	0	0	49	0	9,139	1.1
	No	466,210	123,524	83,458	0	57,975	48,711	11,848	0	791,726	98.9
	Total	**475,158**	**123,574**	**83,550**	**0**	**57,975**	**48,711**	**11,897**	**0**	**800,865**	**100.0**
Cephalopods	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	**352**	**8,517**	**0**	**0**	**0**	**0**	**15**	**0**	**8,884**	**100.0**
	Total	**352**	**8,517**	**0**	**0**	**0**	**0**	**15**	**0**	**8,884**	**100.0**
All Species	**Yes**	**64,165**	**24,821**	**50,776**	**53,147**	**2,117**	**0**	**15,486**	**40**	**210,552**	**2.1**
	No	**4,764,368**	**2,189,213**	**2,164,056**	**402,287**	**76,286**	**71,852**	**149,009**	**875**	**9,817,946**	**97.9**
	Total	**4,828,533**	**2,214,034**	**2,214,832**	**455,434**	**78,403**	**71,852**	**164,495**	**915**	**10,028,498**	**100.0**

Table 14: Genetic status of animals used by species and main categories of scientific purposes (2016)

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Not altered	1,448,135	1,026,697	1,067,308	51,402	2,203	333	67,499	64	3,663,641	60.6
	Non harmful	1,546,445	356,991	49,339	670	49	13,876	8,224	40	1,975,634	32.7
	Harmful	278,525	124,105	1,286	0	0	201	527	28	404,672	6.7
	Total	**3,273,105**	**1,507,793**	**1,117,933**	**52,072**	**2,252**	**14,410**	**76,250**	**132**	**6,043,947**	**100.0**
Rats	Not altered	317,730	243,625	551,023	1,840	4,517	82	43,185	54	1,162,056	97.6
	Non harmful	13,013	3,988	2,620	302	14	142	251	0	20,330	1.7
	Harmful	4,106	4,256	50	0	0	0	12	0	8,424	0.7
	Total	**334,849**	**251,869**	**553,693**	**2,142**	**4,531**	**224**	**43,448**	**54**	**1,190,810**	**100.0**
Guinea-Pigs	Not altered	23,508	9,235	116,318	783	0	0	1,863	0	151,707	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**23,508**	**9,235**	**116,318**	**783**	**0**	**0**	**1,863**	**0**	**151,707**	**100.0**
Hamsters (Syrian)	Not altered	2,853	4,682	10,669	249	0	0	219	0	18,672	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**2,853**	**4,682**	**10,669**	**249**	**0**	**0**	**219**	**0**	**18,672**	**100.0**
Hamsters (Chinese)	Not altered	0	287	230	0	0	0	2	0	519	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**0**	**287**	**230**	**0**	**0**	**0**	**2**	**0**	**519**	**100.0**
Mongolian gerbil	Not altered	1,561	2,267	1,961	198	0	0	85	0	6,072	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,561**	**2,267**	**1,961**	**198**	**0**	**0**	**85**	**0**	**6,072**	**100.0**
Other rodents	Not altered	9,653	559	3,334	0	444	40	19	0	14,049	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**9,653**	**559**	**3,334**	**0**	**444**	**40**	**19**	**0**	**14,049**	**100.0**
Rabbits	Not altered	26,899	15,446	90,910	200,806	196	0	2,097	0	336,354	92.4
	Non harmful	29	0	0	27,719	0	0	0	0	27,748	7.6
	Harmful	30	0	0	0	0	0	0	0	30	0.0
	Total	**26,958**	**15,446**	**90,910**	**228,525**	**196**	**0**	**2,097**	**0**	**364,132**	**100.0**
Cats	Not altered	805	1,619	1,030	27	0	0	214	0	3,695	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**805**	**1,619**	**1,030**	**27**	**0**	**0**	**214**	**0**	**3,695**	**100.0**
Dogs	Not altered	1,777	9,223	11,833	172	0	0	403	0	23,408	99.8
	Non harmful	0	14	0	0	0	0	0	0	14	0.1
	Harmful	13	17	0	0	0	0	0	0	30	0.1
	Total	**1,790**	**9,254**	**11,833**	**172**	**0**	**0**	**403**	**0**	**23,452**	**100.0**
Ferrets	Not altered	196	875	461	14	0	0	64	0	1,610	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**196**	**875**	**461**	**14**	**0**	**0**	**64**	**0**	**1,610**	**100.0**
Other carnivores	Not altered	797	385	531	3	69	52	0	0	1,837	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**797**	**385**	**531**	**3**	**69**	**52**	**0**	**0**	**1,837**	**100.0**
Horses, donkeys and cross-breeds	Not altered	2,405	1,913	286	8,187	12	20	301	0	13,124	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**2,405**	**1,913**	**286**	**8,187**	**12**	**20**	**301**	**0**	**13,124**	**100.0**
Pigs	Not altered	19,069	37,704	13,920	245	522	0	11,319	62	82,841	99.6
	Non harmful	54	124	0	0	0	0	0	0	178	0.2
	Harmful	24	147	0	0	0	0	0	0	171	0.2

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Total	**19,147**	**37,975**	**13,920**	**245**	**522**	**0**	**11,319**	**62**	**83,190**	**100.0**
Goats	Not altered	1,253	532	90	76	50	0	216	0	2,217	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,253**	**532**	**90**	**76**	**50**	**0**	**216**	**0**	**2,217**	**100.0**
Sheep	Not altered	9,233	10,065	1,935	45,111	41	0	1,397	92	67,874	100.0
	Non harmful	20	0	0	0	0	0	0	0	20	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**9,253**	**10,065**	**1,935**	**45,111**	**41**	**0**	**1,397**	**92**	**67,894**	**100.0**
Cattle	Not altered	10,040	11,731	3,084	149	2,033	28	6,213	25	33,303	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**10,040**	**11,731**	**3,084**	**149**	**2,033**	**28**	**6,213**	**25**	**33,303**	**100.0**
Prosimians	Not altered	117	1	0	0	0	0	0	0	118	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**117**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**118**	**100.0**
Marmoset and tamarins	Not altered	243	98	18	16	0	0	1	0	376	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**243**	**98**	**18**	**16**	**0**	**0**	**1**	**0**	**376**	**100.0**
Squirrel monkey	Not altered	8	0	0	0	0	0	0	0	8	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Cynomolgus monkey	Not altered	561	1,220	6,433	1,022	0	0	45	0	9,281	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**561**	**1,220**	**6,433**	**1,022**	**0**	**0**	**45**	**0**	**9,281**	**100.0**
Rhesus monkey	Not altered	254	208	96	3	0	0	5	0	566	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**254**	**208**	**96**	**3**	**0**	**0**	**5**	**0**	**566**	**100.0**
Vervets Chlorocebus spp	Not altered	6	22	0	13	0	0	0	0	41	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**6**	**22**	**0**	**13**	**0**	**0**	**0**	**0**	**41**	**100.0**
Baboons	Not altered	71	29	0	0	0	0	0	0	100	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**71**	**29**	**0**	**0**	**0**	**0**	**0**	**0**	**100**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Not altered	8	18	0	0	0	0	0	0	26	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**8**	**18**	**0**	**0**	**0**	**0**	**0**	**0**	**26**	**100.0**
Other mammals	Not altered	3,146	195	8	29	182	259	87	0	3,906	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**3,146**	**195**	**8**	**29**	**182**	**259**	**87**	**0**	**3,906**	**100.0**
Domestic fowl	Not altered	136,789	106,214	149,782	105,869	3,281	709	3,510	536	506,690	99.9
	Non harmful	354	339	0	0	0	0	0	0	693	0.1
	Harmful	28	0	0	0	0	0	0	0	28	0.0
	Total	**137,171**	**106,553**	**149,782**	**105,869**	**3,281**	**709**	**3,510**	**536**	**507,411**	**100.0**
Other birds	Not altered	60,211	15,546	8,292	10,229	1,547	855	715	14	97,409	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**60,211**	**15,546**	**8,292**	**10,229**	**1,547**	**855**	**715**	**14**	**97,409**	**100.0**
Reptiles	Not altered	8,167	16	0	300	65	0	27	0	8,575	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Total	**8,167**	**16**	**0**	**300**	**65**	**0**	**27**	**0**	**8,575**	**100.0**
Rana	Not altered	676	0	80	0	1,450	0	2,276	0	4,482	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**676**	**0**	**80**	**0**	**1,450**	**0**	**2,276**	**0**	**4,482**	**100.0**
Xenopus	Not altered	20,363	1,508	205	0	608	0	131	0	22,815	81.8
	Non harmful	4,452	73	0	0	0	0	0	0	4,525	16.2
	Harmful	564	0	0	0	0	0	0	0	564	2.0
	Total	**25,379**	**1,581**	**205**	**0**	**608**	**0**	**131**	**0**	**27,904**	**100.0**
Other amphibians	Not altered	7,194	3,238	72	0	2,290	6,417	281	0	19,492	97.8
	Non harmful	435	0	0	0	0	0	0	0	435	2.2
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**7,629**	**3,238**	**72**	**0**	**2,290**	**6,417**	**281**	**0**	**19,927**	**100.0**
Zebra fish	Not altered	115,779	33,684	38,078	0	855	68	1,056	0	189,520	36.6
	Non harmful	259,374	48,473	0	0	0	59	339	0	308,245	59.5
	Harmful	16,050	4,574	0	0	0	0	0	0	20,624	4.0
	Total	**391,203**	**86,731**	**38,078**	**0**	**855**	**127**	**1,395**	**0**	**518,389**	**100.0**
Other fish	Not altered	471,548	119,675	83,395	0	57,975	48,711	11,897	0	793,201	99.0
	Non harmful	3,078	3,899	155	0	0	0	0	0	7,132	0.9
	Harmful	532	0	0	0	0	0	0	0	532	0.1
	Total	**475,158**	**123,574**	**83,550**	**0**	**57,975**	**48,711**	**11,897**	**0**	**800,865**	**100.0**
Cephalopods	Not altered	352	8,517	0	0	0	0	15	0	8,884	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**352**	**8,517**	**0**	**0**	**0**	**0**	**15**	**0**	**8,884**	**100.0**
All Species	**Harmful**	**299,872**	**133,099**	**1,336**	**0**	**0**	**201**	**539**	**28**	**435,075**	**4.3**
	Non harmful	**1,827,254**	**413,901**	**52,114**	**28,691**	**63**	**14,077**	**8,814**	**40**	**2,344,954**	**23.4**
	Not altered	**2,701,407**	**1,667,034**	**2,161,382**	**426,743**	**78,340**	**57,574**	**155,142**	**847**	**7,248,469**	**72.3**
	Total	**4,828,533**	**2,214,034**	**2,214,832**	**455,434**	**78,403**	**71,852**	**164,495**	**915**	**10,028,498**	**100.0**

Part 3: Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

Table 15: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2016)

	Severity	Basic research	Translational and applied research	Total	%
Mice	Non-recovery	11,199	1,429	12,628	3.5
	Mild	253,536	16,280	269,816	75.0
	Moderate	56,436	12,345	68,781	19.1
	Severe	7,988	681	8,669	2.4
	Total	**329,159**	**30,735**	**359,894**	**100.0**
Rats	Non-recovery	519	12	531	8.8
	Mild	2,990	416	3,406	56.4
	Moderate	1,670	53	1,723	28.5
	Severe	347	32	379	6.3
	Total	**5,526**	**513**	**6,039**	**100.0**
Guinea-Pigs	Non-recovery	47	0	47	100.0
	Mild	0	0	0	0.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**47**	**0**	**47**	**100.0**
Other rodents	Non-recovery	6	0	6	100.0
	Mild	0	0	0	0.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**6**	**0**	**6**	**100.0**
Rabbits	Non-recovery	223	371	594	61.4
	Mild	0	0	0	0.0
	Moderate	17	356	373	38.6
	Severe	0	0	0	0.0
	Total	**240**	**727**	**967**	**100.0**
Pigs	Non-recovery	0	0	0	0.0
	Mild	184	12	196	69.0
	Moderate	61	0	61	21.5
	Severe	27	0	27	9.5
	Total	**272**	**12**	**284**	**100.0**
Sheep	Non-recovery	0	0	0	0.0
	Mild	24	0	24	12.6
	Moderate	167	0	167	87.4
	Severe	0	0	0	0.0
	Total	**191**	**0**	**191**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0.0
	Mild	401	114	515	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**401**	**114**	**515**	**100.0**
Xenopus	Non-recovery	0	0	0	0.0
	Mild	965	85	1,050	95.5
	Moderate	50	0	50	4.5
	Severe	0	0	0	0.0
	Total	**1,015**	**85**	**1,100**	**100.0**
Zebra fish	Non-recovery	1,643	0	1,643	1.3
	Mild	107,496	1,779	109,275	89.5
	Moderate	8,868	0	8,868	7.3
	Severe	2,033	263	2,296	1.9
	Total	**120,040**	**2,042**	**122,082**	**100.0**
Other fish	Non-recovery	558	0	558	5.2
	Mild	10,040	0	10,040	93.5
	Moderate	139	0	139	1.3
	Severe	0	0	0	0.0
	Total	**10,737**	**0**	**10,737**	**100.0**

	Severity	Basic research	Translational and applied research	Total	%
All Species	Non-recovery	14,195	1,812	16,007	3.2
	Mild	375,636	18,686	394,322	78.6
	Moderate	67,408	12,754	80,162	16.0
	Severe	10,395	976	11,371	2.3
	Total	467,634	34,228	501,862	100.0

Table 16: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2016)

	Reuse	Basic research	Translational and applied research	Total	%
Mice	Yes	2,396	21	2,417	0.7
	No	326,763	30,714	357,477	99.3
	Total	**329,159**	**30,735**	**359,894**	**100.0**
Rats	Yes	0	0	0	0.0
	No	5,526	513	6,039	100.0
	Total	**5,526**	**513**	**6,039**	**100.0**
Guinea-Pigs	Yes	0	0	0	0.0
	No	47	0	47	100.0
	Total	**47**	**0**	**47**	**100.0**
Other rodents	Yes	0	0	0	0.0
	No	6	0	6	100.0
	Total	**6**	**0**	**6**	**100.0**
Rabbits	Yes	0	0	0	0.0
	No	240	727	967	100.0
	Total	**240**	**727**	**967**	**100.0**
Pigs	Yes	0	0	0	0.0
	No	272	12	284	100.0
	Total	**272**	**12**	**284**	**100.0**
Sheep	Yes	0	0	0	0.0
	No	191	0	191	100.0
	Total	**191**	**0**	**191**	**100.0**
Domestic fowl	Yes	0	0	0	0.0
	No	401	114	515	100.0
	Total	**401**	**114**	**515**	**100.0**
Xenopus	Yes	0	0	0	0.0
	No	1,015	85	1,100	100.0
	Total	**1,015**	**85**	**1,100**	**100.0**
Zebra fish	Yes	6,289	0	6,289	5.2
	No	113,751	2,042	115,793	94.8
	Total	**120,040**	**2,042**	**122,082**	**100.0**
Other fish	Yes	0	0	0	0.0
	No	10,737	0	10,737	100.0
	Total	**10,737**	**0**	**10,737**	**100.0**
All Species	**Yes**	**8,685**	**21**	**8,706**	**1.7**
	No	**458,949**	**34,207**	**493,156**	**98.3**
	Total	**467,634**	**34,228**	**501,862**	**100.0**

Table 17: Uses of animals for the creation of new genetically altered animal lines in basic research by species and type of research (2016)

	Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals															
Rodents															
Mice	60,864	13,916	52,874	213	6,317	5,259	35,124	12,918	8,165	13,900	87,472	207	31,930	**329,159**	**70.4**
Rats	0	1,272	1,697	0	1	0	283	34	0	0	1,336	0	903	**5,526**	**1.2**
Guinea-Pigs	0	0	0	0	0	0	0	47	0	0	0	0	0	**47**	**0**
Other rodents	0	0	0	0	0	0	0	0	0	0	0	6	0	**6**	**0**
Rabbits															
Rabbits	0	76	0	0	0	116	0	24	0	0	0	0	24	**240**	**0.1**
Farm animals															
Pigs	0	3	27	0	0	0	135	0	0	13	94	0	0	**272**	**0.1**
Sheep	0	0	2	22	0	0	0	0	0	0	167	0	0	**191**	**0**
Non-human primates															
Marmoset and tamarins	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Other mammals															
Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Birds															
Domestic fowl	0	0	0	0	0	0	98	54	0	0	249	0	0	**401**	**0.1**
Amphibians															
Xenopus	0	201	176	0	0	0	0	0	300	198	0	0	140	**1,015**	**0.2**
Fish															
Zebra fish	2,879	24,519	23,840	0	540	2,245	9,585	5,934	11,439	2,164	25,629	2,300	8,966	**120,040**	**25.7**
Other fish	126	6	558	0	0	0	0	1,573	7,601	0	860	0	13	**10,737**	**2.3**
Totals															
Total	**63,869**	**39,993**	**79,174**	**235**	**6,858**	**7,620**	**45,225**	**20,584**	**27,505**	**16,275**	**115,807**	**2,513**	**41,976**	**467,634**	**100**
%	**13.7**	**8.6**	**16.9**	**0.1**	**1.5**	**1.6**	**9.7**	**4.4**	**5.9**	**3.5**	**24.8**	**0.5**	**9**	**100**	

Table 18.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species and type of research (Part 1) (2016)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders
Mammals								
Rodents								
Mice	14,063	386	2,391	2,950	407	1,117	481	745
Rats	99	0	0	0	0	0	88	0
Guinea-Pigs	0	0	0	0	0	0	0	0
Other rodents	0	0	0	0	0	0	0	0
Rabbits								
Rabbits	0	0	0	0	0	0	0	0
Farm animals								
Pigs	0	0	0	0	0	0	0	0
Sheep	0	0	0	0	0	0	0	0
Non-human primates								
Marmoset and tamarins	0	0	0	0	0	0	0	0
Other mammals								
Other mammals	0	0	0	0	0	0	0	0
Birds								
Domestic fowl	0	0	0	0	0	0	0	0
Amphibians								
Xenopus	0	0	0	0	0	0	0	0
Fish								
Zebra fish	0	461	100	0	0	0	396	0
Other fish	0	0	0	0	0	0	0	0
Totals								
Total	**14,162**	**847**	**2,491**	**2,950**	**407**	**1,117**	**965**	**745**
%	**41.7**	**2.5**	**7.3**	**8.7**	**1.2**	**3.3**	**2.8**	**2.2**

Table 18.2: Uses of animals for the creation of new genetically altered animal lines in basic translational and applied research by species and type of research (Part 2) (2016)

	Human Urogenital/Reproductive Disorders	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	481	487	5,682	1,107	197	0	239	2	**30,735**	**89.8**
Rats	0	234	0	0	0	92	0	0	**513**	**1.5**
Guinea-Pigs	0	0	0	0	0	0	0	0	**0**	**0**
Other rodents	0	0	0	0	0	0	0	0	**0**	**0**
Rabbits										
Rabbits	0	0	565	0	162	0	0	0	**727**	**2.1**
Farm animals										
Pigs	0	0	0	0	12	0	0	0	**12**	**0**
Sheep	0	0	0	0	0	0	0	0	**0**	**0**
Non-human primates										
Marmoset and tamarins	0	0	0	0	0	0	0	0	**0**	**0**
Other mammals										
Other mammals	0	0	0	0	0	0	0	0	**0**	**0**
Birds										
Domestic fowl	0	0	0	20	94	0	0	0	**114**	**0.3**
Amphibians										
Xenopus	0	85	0	0	0	0	0	0	**85**	**0.2**
Fish										
Zebra fish	0	1,073	0	12	0	0	0	0	**2,042**	**6**
Other fish	0	0	0	0	0	0	0	0	**0**	**0**
Totals										
Total	**481**	**1,879**	**6,247**	**1,139**	**465**	**92**	**239**	**2**	**34,228**	**100**
%	**1.4**	**5.5**	**18.3**	**3.3**	**1.4**	**0.3**	**0.7**	**0**	**100**	

Table 19: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, severity and genetic status (2016)

	Severity	Genetically altered with a harmful phenotype	Genetically altered without a harmful phenotype	Not genetically altered	Total	%
Mice	Non-recovery	244	425	47	716	0.1
	Mild	133,810	372,090	32,786	538,686	86.3
	Moderate	22,041	15,269	8,357	45,667	7.3
	Severe	29,336	9,515	68	38,919	6.2
	Total	**185,431**	**397,299**	**41,258**	**623,988**	**100.0**
Rats	Non-recovery	0	0	0	0	0.0
	Mild	3,887	3,101	258	7,246	78.0
	Moderate	436	56	1,059	1,551	16.7
	Severe	428	47	22	497	5.3
	Total	**4,751**	**3,204**	**1,339**	**9,294**	**100.0**
Dogs	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	0	0	0	0	0.0
	Severe	17	0	0	17	100.0
	Total	**17**	**0**	**0**	**17**	**100.0**
Other mammals	Non-recovery	0	0	0	0	0.0
	Mild	0	0	4	4	100.0
	Moderate	0	0	0	0	0.0
	Severe	0	0	0	0	0.0
	Total	**0**	**0**	**4**	**4**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0	0.0
	Mild	0	345	32	377	64.8
	Moderate	135	0	0	135	23.2
	Severe	70	0	0	70	12.0
	Total	**205**	**345**	**32**	**582**	**100.0**
Xenopus	Non-recovery	0	0	0	0	0.0
	Mild	0	141	79	220	84.9
	Moderate	0	14	0	14	5.4
	Severe	0	25	0	25	9.7
	Total	**0**	**180**	**79**	**259**	**100.0**
Zebra fish	Non-recovery	0	286	29	315	0.5
	Mild	3,018	55,371	4,217	62,606	93.7
	Moderate	480	2,694	187	3,361	5.0
	Severe	3	503	6	512	0.8
	Total	**3,501**	**58,854**	**4,439**	**66,794**	**100.0**
Other fish	Non-recovery	0	0	0	0	0.0
	Mild	1	0	0	1	0.2
	Moderate	0	570	0	570	99.8
	Severe	0	0	0	0	0.0
	Total	**1**	**570**	**0**	**571**	**100.0**
All Species	**Non-recovery**	**244**	**711**	**76**	**1,031**	**0.1**
	Mild	**140,716**	**431,048**	**37,376**	**609,140**	**86.8**
	Moderate	**23,092**	**18,603**	**9,603**	**51,298**	**7.3**
	Severe	**29,854**	**10,090**	**96**	**40,040**	**5.7**
	Total	**193,906**	**460,452**	**47,151**	**701,509**	**100.0**

Table 20: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and genetic status (2016)

	Reuse	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	%
Mice	Yes	0	191	0	191	0.0
	No	41,258	397,108	185,431	623,797	100.0
	Total	**41,258**	**397,299**	**185,431**	**623,988**	**100.0**
Rats	Yes	0	0	0	0	0.0
	No	1,339	3,204	4,751	9,294	100.0
	Total	**1,339**	**3,204**	**4,751**	**9,294**	**100.0**
Dogs	Yes	0	0	0	0	0.0
	No	0	0	17	17	100.0
	Total	**0**	**0**	**17**	**17**	**100.0**
Other mammals	Yes	0	0	0	0	0.0
	No	4	0	0	4	100.0
	Total	**4**	**0**	**0**	**4**	**100.0**
Domestic fowl	Yes	0	0	0	0	0.0
	No	32	345	205	582	100.0
	Total	**32**	**345**	**205**	**582**	**100.0**
Xenopus	Yes	69	41	0	110	42.5
	No	10	139	0	149	57.5
	Total	**79**	**180**	**0**	**259**	**100.0**
Zebra fish	Yes	303	369	0	672	1.0
	No	4,136	58,485	3,501	66,122	99.0
	Total	**4,439**	**58,854**	**3,501**	**66,794**	**100.0**
Other fish	Yes	0	0	0	0	0.0
	No	0	570	1	571	100.0
	Total	**0**	**570**	**1**	**571**	**100.0**
All Species	**Yes**	**372**	**601**	**0**	**973**	**0.1**
	No	**46,779**	**459,851**	**193,906**	**700,536**	**99.9**
	Total	**47,151**	**460,452**	**193,906**	**701,509**	**100.0**

EU statistical tables 2017

Part 1: Numbers of animals used for research, testing, routine production and educational purposes in the EU

Table 1: Numbers of animals used for the first time by species (2017)

		Number of animals	%
Mammals			
	Rodents		
	Mice	5,707,471	**60.8**
	Rats	1,146,299	**12.2**
	Guinea-Pigs	144,824	**1.5**
	Hamsters (Syrian)	12,700	**0.1**
	Hamsters (Chinese)	187	**0**
	Mongolian gerbil	5,239	**0.1**
	Other rodents	25,172	**0.3**
	Rabbits		
	Rabbits	351,961	**3.7**
	Carnivores		
	Cats	1,879	**0**
	Dogs	13,688	**0.1**
	Ferrets	2,016	**0**
	Other carnivores	2,386	**0**
	Farm animals		
	Horses, donkeys and cross-breeds	2,414	**0**
	Pigs	71,522	**0.8**
	Goats	1,563	**0**
	Sheep	18,812	**0.2**
	Cattle	30,643	**0.3**
	Non-human primates		
	Prosimians	98	**0**
	Marmoset and tamarins	465	**0**
	Squirrel monkey	8	**0**
	Other species of new world monkeys (Ceboidea)	3	**0**
	Cynomolgus monkey	7,227	**0.1**
	Rhesus monkey	353	**0**
	Vervets (Chlorocebus spp.)	33	**0**
	Baboons	25	**0**
	Other species of old world monkeys (Cercopithecoidea)	23	**0**
	Other mammals		
	Other mammals	26,335	**0.3**
Birds			
	Domestic fowl	464,553	**4.9**
	Other birds	99,410	**1.1**
Reptiles			
	Reptiles	2,937	**0**
Amphibians			
	Rana	3,485	**0**
	Xenopus	13,539	**0.1**
	Other amphibians	10,683	**0.1**
Fish			
	Zebra fish	499,763	**5.3**
	Other fish	719,932	**7.7**
Cephalopods			
	Cephalopods	514	**0**
Totals			
	Total	**9,388,162**	**100**
	%	**100**	

Table 2: Place of birth by species (other than non-human primates) (2017)

	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of world	Total	%
Mammals						
Rodents						
Mice	5,444,375	204,383	14,171	44,542	**5,707,471**	**60.8**
Rats	1,125,076	14,131	1,909	5,183	**1,146,299**	**12.2**
Guinea-Pigs	143,202	1,622	0	0	**144,824**	**1.5**
Hamsters (Syrian)	11,573	0	9	1,118	**12,700**	**0.1**
Hamsters (Chinese)	175	0	0	12	**187**	**0**
Mongolian gerbil	4,998	230	0	11	**5,239**	**0.1**
Other rodents	9,415	15,104	98	555	**25,172**	**0.3**
Rabbits						
Rabbits	348,078	2,242	148	1,493	**351,961**	**3.8**
Carnivores						
Cats	893	828	0	158	**1,879**	**0**
Dogs	4,740	4,408	0	4,540	**13,688**	**0.1**
Ferrets	1,836	100	24	56	**2,016**	**0**
Other carnivores	829	1,550	7	0	**2,386**	**0**
Farm animals						
Horses, donkeys and cross-breeds	510	1,904	0	0	**2,414**	**0**
Pigs	37,465	33,994	54	9	**71,522**	**0.8**
Goats	497	1,055	11	0	**1,563**	**0**
Sheep	8,069	10,472	271	0	**18,812**	**0.2**
Cattle	9,174	21,234	235	0	**30,643**	**0.3**
Other mammals						
Other mammals	1,855	6,399	4	18,077	**26,335**	**0.3**
Birds						
Domestic fowl	345,031	119,522	0	0	**464,553**	**5**
Other birds	38,965	59,241	563	641	**99,410**	**1.1**
Reptiles						
Reptiles	53	2,357	259	268	**2,937**	**0**
Amphibians						
Rana	2,462	1,023	0	0	**3,485**	**0**
Xenopus	9,627	598	96	3,218	**13,539**	**0.1**
Other amphibians	3,630	6,924	73	56	**10,683**	**0.1**
Fish						
Zebra fish	467,011	28,081	2,376	2,295	**499,763**	**5.3**
Other fish	417,282	224,826	52,644	25,180	**719,932**	**7.7**
Cephalopods						
Cephalopods	450	60	0	4	**514**	**0**
Totals						
Total	**8,437,271**	**762,288**	**72,952**	**107,416**	**9,379,927**	**100**
%	**90**	**8.1**	**0.8**	**1.1**	**100**	

Table 3: Source of non-human primates by species (2017)

	Animals born at a registered breeder within EU	Animals born in rest of Europe	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total	%
Non-human primates								
New World Monkeys								
Prosimians	98	0	0	0	0	0	**98**	**1.2**
Marmoset and tamarins	377	0	0	0	42	46	**465**	**5.6**
Squirrel monkey	5	0	0	2	0	1	**8**	**0.1**
Other species of new world monkeys (Ceboidea)	3	0	0	0	0	0	**3**	**0**
Old World Monkeys								
Cynomolgus monkey	218	5	2,591	0	4,290	123	**7,227**	**87.8**
Rhesus monkey	317	0	14	19	3	0	**353**	**4.3**
Vervets (Chlorocebus spp.)	0	0	0	33	0	0	**33**	**0.4**
Baboons	25	0	0	0	0	0	**25**	**0.3**
Other species of old world monkeys (Cercopithecoidea)	14	0	9	0	0	0	**23**	**0.3**
Totals								
Total	**1,057**	**5**	**2,614**	**54**	**4,335**	**170**	**8,235**	**100**
%	**12.8**	**0.1**	**31.7**	**0.7**	**52.6**	**2.1**	**100**	

Table 4: Generation of non-human primates by species (2017)

	F0	F1	F2 or greater	Self-sustaining colony	Total	%
Non-human primates						
New World Monkeys						
Prosimians	0	0	0	98	**98**	**1.2**
Marmoset and tamarins	0	0	244	221	**465**	**5.6**
Squirrel monkey	0	2	6	0	**8**	**0.1**
Other species of new world monkeys (Ceboidea)	0	0	3	0	**3**	**0**
Old World Monkeys						
Cynomolgus monkey	0	1,335	3,956	1,936	**7,227**	**87.8**
Rhesus monkey	0	7	109	237	**353**	**4.3**
Vervets (Chlorocebus spp.)	0	14	19	0	**33**	**0.4**
Baboons	0	5	8	12	**25**	**0.3**
Other species of old world monkeys (Cercopithecoidea)	0	0	23	0	**23**	**0.3**
Totals						
Total	**0**	**1,363**	**4,368**	**2,504**	**8,235**	**100**
%	**0**	**16.6**	**53**	**30.4**	**100**	

Part 2: Details of all uses of animals for research, testing, routine production and educational purposes in the EU

Table 5: Uses of animals by species, main categories of scientific purposes and severities (2017)

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Non-recovery	325,637	41,412	2,526	59	3	0	17,895	0	387,532	6.7
	Mild	1,301,419	553,601	533,064	2,536	2,360	13,313	45,524	8	2,451,825	42.6
Mice	Moderate	1,161,119	716,532	223,700	15,291	330	39	21,420	0	2,138,431	37.2
	Severe	246,193	219,421	280,515	31,664	54	0	486	0	778,333	13.5
	Total	**3,034,368**	**1,530,966**	**1,039,805**	**49,550**	**2,747**	**13,352**	**85,325**	**8**	**5,756,121**	**100.0**
	Non-recovery	66,361	23,448	5,187	1,203	6	0	22,105	0	118,310	10.2
	Mild	83,756	86,567	368,165	1,319	127	0	13,407	0	553,341	47.5
Rats	Moderate	130,341	109,438	173,627	23	1,004	0	5,582	0	420,015	36.1
	Severe	43,573	15,886	11,590	150	1,247	0	55	0	72,501	6.2
	Total	**324,031**	**235,339**	**558,569**	**2,695**	**2,384**	**0**	**41,149**	**0**	**1,164,167**	**100.0**
	Non-recovery	18,948	878	282	266	0	0	265	0	20,639	14.1
	Mild	1,352	4,240	63,258	498	10	0	1,619	0	70,977	48.6
Guinea-Pigs	Moderate	1,735	2,190	34,927	229	0	0	207	0	39,288	26.9
	Severe	140	227	14,765	0	0	0	1	0	15,133	10.4
	Total	**22,175**	**7,535**	**113,232**	**993**	**10**	**0**	**2,092**	**0**	**146,037**	**100.0**
	Non-recovery	143	23	0	0	0	0	34	0	200	1.6
	Mild	461	1,089	4,314	54	0	0	228	0	6,146	48.3
Hamsters (Syrian)	Moderate	678	1,677	347	34	0	0	5	0	2,741	21.5
	Severe	208	1,222	2,149	12	0	0	45	0	3,636	28.6
	Total	**1,490**	**4,011**	**6,810**	**100**	**0**	**0**	**312**	**0**	**12,723**	**100.0**
	Non-recovery	0	0	0	0	0	0	5	0	5	2.7
	Mild	3	0	59	0	0	0	0	0	62	33.2
Hamsters (Chinese)	Moderate	0	90	0	0	0	0	0	0	90	48.1
	Severe	0	30	0	0	0	0	0	0	30	16.0
	Total	**3**	**120**	**59**	**0**	**0**	**0**	**5**	**0**	**187**	**100.0**
	Non-recovery	323	0	0	0	0	0	53	0	376	7.0
	Mild	570	911	1,438	81	0	10	49	0	3,059	56.8
Mongolian gerbil	Moderate	600	1,074	6	28	0	0	7	0	1,715	31.8
	Severe	1	198	36	0	0	0	0	0	235	4.4
	Total	**1,494**	**2,183**	**1,480**	**109**	**0**	**10**	**109**	**0**	**5,385**	**100.0**
	Non-recovery	344	15	33	0	1	0	37	0	430	1.7
	Mild	13,314	398	9,057	0	53	52	248	0	23,122	90.8
Other rodents	Moderate	821	44	108	0	35	25	0	0	1,033	4.1
	Severe	754	7	26	0	80	0	0	0	867	3.4
	Total	**15,233**	**464**	**9,224**	**0**	**169**	**77**	**285**	**0**	**25,452**	**100.0**
	Non-recovery	3,256	2,088	12,304	20	0	0	812	0	18,480	5.1
	Mild	12,849	3,936	56,131	170,117	316	0	924	0	244,273	67.0
Rabbits	Moderate	3,825	4,826	24,511	57,180	13	0	235	0	90,590	24.9
	Severe	3,584	1,011	1,369	5,122	2	0	0	0	11,088	3.0
	Total	**23,514**	**11,861**	**94,315**	**232,439**	**331**	**0**	**1,971**	**0**	**364,431**	**100.0**
	Non-recovery	35	0	0	0	0	0	0	0	35	1.0
	Mild	686	1,008	1,087	10	0	0	73	0	2,864	85.8
Cats	Moderate	29	114	285	0	0	0	0	0	428	12.8
	Severe	0	11	0	0	0	0	0	0	11	0.3
	Total	**750**	**1,133**	**1,372**	**10**	**0**	**0**	**73**	**0**	**3,338**	**100.0**
	Non-recovery	43	92	89	10	0	0	5	0	239	1.1
	Mild	1,347	7,176	6,271	308	15	0	505	0	15,622	73.1
Dogs	Moderate	229	839	4,072	11	0	0	50	0	5,201	24.4
	Severe	4	87	205	1	0	0	0	0	297	1.4
	Total	**1,623**	**8,194**	**10,637**	**330**	**15**	**0**	**560**	**0**	**21,359**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Ferrets	Non-recovery	6	0	0	6	0	0	8	0	20	0.9
	Mild	90	526	476	57	0	0	64	0	1,213	57.4
	Moderate	218	577	0	0	0	0	0	0	795	37.6
	Severe	5	79	0	0	0	0	0	0	84	4.0
	Total	**319**	**1,182**	**476**	**63**	**0**	**0**	**72**	**0**	**2,112**	**100.0**
Other carnivores	Non-recovery	83	0	0	0	0	0	0	0	83	3.3
	Mild	213	291	183	20	39	107	0	0	853	33.9
	Moderate	580	294	573	0	40	14	0	0	1,501	59.7
	Severe	0	33	0	0	44	0	0	0	77	3.1
	Total	**876**	**618**	**756**	**20**	**123**	**121**	**0**	**0**	**2,514**	**100.0**
Horses, donkeys and cross-breeds	Non-recovery	0	17	0	0	0	0	19	0	36	0.3
	Mild	1,691	1,484	276	9,575	6	0	268	0	13,300	97.6
	Moderate	63	67	44	33	0	0	69	0	276	2.0
	Severe	0	2	0	10	0	0	0	0	12	0.1
	Total	**1,754**	**1,570**	**320**	**9,618**	**6**	**0**	**356**	**0**	**13,624**	**100.0**
Pigs	Non-recovery	4,303	2,512	560	47	0	0	7,282	0	14,704	19.4
	Mild	8,629	18,424	8,091	401	374	2	1,462	36	37,419	49.3
	Moderate	4,420	9,277	3,825	12	234	0	2,283	0	20,051	26.4
	Severe	970	2,502	221	0	0	0	8	0	3,701	4.9
	Total	**18,322**	**32,715**	**12,697**	**460**	**608**	**2**	**11,035**	**36**	**75,875**	**100.0**
Goats	Non-recovery	17	110	0	0	0	0	3	0	130	5.7
	Mild	817	322	105	44	0	0	184	0	1,472	64.9
	Moderate	285	264	12	2	0	0	42	0	605	26.7
	Severe	25	32	4	0	0	0	0	0	61	2.7
	Total	**1,144**	**728**	**121**	**46**	**0**	**0**	**229**	**0**	**2,268**	**100.0**
Sheep	Non-recovery	140	403	0	0	0	0	599	0	1,142	1.7
	Mild	7,060	5,284	1,076	45,608	105	0	724	88	59,945	91.5
	Moderate	1,049	1,950	278	49	14	0	159	0	3,499	5.3
	Severe	308	617	8	8	0	0	0	0	941	1.4
	Total	**8,557**	**8,254**	**1,362**	**45,665**	**119**	**0**	**1,482**	**88**	**65,527**	**100.0**
Cattle	Non-recovery	30	2	0	0	0	0	50	0	82	0.2
	Mild	14,321	8,436	3,288	595	2,445	0	3,078	26	32,189	86.4
	Moderate	439	1,789	468	6	8	0	2,120	0	4,830	13.0
	Severe	7	160	1	0	0	0	7	0	175	0.5
	Total	**14,797**	**10,387**	**3,757**	**601**	**2,453**	**0**	**5,255**	**26**	**37,276**	**100.0**
Prosimians	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	87	0	0	0	0	0	0	0	87	50.3
	Moderate	86	0	0	0	0	0	0	0	86	49.7
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**173**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**173**	**100.0**
Marmoset and tamarins	Non-recovery	2	2	0	0	0	0	0	0	4	0.6
	Mild	107	71	53	86	0	0	1	0	318	49.2
	Moderate	73	81	162	0	0	0	0	0	316	48.9
	Severe	0	8	0	0	0	0	0	0	8	1.2
	Total	**182**	**162**	**215**	**86**	**0**	**0**	**1**	**0**	**646**	**100.0**
Squirrel monkey	Non-recovery	6	0	0	0	0	0	0	0	6	75.0
	Mild	0	0	0	0	0	0	0	0	0	0.0
	Moderate	1	1	0	0	0	0	0	0	2	25.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**7**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Other species of new world monkeys (Ceboidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	3	0	0	0	0	0	0	0	3	100.0
	Moderate	0	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**100.0**
Cynomolgus monkey	Non-recovery	11	8	0	4	0	0	3	0	26	0.3
	Mild	302	711	3,437	1,049	0	0	8	0	5,507	55.0
	Moderate	216	307	3,780	0	0	0	6	0	4,309	43.1
	Severe	0	99	66	0	0	0	0	0	165	1.6
	Total	**529**	**1,125**	**7,283**	**1,053**	**0**	**0**	**17**	**0**	**10,007**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Rhesus monkey	Non-recovery	21	1	0	0	0	0	0	0	22	3.5
	Mild	81	162	11	29	0	0	4	0	287	45.7
	Moderate	143	169	0	0	0	0	0	0	312	49.7
	Severe	5	2	0	0	0	0	0	0	7	1.1
	Total	**250**	**334**	**11**	**29**	**0**	**0**	**4**	**0**	**628**	**100.0**
Vervets (Chlorocebus spp.)	Non-recovery	11	0	0	0	0	0	0	0	11	20.8
	Mild	11	15	0	5	0	0	0	0	31	58.5
	Moderate	0	11	0	0	0	0	0	0	11	20.8
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**22**	**26**	**0**	**5**	**0**	**0**	**0**	**0**	**53**	**100.0**
Baboons	Non-recovery	0	1	0	0	0	0	0	0	1	2.2
	Mild	10	10	0	0	0	0	0	0	20	43.5
	Moderate	0	19	0	0	0	0	0	0	19	41.3
	Severe	0	6	0	0	0	0	0	0	6	13.0
	Total	**10**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**46**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	14	12	0	0	0	0	0	0	26	74.3
	Moderate	0	9	0	0	0	0	0	0	9	25.7
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**14**	**21**	**0**	**0**	**0**	**0**	**0**	**0**	**35**	**100.0**
Other mammals	Non-recovery	60	0	0	0	0	0	0	0	60	0.2
	Mild	4,074	21,523	0	1	71	274	121	0	26,064	96.3
	Moderate	893	7	0	0	0	0	0	0	900	3.3
	Severe	9	10	0	0	23	0	0	0	42	0.2
	Total	**5,036**	**21,540**	**0**	**1**	**94**	**274**	**121**	**0**	**27,066**	**100.0**
Domestic fowl	Non-recovery	5,886	839	261	189	0	0	387	0	7,562	1.6
	Mild	70,751	81,809	112,004	87,000	2,406	343	1,705	315	356,333	75.5
	Moderate	30,401	15,663	29,352	15,089	353	0	2,120	0	92,978	19.7
	Severe	1,347	8,712	4,871	127	0	0	82	0	15,139	3.2
	Total	**108,385**	**107,023**	**146,488**	**102,405**	**2,759**	**343**	**4,294**	**315**	**472,012**	**100.0**
Other birds	Non-recovery	625	671	0	0	0	0	54	0	1,350	1.3
	Mild	49,265	10,880	4,288	303	2,567	690	464	0	68,457	66.9
	Moderate	7,187	805	563	22,518	0	6	172	0	31,251	30.5
	Severe	279	736	153	0	0	0	120	0	1,288	1.3
	Total	**57,356**	**13,092**	**5,004**	**22,821**	**2,567**	**696**	**810**	**0**	**102,346**	**100.0**
Reptiles	Non-recovery	237	18	0	0	0	0	0	0	255	3.9
	Mild	1,912	63	0	0	8	70	100	0	2,153	32.8
	Moderate	4,118	36	0	0	0	0	0	0	4,154	63.3
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	**6,267**	**117**	**0**	**0**	**8**	**70**	**100**	**0**	**6,562**	**100.0**
Rana	Non-recovery	0	0	0	0	0	0	138	0	138	3.9
	Mild	290	0	0	0	0	0	257	0	547	15.6
	Moderate	400	108	0	0	200	0	1,906	0	2,614	74.7
	Severe	108	0	91	0	0	0	0	0	199	5.7
	Total	**798**	**108**	**91**	**0**	**200**	**0**	**2,301**	**0**	**3,498**	**100.0**
Xenopus	Non-recovery	1,268	0	0	0	0	0	257	0	1,525	7.1
	Mild	12,845	3,530	0	0	2	0	107	0	16,484	76.9
	Moderate	650	116	0	210	900	0	38	0	1,914	8.9
	Severe	867	0	653	0	0	0	0	0	1,520	7.1
	Total	**15,630**	**3,646**	**653**	**210**	**902**	**0**	**402**	**0**	**21,443**	**100.0**
Other amphibians	Non-recovery	95	336	0	0	1,565	0	190	0	2,186	20.0
	Mild	3,401	623	0	0	246	336	15	0	4,621	42.2
	Moderate	2,691	60	0	0	0	62	0	0	2,813	25.7
	Severe	1,235	32	59	0	0	0	0	0	1,326	12.1
	Total	**7,422**	**1,051**	**59**	**0**	**1,811**	**398**	**205**	**0**	**10,946**	**100.0**
Zebra fish	Non-recovery	19,020	400	188	0	2	0	296	0	19,906	3.9
	Mild	288,687	69,735	13,369	0	2,414	140	1,344	0	375,689	74.5
	Moderate	39,965	26,291	14,892	0	0	0	41	0	81,189	16.1
	Severe	6,664	3,811	16,924	0	0	0	0	0	27,399	5.4
	Total	**354,336**	**100,237**	**45,373**	**0**	**2,416**	**140**	**1,681**	**0**	**504,183**	**100.0**

	Severity	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Other fish	Non-recovery	17,181	3,788	4	0	1,649	2,245	692	0	25,559	3.5
	Mild	244,988	35,901	99,525	49	54,888	52,866	2,695	0	490,912	67.9
	Moderate	41,294	17,304	8,144	0	42,704	8,286	125	0	117,857	16.3
	Severe	27,298	36,729	19,017	0	5,791	13	0	0	88,848	12.3
	Total	**330,761**	**93,722**	**126,690**	**49**	**105,032**	**63,410**	**3,512**	**0**	**723,176**	**100.0**
Cephalopods	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	22	450	0	0	24	0	4	0	500	97.3
	Moderate	0	5	0	0	0	0	0	0	5	1.0
	Severe	0	0	0	0	9	0	0	0	9	1.8
	Total	**22**	**455**	**0**	**0**	**33**	**0**	**4**	**0**	**514**	**100.0**
All Species	**Non-recovery**	**464,092**	**77,064**	**21,434**	**1,804**	**3,226**	**2,245**	**51,189**	**0**	**621,054**	**6.5**
	Mild	**2,125,428**	**919,188**	**1,289,026**	**319,745**	**68,476**	**68,203**	**75,182**	**473**	**4,865,721**	**50.8**
	Moderate	**1,434,549**	**912,034**	**523,676**	**110,715**	**45,835**	**8,432**	**36,587**	**0**	**3,071,828**	**32.1**
	Severe	**333,584**	**291,670**	**352,723**	**37,094**	**7,250**	**13**	**804**	**0**	**1,023,138**	**10.7**
	Total	**4,357,653**	**2,199,956**	**2,186,859**	**469,358**	**124,787**	**78,893**	**163,762**	**473**	**9,581,741**	**100.0**

Table 5.1: Uses of animals in all sub-categories of research and testing by severities (2017)

	Non-recovery	Mild	Moderate	Severe	Total	%
Basic research						
Oncology	30,689	229,180	296,237	56,238	**612,344**	**6.4**
Cardiovascular Blood and Lymphatic System	60,428	131,992	101,476	17,780	**311,676**	**3.3**
Nervous System	105,674	433,216	342,511	87,874	**969,275**	**10.1**
Respiratory System	8,594	27,781	30,959	6,612	**73,946**	**0.8**
Gastrointestinal System including Liver	16,627	52,466	49,801	10,699	**129,593**	**1.4**
Musculoskeletal System	4,388	42,345	35,170	8,500	**90,403**	**0.9**
Immune System	57,067	365,100	250,156	74,584	**746,907**	**7.8**
Urogenital/Reproductive System	9,048	57,656	27,085	1,686	**95,475**	**1**
Sensory Organs (skin, eyes and ears)	7,430	39,000	16,115	2,956	**65,501**	**0.7**
Endocrine System/Metabolism	21,328	101,642	71,957	20,285	**215,212**	**2.2**
Multisystemic	11,865	127,470	65,864	10,063	**215,262**	**2.2**
Ethology / Animal Behaviour /Animal Biology	6,499	356,298	83,480	9,198	**455,475**	**4.8**
Other basic research	124,455	161,282	63,738	27,109	**376,584**	**3.9**
Translational and applied research						
Human Cancer	4,005	198,550	342,158	39,888	**584,601**	**6.1**
Human Infectious Disorders	3,508	156,726	80,143	31,470	**271,847**	**2.8**
Human Cardiovascular Disorders	14,250	21,383	29,194	4,779	**69,606**	**0.7**
Human Nervous and Mental Disorders	13,728	127,972	136,480	27,602	**305,782**	**3.2**
Human Respiratory Disorders	4,340	28,926	30,002	4,127	**67,395**	**0.7**
Human Gastrointestinal Disorders including Liver	1,823	15,014	27,091	4,702	**48,630**	**0.5**
Human Musculoskeletal Disorders	3,276	10,966	17,835	6,238	**38,315**	**0.4**
Human Immune Disorders	3,390	25,176	30,471	16,305	**75,342**	**0.8**
Human Urogenital/Reproductive Disorders	1,715	6,603	7,801	1,050	**17,169**	**0.2**
Human Sensory Organ Disorders (skin, eyes and ears)	1,012	31,072	20,000	757	**52,841**	**0.6**
Human Endocrine/Metabolism Disorders	4,515	39,634	51,836	4,678	**100,663**	**1.1**
Other Human Disorders	8,802	9,395	17,927	6,530	**42,654**	**0.4**
Animal Diseases and Disorders	3,809	112,447	47,606	52,859	**216,721**	**2.3**
Animal Welfare	2,313	51,656	4,452	3,946	**62,367**	**0.7**
Diagnosis of diseases	3,580	25,417	39,451	81,239	**149,687**	**1.6**
Plant diseases	0	87	89	0	**176**	**0**
Non-regulatory toxicology and ecotoxicology	2,998	58,164	29,498	5,500	**96,160**	**1**
Regulatory use						
Quality control (incl batch safety and potency testing)						
Batch safety testing	0	120,743	12,381	6,478	**139,602**	**1.5**
Pyrogenicity testing	80	18,070	16,716	306	**35,172**	**0.4**
Batch potency testing	13,658	382,887	231,545	264,633	**892,723**	**9.3**
Other quality controls	343	44,827	14,060	4,853	**64,083**	**0.7**
Toxicity and other safety testing including pharmacology						
Acute and sub-acute toxicity testing methods						
LD50, LC50	0	28,599	5,188	13,152	**46,939**	**0.5**
Other lethal methods	0	498	3,519	1,231	**5,248**	**0.1**
Non lethal methods	0	17,791	12,557	870	**31,218**	**0.3**
Skin irritation/corrosion	0	3,267	825	28	**4,120**	**0**
Skin sensitisation	0	41,502	5,490	349	**47,341**	**0.5**
Eye irritation/corrosion	0	320	473	21	**814**	**0**
Repeated dose toxicity						
up to 28 days	0	34,793	23,635	2,916	**61,344**	**0.6**
29 - 90 days	110	20,248	14,281	292	**34,931**	**0.4**
> 90 days	0	11,808	6,088	402	**18,298**	**0.2**
Carcinogenicity	100	6,200	5,871	322	**12,493**	**0.1**
Genotoxicity	125	8,337	1,509	332	**10,303**	**0.1**
Reproductive toxicity	0	105,468	31,161	3,884	**140,513**	**1.5**
Developmental toxicity	0	66,352	18,792	12,527	**97,671**	**1**
Neurotoxicity	0	1,934	193	642	**2,769**	**0**
Kinetics	244	43,187	25,315	627	**69,373**	**0.7**
Pharmaco-dynamics (incl safety pharmacology)	5,235	57,740	32,878	3,500	**99,353**	**1**
Phototoxicity	0	353	142	30	**525**	**0**
Ecotoxicity						
Acute toxicity	188	25,364	2,934	16,429	**44,915**	**0.5**
Chronic toxicity	0	8,855	17,709	2,174	**28,738**	**0.3**
Reproductive ecotoxicity	0	546	904	0	**1,450**	**0**
Endocrine activity	0	5,724	0	200	**5,924**	**0.1**
Bioaccumulation	0	2,796	540	774	**4,110**	**0**
Other ecotoxicity	33	8,705	18	454	**9,210**	**0.1**
Safety testing in food and feed area	0	34,115	703	10,982	**45,800**	**0.5**
Target animal safety	4	7,357	1,272	84	**8,717**	**0.1**
Other toxicity/safety testing	4	6,906	3,837	511	**11,258**	**0.1**
Other efficacy and tolerance testing						
Other efficacy and tolerance testing	1,310	173,734	33,140	3,720	**211,904**	**2.2**
Routine production						
Blood based products	1,585	202,172	55,736	287	**259,780**	**2.7**
Monoclonal antibody by mouse ascites method	0	892	12,468	31,664	**45,024**	**0.5**
Other product types	219	116,681	42,511	5,143	**164,554**	**1.7**
Other						
Protection of the natural environment in the interests of the health or welfare	3,226	68,476	45,835	7,250	**124,787**	**1.3**

		Non-recovery	Mild	Moderate	Severe	Total	%
	of human beings or animals						
	Preservation of species	2,245	68,203	8,432	13	**78,893**	**0.8**
	Higher education or training for the acquisition, maintenance or improvement of vocational skills	51,189	75,182	36,587	804	**163,762**	**1.7**
	Forensic enquiries	0	473	0	0	**473**	**0**
Total		**621,054**	**4,865,721**	**3,071,828**	**1,023,138**	**9,581,741**	**100**
%		**6.5**	**50.8**	**32.1**	**10.7**	**100**	

Table 6: Basic research related uses by species and type of research (2017)

		Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals																
	Rodents															
	Mice	527,825	239,271	684,862	64,452	97,905	68,564	660,554	80,681	52,436	161,545	156,029	17,344	222,900	**3,034,368**	**69.6**
	Rats	6,004	41,095	146,460	5,846	13,624	6,040	10,819	6,350	5,775	31,344	12,564	15,209	22,901	**324,031**	**7.4**
	Guinea-Pigs	54	499	562	1,275	5	24	163	4	572	137	7	50	18,823	**22,175**	**0.5**
	Hamsters (Syrian)	100	0	153	0	136	0	198	0	0	168	274	23	438	**1,490**	**0**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	3	0	0	0	0	**3**	**0**
	Mongolian gerbil	0	76	627	0	9	11	262	0	265	0	0	41	203	**1,494**	**0**
	Other rodents	127	0	693	90	0	0	1,561	20	153	284	111	5,234	6,960	**15,233**	**0.3**
	Rabbits															
	Rabbits	162	1,371	226	868	149	456	607	715	579	1,642	269	8,367	8,103	**23,514**	**0.5**
	Carnivores															
	Cats	0	0	70	0	24	5	0	0	8	49	303	0	291	**750**	**0**
	Dogs	8	143	53	0	67	225	100	97	49	31	105	54	691	**1,623**	**0**
	Ferrets	0	0	249	62	4	0	4	0	0	0	0	0	0	**319**	**0**
	Other carnivores	0	4	0	0	78	0	521	0	0	0	0	263	10	**876**	**0**
	Farm animals															
	Horses, donkeys and cross-breeds	0	55	0	48	9	185	411	251	0	567	4	88	136	**1,754**	**0**
	Pigs	57	1,899	635	285	4,809	346	1,628	446	109	1,940	1,303	3,025	1,840	**18,322**	**0.4**
	Goats	0	14	0	0	17	8	117	141	0	158	0	574	115	**1,144**	**0**
	Sheep	24	431	66	17	544	1,020	1,414	438	0	422	110	2,104	1,967	**8,557**	**0.2**
	Cattle	0	55	30	95	1,188	4	6,006	1,066	17	1,351	1,061	2,790	1,134	**14,797**	**0.3**
	Non-human primates															
	Prosimians	0	0	4	0	0	0	0	0	0	82	0	87	0	**173**	**0**
	Marmoset and tamarins	1	0	51	0	0	0	0	12	0	24	6	46	42	**182**	**0**
	Squirrel monkey	0	0	7	0	0	0	0	0	0	0	0	0	0	**7**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	3	0	**3**	**0**
	Cynomolgus monkey	0	40	144	35	0	2	9	0	6	4	7	0	282	**529**	**0**
	Rhesus monkey	0	51	116	0	0	0	24	0	0	0	32	0	27	**250**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	11	0	0	0	0	0	11	**22**	**0**
	Baboons	0	0	0	0	0	0	10	0	0	0	0	0	0	**10**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	14	0	**14**	**0**
	Other mammals															
	Other mammals	0	9	228	0	11	1	0	22	28	0	89	4,427	221	**5,036**	**0.1**
Birds																
	Domestic fowl	785	248	3,211	0	6,559	102	7,123	392	138	4,352	2,210	70,390	12,875	**108,385**	**2.5**
	Other birds	0	234	549	0	43	33	106	79	1	439	10	53,443	2,419	**57,356**	**1.3**
Reptiles																
	Reptiles	0	110	260	0	0	10	0	0	3	43	0	5,756	85	**6,267**	**0.1**
Amphibians																
	Rana	0	0	400	0	0	0	0	0	0	0	0	112	286	**798**	**0**
	Xenopus	822	390	4,365	3	0	848	0	1,417	356	39	1,584	39	5,767	**15,630**	**0.4**
	Other amphibians	0	0	1,117	0	0	1,092	7	27	0	240	33	4,118	788	**7,422**	**0.2**
Fish																
	Zebra fish	76,185	25,098	122,697	0	3,017	10,817	18,659	2,818	4,456	6,641	35,347	12,400	36,201	**354,336**	**8.1**
	Other fish	190	583	1,434	870	1,395	610	36,593	499	547	3,710	3,804	249,458	31,068	**330,761**	**7.6**
Cephalopods																
	Cephalopods	0	0	6	0	0	0	0	0	0	0	0	16	0	**22**	**0**
Totals																
	Total	**612,344**	**311,676**	**969,275**	**73,946**	**129,593**	**90,403**	**746,907**	**95,475**	**65,501**	**215,212**	**215,262**	**455,475**	**376,584**	**4,357,653**	**100**
	%	**14.1**	**7.2**	**22.2**	**1.7**	**3**	**2.1**	**17.1**	**2.2**	**1.5**	**4.9**	**4.9**	**10.5**	**8.6**	**100**	

Table 7.1: Translational and applied research related uses by species and type of research (Part 1) (2017)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders	Human Urogenital/Reproductive Disorders
Mammals									
Rodents									
Mice	575,924	201,086	41,449	194,708	47,685	36,526	24,908	70,565	11,299
Rats	5,442	5,236	21,612	87,139	15,302	9,425	9,634	3,960	4,960
Guinea-Pigs	66	1,391	619	276	2,486	14	0	287	0
Hamsters (Syrian)	213	1,708	27	197	0	0	0	0	0
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0
Mongolian gerbil	0	1,453	0	118	0	0	0	0	0
Other rodents	0	320	0	0	82	0	0	30	0
Rabbits									
Rabbits	1,927	1,140	913	181	862	59	779	319	162
Carnivores									
Cats	0	0	0	0	0	0	0	0	0
Dogs	12	30	160	134	59	18	118	60	0
Ferrets	0	995	0	0	0	96	0	0	0
Other carnivores	0	0	0	0	0	0	0	0	0
Farm animals									
Horses, donkeys and cross-breeds	0	395	0	0	0	6	7	3	0
Pigs	266	235	3,382	431	646	2,311	214	68	485
Goats	7	18	30	2	0	0	21	0	1
Sheep	16	183	863	181	79	0	547	0	203
Cattle	12	40	6	0	45	6	0	0	0
Non-human primates									
Prosimians	0	0	0	0	0	0	0	0	0
Marmoset and tamarins	3	87	0	59	0	0	0	11	0
Squirrel monkey	0	1	0	0	0	0	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	26	319	36	139	23	12	0	30	54
Rhesus monkey	0	328	0	4	0	0	0	0	2
Vervets (Chlorocebus spp.)	0	26	0	0	0	0	0	0	0
Baboons	0	19	14	0	0	0	0	0	3
Other species of old world monkeys (Cercopithecoidea)	0	12	0	0	0	0	0	0	0
Other mammals									
Other mammals	31	18,217	19	0	8	0	0	2	0
Birds									
Domestic fowl	33	751	72	2	118	157	0	7	0
Other birds	0	5,202	4	0	0	0	0	0	0
Reptiles									
Reptiles	0	0	0	0	0	0	0	0	0
Amphibians									
Rana	0	0	0	0	0	0	0	0	0
Xenopus	185	0	0	25	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0
Fish									
Zebra fish	438	32,655	400	22,186	0	0	2,087	0	0
Other fish	0	0	0	0	0	0	0	0	0
Cephalopods									
Cephalopods	0	0	0	0	0	0	0	0	0
Totals									
Total	**584,601**	**271,847**	**69,606**	**305,782**	**67,395**	**48,630**	**38,315**	**75,342**	**17,169**
%	**26.6**	**12.4**	**3.2**	**13.9**	**3.1**	**2.2**	**1.7**	**3.4**	**0.8**

Table 7.2: Translational and applied research related uses by species and type of research (Part 2) (2017)

	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	43,473	68,703	24,626	30,449	1,063	139,893	119	18,490	**1,530,966**	**69.6**
Rats	5,851	25,865	17,111	1,605	613	3,928	25	17,631	**235,339**	**10.7**
Guinea-Pigs	373	62	101	900	9	473	0	478	**7,535**	**0.3**
Hamsters (Syrian)	0	677	17	1,172	0	0	0	0	**4,011**	**0.2**
Hamsters (Chinese)	0	0	0	120	0	0	0	0	**120**	**0**
Mongolian gerbil	0	0	0	612	0	0	0	0	**2,183**	**0.1**
Other rodents	0	0	0	17	0	0	0	15	**464**	**0**
Rabbits										
Rabbits	1,017	241	300	2,697	133	858	32	241	**11,861**	**0.5**
Carnivores										
Cats	0	0	0	1,057	0	70	0	6	**1,133**	**0.1**
Dogs	30	81	49	5,029	84	264	0	2,066	**8,194**	**0.4**
Ferrets	0	0	4	82	0	5	0	0	**1,182**	**0.1**
Other carnivores	0	0	0	364	254	0	0	0	**618**	**0**
Farm animals										
Horses, donkeys and cross-breeds	0	0	0	1,025	51	83	0	0	**1,570**	**0.1**
Pigs	401	1,032	232	14,915	7,530	326	0	241	**32,715**	**1.5**
Goats	0	0	0	394	178	77	0	0	**728**	**0**
Sheep	0	56	176	2,968	1,954	995	0	33	**8,254**	**0.4**
Cattle	0	182	0	7,134	2,878	67	0	17	**10,387**	**0.5**
Non-human primates										
Prosimians	0	0	0	0	0	0	0	0	**0**	**0**
Marmoset and tamarins	2	0	0	0	0	0	0	0	**162**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	**1**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	**0**	**0**
Cynomolgus monkey	43	52	16	0	0	0	0	375	**1,125**	**0.1**
Rhesus monkey	0	0	0	0	0	0	0	0	**334**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	**26**	**0**
Baboons	0	0	0	0	0	0	0	0	**36**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	9	0	0	0	0	0	**21**	**0**
Other mammals										
Other mammals	0	3	0	29	3,201	30	0	0	**21,540**	**1**
Birds										
Domestic fowl	0	0	0	77,727	25,183	1,746	0	1,227	**107,023**	**4.9**
Other birds	0	0	0	5,791	1,345	222	0	528	**13,092**	**0.6**
Reptiles										
Reptiles	0	0	0	56	61	0	0	0	**117**	**0**
Amphibians										
Rana	0	0	0	0	0	0	0	108	**108**	**0**
Xenopus	0	21	0	0	0	0	0	3,415	**3,646**	**0.2**
Other amphibians	0	0	11	200	0	0	0	840	**1,051**	**0**
Fish										
Zebra fish	1,651	3,543	2	787	0	0	0	36,488	**100,237**	**4.6**
Other fish	0	145	0	61,586	17,380	650	0	13,961	**93,722**	**4.3**
Cephalopods										
Cephalopods	0	0	0	5	450	0	0	0	**455**	**0**
Totals										
Total	**52,841**	**100,663**	**42,654**	**216,721**	**62,367**	**149,687**	**176**	**96,160**	**2,199,956**	**100**
%	**2.4**	**4.6**	**1.9**	**9.9**	**2.8**	**6.8**	**0**	**4.4**	**100**	

Table 8: Regulatory uses by species and type of use (2017)

		Quality				Toxicity	Other		
		Quality: Batch safety testing	Quality: Pyrogenicity testing	Quality: Batch potency testing	Quality: Other quality controls	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing	Total	%
Mammals									
	Rodents								
	Mice	82,331	0	594,913	40,267	245,984	76,310	**1,039,805**	**47.5**
	Rats	4,287	0	157,176	1,717	386,969	8,420	**558,569**	**25.5**
	Guinea-Pigs	16,612	0	62,104	1,097	32,530	889	**113,232**	**5.2**
	Hamsters (Syrian)	20	0	3,826	2,285	383	296	**6,810**	**0.3**
	Hamsters (Chinese)	0	0	0	0	59	0	**59**	**0**
	Mongolian gerbil	0	0	0	0	1,421	59	**1,480**	**0.1**
	Other rodents	104	0	0	0	9,060	60	**9,224**	**0.4**
	Rabbits								
	Rabbits	1,257	35,172	22,318	2,121	30,864	2,583	**94,315**	**4.3**
	Carnivores								
	Cats	33	0	121	110	772	336	**1,372**	**0.1**
	Dogs	307	0	58	328	8,845	1,099	**10,637**	**0.5**
	Ferrets	192	0	250	0	34	0	**476**	**0**
	Other carnivores	359	0	310	0	81	6	**756**	**0**
	Farm animals								
	Horses, donkeys and cross-breeds	2	0	0	0	71	247	**320**	**0**
	Pigs	1,354	0	2,158	690	4,672	3,823	**12,697**	**0.6**
	Goats	0	0	12	0	75	34	**121**	**0**
	Sheep	271	0	445	91	313	242	**1,362**	**0.1**
	Cattle	449	0	1,065	33	1,078	1,132	**3,757**	**0.2**
	Non-human primates								
	Prosimians	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	0	0	215	0	**215**	**0**
	Squirrel monkey	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	0	0	0	7,191	92	**7,283**	**0.3**
	Rhesus monkey	0	0	0	8	3	0	**11**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	**0**	**0**
	Other mammals								
	Other mammals	0	0	0	0	0	0	**0**	**0**
Birds									
	Domestic fowl	31,808	0	43,316	14,479	14,058	42,827	**146,488**	**6.7**
	Other birds	180	0	728	673	974	2,449	**5,004**	**0.2**
Reptiles									
	Reptiles	0	0	0	0	0	0	**0**	**0**
Amphibians									
	Rana	0	0	0	0	91	0	**91**	**0**
	Xenopus	0	0	0	0	653	0	**653**	**0**
	Other amphibians	0	0	0	0	59	0	**59**	**0**
Fish									
	Zebra fish	0	0	0	84	45,289	0	**45,373**	**2.1**
	Other fish	36	0	3,923	100	51,631	71,000	**126,690**	**5.8**
Cephalopods									
	Cephalopods	0	0	0	0	0	0	**0**	**0**
Totals									
	Total	**139,602**	**35,172**	**892,723**	**64,083**	**843,375**	**211,904**	**2,186,859**	**100**
	%	**6.4**	**1.6**	**40.8**	**2.9**	**38.6**	**9.7**	**100**	

Table 9.1: Toxicity and other safety testing including pharmacology by species and type of use (Part 1) (2017)

		Acute						Repeated Dose						
		LD50, LC50	Other lethal methods	Non lethal methods	Skin irritation / corrosion	Skin sensitisation	Eye irritation / corrosion	up to 28 days	29 - 90 days	> 90 days	Carcinogenicity	Genotoxicity	Developmental toxicity	Safety testing in food and feed area
Mammals														
	Rodents													
	Mice	30,521	666	11,694	28	16,478	0	13,621	7,359	1,783	5,971	4,236	977	40,556
	Rats	5,006	1,042	16,778	244	0	0	40,791	23,460	13,522	6,522	6,067	70,778	0
	Guinea-Pigs	40	0	543	0	30,785	0	92	92	0	0	0	0	0
	Hamsters (Syrian)	0	0	225	84	0	0	6	0	0	0	0	0	0
	Hamsters (Chinese)	0	0	0	47	0	0	0	0	0	0	0	0	0
	Mongolian gerbil	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other rodents	0	0	6	0	0	0	0	0	0	0	0	0	0
	Rabbits													
	Rabbits	0	10	776	3,691	68	814	1,354	834	270	0	0	14,910	0
	Carnivores													
	Cats	0	0	0	0	0	0	28	0	30	0	0	0	0
	Dogs	0	0	703	0	0	0	2,567	1,277	1,272	0	0	88	0
	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0
	Farm animals													
	Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	0	0	0	0
	Pigs	0	0	76	26	10	0	774	287	323	0	0	0	41
	Goats	0	0	0	0	0	0	0	0	0	0	0	0	4
	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	144
	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	145
	Non-human primates													
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0
	Marmoset and tamarins	0	0	0	0	0	0	129	46	3	0	0	0	0
	Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
	Cynomolgus monkey	0	0	311	0	0	0	1,979	1,576	1,095	0	0	264	0
	Rhesus monkey	0	0	0	0	0	0	3	0	0	0	0	0	0
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other mammals													
	Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	0
Birds														
	Domestic fowl	5,555	0	0	0	0	0	0	0	0	0	0	0	4,437
	Other birds	162	0	62	0	0	0	0	0	0	0	0	0	53
Reptiles														
	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0
Amphibians														
	Rana	0	0	0	0	0	0	0	0	0	0	0	0	0
	Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0
	Other amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish														
	Zebra fish	475	3,530	44	0	0	0	0	0	0	0	0	9,774	0
	Other fish	5,180	0	0	0	0	0	0	0	0	0	0	880	420
Cephalopods														
	Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals														
	Total	**46,939**	**5,248**	**31,218**	**4,120**	**47,341**	**814**	**61,344**	**34,931**	**18,298**	**12,493**	**10,303**	**97,671**	**45,800**
	%	**5.6**	**0.6**	**3.7**	**0.5**	**5.6**	**0.1**	**7.3**	**4.1**	**2.2**	**1.5**	**1.2**	**11.6**	**5.4**

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Table 9.2: Toxicity and other safety testing including pharmacology by species and type of use (Part 2) (2017)

							EcoToxicity								
		Target animal safety	Neurotoxicity	Kinetics	Pharmaco - dynamics (incl safety pharmacology)	Phototoxicity	Acute toxicity	Chronic toxicity	Reproductive toxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Other toxicity / safety testing	Total	%
Mammals															
	Rodents														
	Mice	549	332	36,480	57,482	440	9,764	50	1,762	0	0	447	4,788	**245,984**	**29.2**
	Rats	33	420	26,659	36,615	85	1,035	1,107	132,639	0	0	0	3,652	**386,455**	**45.9**
	Guinea-Pigs	0	0	110	506	0	138	0	0	0	0	142	82	**32,530**	**3.9**
	Hamsters (Syrian)	0	0	0	68	0	0	0	0	0	0	0	0	**383**	**0**
	Hamsters (Chinese)	0	0	12	0	0	0	0	0	0	0	0	0	**59**	**0**
	Mongolian gerbil	0	0	66	1,355	0	0	0	0	0	0	0	0	**1,421**	**0.2**
	Other rodents	2,500	0	0	0	0	0	0	0	0	0	6,554	0	**9,060**	**1.1**
	Rabbits														
	Rabbits	121	0	539	1,141	0	0	86	5,097	0	0	0	1,121	**30,832**	**3.7**
	Carnivores														
	Cats	167	0	424	123	0	0	0	0	0	0	0	0	**772**	**0.1**
	Dogs	112	0	1,728	976	0	0	0	0	0	0	0	122	**8,845**	**1.1**
	Ferrets	34	0	0	0	0	0	0	0	0	0	0	0	**34**	**0**
	Other carnivores	81	0	0	0	0	0	0	0	0	0	0	0	**81**	**0**
	Farm animals														
	Horses, donkeys and cross-breeds	8	0	42	5	0	0	0	0	0	0	16	0	**71**	**0**
	Pigs	891	0	1,121	423	0	0	0	0	0	0	0	700	**4,672**	**0.6**
	Goats	0	0	23	48	0	0	0	0	0	0	0	0	**75**	**0**
	Sheep	124	0	26	0	0	0	0	0	0	0	0	19	**313**	**0**
	Cattle	288	0	184	357	0	0	0	0	0	0	72	20	12	**1,078**	**0.1**
	Non-human primates														
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	0	0	16	0	0	0	0	0	0	0	0	21	**215**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	0	0	1,414	254	0	0	0	0	0	0	0	298	**7,191**	**0.9**
	Rhesus monkey	0	0	0	0	0	0	0	0	0	0	0	0	**3**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals														
	Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Birds															
	Domestic fowl	3,385	0	361	0	0	12	0	0	0	0	0	308	**14,058**	**1.7**
	Other birds	200	0	168	0	0	27	0	128	0	0	39	135	**974**	**0.1**
Reptiles															
	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians															
	Rana	0	0	0	0	0	91	0	0	0	0	0	0	**91**	**0**
	Xenopus	0	0	0	0	0	128	0	0	0	525	0	0	**653**	**0.1**
	Other amphibians	0	0	0	0	0	59	0	0	0	0	0	0	**59**	**0**
Fish															
	Zebra fish	0	2,017	0	0	0	9,458	12,497	887	5,040	369	294	0	**44,385**	**5.3**
	Other fish	224	0	0	0	0	24,203	14,998	0	884	3,144	1,698	0	**51,631**	**6.1**
Cephalopods															
	Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals															
	Total	**8,717**	**2,769**	**69,373**	**99,353**	**525**	**44,915**	**28,738**	**140,513**	**5,924**	**4,110**	**9,210**	**11,258**	**841,925**	**100**
	%	**1**	**0.3**	**8.2**	**11.8**	**0.1**	**5.3**	**3.4**	**16.7**	**0.7**	**0.5**	**1.1**	**1.3**	**100**	

Table 10: Regulatory uses by species and type of legislation (2017)

		Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Other legislation	Total	%
Mammals												
	Rodents											
	Mice	839,113	121,753	18,850	8,752	7,545	826	41,515	889	562	**1,039,805**	**47.5**
	Rats	317,250	17,220	3,879	182,624	29,679	1,011	2,641	3,211	1,054	**558,569**	**25.5**
	Guinea-Pigs	69,557	15,199	26,208	2,080	89	73	0	0	26	**113,232**	**5.2**
	Hamsters (Syrian)	542	5,916	346	0	0	6	0	0	0	**6,810**	**0.3**
	Hamsters (Chinese)	0	0	47	12	0	0	0	0	0	**59**	**0**
	Mongolian gerbil	0	1,480	0	0	0	0	0	0	0	**1,480**	**0.1**
	Other rodents	104	0	0	0	9,054	6	0	0	60	**9,224**	**0.4**
	Rabbits											
	Rabbits	63,997	10,828	4,862	10,648	2,697	263	18	24	978	**94,315**	**4.3**
	Carnivores											
	Cats	24	1,348	0	0	0	0	0	0	0	**1,372**	**0.1**
	Dogs	8,343	2,093	31	20	136	0	0	0	14	**10,637**	**0.5**
	Ferrets	442	34	0	0	0	0	0	0	0	**476**	**0**
	Other carnivores	0	756	0	0	0	0	0	0	0	**756**	**0**
	Farm animals											
	Horses, donkeys and cross-breeds	38	261	0	0	0	0	0	21	0	**320**	**0**
	Pigs	3,456	8,464	214	3	0	0	0	557	3	**12,697**	**0.6**
	Goats	12	78	4	0	27	0	0	0	0	**121**	**0**
	Sheep	39	1,118	79	0	0	0	99	27	0	**1,362**	**0.1**
	Cattle	0	3,570	0	0	44	0	0	143	0	**3,757**	**0.2**
	Non-human primates											
	Prosimians	0	0	0	0	0	0	0	0	0	**0**	**0**
	Marmoset and tamarins	215	0	0	0	0	0	0	0	0	**215**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Cynomolgus monkey	7,283	0	0	0	0	0	0	0	0	**7,283**	**0.3**
	Rhesus monkey	3	0	8	0	0	0	0	0	0	**11**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	**0**	**0**
	Other mammals											
	Other mammals	0	0	0	0	0	0	0	0	0	**0**	**0**
Birds												
	Domestic fowl	2,398	126,181	0	0	391	0	0	17,498	20	**146,488**	**6.7**
	Other birds	130	4,213	0	10	278	0	0	373	0	**5,004**	**0.2**
Reptiles												
	Reptiles	0	0	0	0	0	0	0	0	0	**0**	**0**
Amphibians												
	Rana	0	0	0	0	91	0	0	0	0	**91**	**0**
	Xenopus	0	0	0	525	128	0	0	0	0	**653**	**0**
	Other amphibians	0	0	0	0	59	0	0	0	0	**59**	**0**
Fish												
	Zebra fish	9,158	209	3,250	14,142	10,004	1,620	0	145	6,845	**45,373**	**2.1**
	Other fish	6,844	4,765	534	11,361	14,983	324	0	71,627	16,252	**126,690**	**5.8**
Cephalopods												
	Cephalopods	0	0	0	0	0	0	0	0	0	**0**	**0**
Totals												
	Total	**1,328,948**	**325,486**	**58,312**	**230,177**	**75,205**	**4,129**	**44,273**	**94,515**	**25,814**	**2,186,859**	**100**
	%	**60.8**	**14.9**	**2.7**	**10.5**	**3.4**	**0.2**	**2**	**4.3**	**1.2**	**100**	

Table 11: Regulatory uses by species and origin of regulatory requirement (2017)

	Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total	%
Mammals					
Rodents					
Mice	987,608	8,465	43,732	**1,039,805**	**47.5**
Rats	552,596	1,812	4,161	**558,569**	**25.5**
Guinea-Pigs	106,808	1,244	5,180	**113,232**	**5.2**
Hamsters (Syrian)	6,140	0	670	**6,810**	**0.3**
Hamsters (Chinese)	59	0	0	**59**	**0**
Mongolian gerbil	1,480	0	0	**1,480**	**0.1**
Other rodents	9,158	66	0	**9,224**	**0.4**
Rabbits					
Rabbits	73,568	61	20,686	**94,315**	**4.3**
Carnivores					
Cats	1,372	0	0	**1,372**	**0.1**
Dogs	10,579	12	46	**10,637**	**0.5**
Ferrets	476	0	0	**476**	**0**
Other carnivores	756	0	0	**756**	**0**
Farm animals					
Horses, donkeys and cross-breeds	320	0	0	**320**	**0**
Pigs	11,350	0	1,347	**12,697**	**0.6**
Goats	121	0	0	**121**	**0**
Sheep	1,356	0	6	**1,362**	**0.1**
Cattle	3,717	32	8	**3,757**	**0.2**
Non-human primates					
Prosimians	0	0	0	**0**	**0**
Marmoset and tamarins	215	0	0	**215**	**0**
Squirrel monkey	0	0	0	**0**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
Cynomolgus monkey	7,107	131	45	**7,283**	**0.3**
Rhesus monkey	11	0	0	**11**	**0**
Vervets (Chlorocebus spp.)	0	0	0	**0**	**0**
Baboons	0	0	0	**0**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
Other mammals					
Other mammals	0	0	0	**0**	**0**
Birds					
Domestic fowl	140,752	35	5,701	**146,488**	**6.7**
Other birds	4,989	0	15	**5,004**	**0.2**
Reptiles					
Reptiles	0	0	0	**0**	**0**
Amphibians					
Rana	91	0	0	**91**	**0**
Xenopus	653	0	0	**653**	**0**
Other amphibians	59	0	0	**59**	**0**
Fish					
Zebra fish	44,123	1,250	0	**45,373**	**2.1**
Other fish	115,618	9,774	1,298	**126,690**	**5.8**
Cephalopods					
Cephalopods	0	0	0	**0**	**0**
Totals					
Total	**2,081,082**	**22,882**	**82,895**	**2,186,859**	**100**
%	**95.2**	**1**	**3.8**	**100**	

Table 12: Routine production uses by species and product type (2017)

		Blood based products	Other product types	Monoclonal antibody by mouse ascites method	Total	%
Mammals						
	Rodents					
	Mice	1,623	3,353	44,574	**49,550**	**10.6**
	Rats	2,437	225	33	**2,695**	**0.6**
	Guinea-Pigs	954	39	0	**993**	**0.2**
	Hamsters (Syrian)	0	100	0	**100**	**0**
	Hamsters (Chinese)	0	0	0	**0**	**0**
	Mongolian gerbil	0	109	0	**109**	**0**
	Other rodents	0	0	0	**0**	**0**
	Rabbits					
	Rabbits	196,761	35,261	417	**232,439**	**49.5**
	Carnivores					
	Cats	0	10	0	**10**	**0**
	Dogs	274	56	0	**330**	**0.1**
	Ferrets	37	26	0	**63**	**0**
	Other carnivores	20	0	0	**20**	**0**
	Farm animals					
	Horses, donkeys and cross-breeds	9,577	41	0	**9,618**	**2**
	Pigs	17	443	0	**460**	**0.1**
	Goats	45	1	0	**46**	**0**
	Sheep	44,308	1,357	0	**45,665**	**9.7**
	Cattle	375	226	0	**601**	**0.1**
	Non-human primates					
	Prosimians	0	0	0	**0**	**0**
	Marmoset and tamarins	86	0	0	**86**	**0**
	Squirrel monkey	0	0	0	**0**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	**0**	**0**
	Cynomolgus monkey	854	199	0	**1,053**	**0.2**
	Rhesus monkey	29	0	0	**29**	**0**
	Vervets (Chlorocebus spp.)	5	0	0	**5**	**0**
	Baboons	0	0	0	**0**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	**0**	**0**
	Other mammals					
	Other mammals	0	1	0	**1**	**0**
Birds						
	Domestic fowl	2,345	100,060	0	**102,405**	**21.8**
	Other birds	33	22,788	0	**22,821**	**4.9**
Reptiles						
	Reptiles	0	0	0	**0**	**0**
Amphibians						
	Rana	0	0	0	**0**	**0**
	Xenopus	0	210	0	**210**	**0**
	Other amphibians	0	0	0	**0**	**0**
Fish						
	Zebra fish	0	0	0	**0**	**0**
	Other fish	0	49	0	**49**	**0**
Cephalopods						
	Cephalopods	0	0	0	**0**	**0**
Totals						
	Total	**259,780**	**164,554**	**45,024**	**469,358**	**100**
	%	**55.3**	**35.1**	**9.6**	**100**	

Table 13: Reuses of animals by species and main categories of scientific purposes in research, testing routine production and education (2017)

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Yes	20,981	11,335	11,544	412	0	7	4,371	0	48,650	0.8
	No	3,013,387	1,519,631	1,028,261	49,138	2,747	13,345	80,954	8	5,707,471	99.2
	Total	**3,034,368**	**1,530,966**	**1,039,805**	**49,550**	**2,747**	**13,352**	**85,325**	**8**	**5,756,121**	**100.0**
Rats	Yes	6,662	4,395	3,777	535	0	0	2,499	0	17,868	1.5
	No	317,369	230,944	554,792	2,160	2,384	0	38,650	0	1,146,299	98.5
	Total	**324,031**	**235,339**	**558,569**	**2,695**	**2,384**	**0**	**41,149**	**0**	**1,164,167**	**100.0**
Guinea-Pigs	Yes	25	142	586	55	0	0	405	0	1,213	0.8
	No	22,150	7,393	112,646	938	10	0	1,687	0	144,824	99.2
	Total	**22,175**	**7,535**	**113,232**	**993**	**10**	**0**	**2,092**	**0**	**146,037**	**100.0**
Hamsters (Syrian)	Yes	8	0	0	0	0	0	15	0	23	0.2
	No	1,482	4,011	6,810	100	0	0	297	0	12,700	99.8
	Total	**1,490**	**4,011**	**6,810**	**100**	**0**	**0**	**312**	**0**	**12,723**	**100.0**
Hamsters (Chinese)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	3	120	59	0	0	0	5	0	187	100.0
	Total	**3**	**120**	**59**	**0**	**0**	**0**	**5**	**0**	**187**	**100.0**
Mongolian gerbil	Yes	45	101	0	0	0	0	0	0	146	2.7
	No	1,449	2,082	1,480	109	0	10	109	0	5,239	97.3
	Total	**1,494**	**2,183**	**1,480**	**109**	**0**	**10**	**109**	**0**	**5,385**	**100.0**
Other rodents	Yes	254	0	0	0	0	0	26	0	280	1.1
	No	14,979	464	9,224	0	169	77	259	0	25,172	98.9
	Total	**15,233**	**464**	**9,224**	**0**	**169**	**77**	**285**	**0**	**25,452**	**100.0**
Rabbits	Yes	159	524	10,286	992	0	0	509	0	12,470	3.4
	No	23,355	11,337	84,029	231,447	331	0	1,462	0	351,961	96.6
	Total	**23,514**	**11,861**	**94,315**	**232,439**	**331**	**0**	**1,971**	**0**	**364,431**	**100.0**
Cats	Yes	511	211	719	0	0	0	18	0	1,459	43.7
	No	239	922	653	10	0	0	55	0	1,879	56.3
	Total	**750**	**1,133**	**1,372**	**10**	**0**	**0**	**73**	**0**	**3,338**	**100.0**
Dogs	Yes	1,111	2,774	3,144	274	0	0	368	0	7,671	35.9
	No	512	5,420	7,493	56	15	0	192	0	13,688	64.1
	Total	**1,623**	**8,194**	**10,637**	**330**	**15**	**0**	**560**	**0**	**21,359**	**100.0**
Ferrets	Yes	5	35	0	0	0	0	56	0	96	4.5
	No	314	1,147	476	63	0	0	16	0	2,016	95.5
	Total	**319**	**1,182**	**476**	**63**	**0**	**0**	**72**	**0**	**2,112**	**100.0**
Other carnivores	Yes	101	12	0	0	12	3	0	0	128	5.1
	No	775	606	756	20	111	118	0	0	2,386	94.9
	Total	**876**	**618**	**756**	**20**	**123**	**121**	**0**	**0**	**2,514**	**100.0**
Horses, donkeys and cross-breeds	Yes	1,305	174	63	9,494	4	0	170	0	11,210	82.3
	No	449	1,396	257	124	2	0	186	0	2,414	17.7
	Total	**1,754**	**1,570**	**320**	**9,618**	**6**	**0**	**356**	**0**	**13,624**	**100.0**
Pigs	Yes	1,415	785	1,270	0	0	0	883	0	4,353	5.7
	No	16,907	31,930	11,427	460	608	2	10,152	36	71,522	94.3
	Total	**18,322**	**32,715**	**12,697**	**460**	**608**	**2**	**11,035**	**36**	**75,875**	**100.0**
Goats	Yes	546	12	24	19	0	0	104	0	705	31.1
	No	598	716	97	27	0	0	125	0	1,563	68.9
	Total	**1,144**	**728**	**121**	**46**	**0**	**0**	**229**	**0**	**2,268**	**100.0**
Sheep	Yes	3,041	819	327	42,309	2	0	217	0	46,715	71.3
	No	5,516	7,435	1,035	3,356	117	0	1,265	88	18,812	28.7
	Total	**8,557**	**8,254**	**1,362**	**45,665**	**119**	**0**	**1,482**	**88**	**65,527**	**100.0**
Cattle	Yes	1,665	1,391	550	215	151	0	2,661	0	6,633	17.8
	No	13,132	8,996	3,207	386	2,302	0	2,594	26	30,643	82.2
	Total	**14,797**	**10,387**	**3,757**	**601**	**2,453**	**0**	**5,255**	**26**	**37,276**	**100.0**
Prosimians	Yes	75	0	0	0	0	0	0	0	75	43.4
	No	98	0	0	0	0	0	0	0	98	56.6

	Reuse	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
	Total	**173**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**173**	**100.0**
Marmoset and tamarins	Yes	32	51	12	86	0	0	0	0	181	28.0
	No	150	111	203	0	0	0	1	0	465	72.0
	Total	**182**	**162**	**215**	**86**	**0**	**0**	**1**	**0**	**646**	**100.0**
Squirrel monkey	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	7	1	0	0	0	0	0	0	8	100.0
	Total	**7**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Other species of new world monkeys (Ceboidea)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	3	0	0	0	0	0	0	0	3	100.0
	Total	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**100.0**
Cynomolgus monkey	Yes	130	523	1,100	1,017	0	0	10	0	2,780	27.8
	No	399	602	6,183	36	0	0	7	0	7,227	72.2
	Total	**529**	**1,125**	**7,283**	**1,053**	**0**	**0**	**17**	**0**	**10,007**	**100.0**
Rhesus monkey	Yes	143	103	0	29	0	0	0	0	275	43.8
	No	107	231	11	0	0	0	4	0	353	56.2
	Total	**250**	**334**	**11**	**29**	**0**	**0**	**4**	**0**	**628**	**100.0**
Vervets (Chlorocebus spp.)	Yes	0	15	0	5	0	0	0	0	20	37.7
	No	22	11	0	0	0	0	0	0	33	62.3
	Total	**22**	**26**	**0**	**5**	**0**	**0**	**0**	**0**	**53**	**100.0**
Baboons	Yes	10	11	0	0	0	0	0	0	21	45.7
	No	0	25	0	0	0	0	0	0	25	54.3
	Total	**10**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**46**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Yes	0	12	0	0	0	0	0	0	12	34.3
	No	14	9	0	0	0	0	0	0	23	65.7
	Total	**14**	**21**	**0**	**0**	**0**	**0**	**0**	**0**	**35**	**100.0**
Other mammals	Yes	605	124	0	0	0	0	2	0	731	2.7
	No	4,431	21,416	0	1	94	274	119	0	26,335	97.3
	Total	**5,036**	**21,540**	**0**	**1**	**94**	**274**	**121**	**0**	**27,066**	**100.0**
Domestic fowl	Yes	488	4,694	1,339	153	240	0	545	0	7,459	1.6
	No	107,897	102,329	145,149	102,252	2,519	343	3,749	315	464,553	98.4
	Total	**108,385**	**107,023**	**146,488**	**102,405**	**2,759**	**343**	**4,294**	**315**	**472,012**	**100.0**
Other birds	Yes	2,182	139	0	21	278	1	315	0	2,936	2.9
	No	55,174	12,953	5,004	22,800	2,289	695	495	0	99,410	97.1
	Total	**57,356**	**13,092**	**5,004**	**22,821**	**2,567**	**696**	**810**	**0**	**102,346**	**100.0**
Reptiles	Yes	3,601	0	0	0	0	0	24	0	3,625	55.2
	No	2,666	117	0	0	8	70	76	0	2,937	44.8
	Total	**6,267**	**117**	**0**	**0**	**8**	**70**	**100**	**0**	**6,562**	**100.0**
Rana	Yes	4	0	0	0	0	0	9	0	13	0.4
	No	794	108	91	0	200	0	2,292	0	3,485	99.6
	Total	**798**	**108**	**91**	**0**	**200**	**0**	**2,301**	**0**	**3,498**	**100.0**
Xenopus	Yes	6,750	873	0	210	0	0	71	0	7,904	36.9
	No	8,880	2,773	653	0	902	0	331	0	13,539	63.1
	Total	**15,630**	**3,646**	**653**	**210**	**902**	**0**	**402**	**0**	**21,443**	**100.0**
Other amphibians	Yes	72	11	0	0	180	0	0	0	263	2.4
	No	7,350	1,040	59	0	1,631	398	205	0	10,683	97.6
	Total	**7,422**	**1,051**	**59**	**0**	**1,811**	**398**	**205**	**0**	**10,946**	**100.0**
Zebra fish	Yes	4,396	18	0	0	0	0	6	0	4,420	0.9
	No	349,940	100,219	45,373	0	2,416	140	1,675	0	499,763	99.1
	Total	**354,336**	**100,237**	**45,373**	**0**	**2,416**	**140**	**1,681**	**0**	**504,183**	**100.0**
Other fish	Yes	2,177	514	122	0	392	0	39	0	3,244	0.4
	No	328,584	93,208	126,568	49	104,640	63,410	3,473	0	719,932	99.6
	Total	**330,761**	**93,722**	**126,690**	**49**	**105,032**	**63,410**	**3,512**	**0**	**723,176**	**100.0**
Cephalopods	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	**22**	**455**	**0**	**0**	**33**	**0**	**4**	**0**	**514**	**100.0**
	Total	**22**	**455**	**0**	**0**	**33**	**0**	**4**	**0**	**514**	**100.0**
All Species	**Yes**	**58,499**	**29,798**	**34,863**	**55,826**	**1,259**	**11**	**13,323**	**0**	**193,579**	**2.0**
	No	**4,299,154**	**2,170,158**	**2,151,996**	**413,532**	**123,528**	**78,882**	**150,439**	**473**	**9,388,162**	**98.0**
	Total	**4,357,653**	**2,199,956**	**2,186,859**	**469,358**	**124,787**	**78,893**	**163,762**	**473**	**9,581,741**	**100.0**

Table 14: Genetic status of animals used by species and main categories of scientific purposes (2017)

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Mice	Not altered	1,399,831	1,038,855	994,986	49,235	2,747	540	73,126	0	3,559,320	61.8
	Non harmful	1,366,539	369,566	43,196	315	0	12,434	11,539	0	1,803,589	31.3
	Harmful	267,998	122,545	1,623	0	0	378	660	8	393,212	6.8
	Total	**3,034,368**	**1,530,966**	**1,039,805**	**49,550**	**2,747**	**13,352**	**85,325**	**8**	**5,756,121**	**100.0**
Rats	Not altered	303,734	226,481	556,201	2,572	2,384	0	40,396	0	1,131,768	97.2
	Non harmful	15,959	4,910	2,270	123	0	0	712	0	23,974	2.1
	Harmful	4,338	3,948	98	0	0	0	41	0	8,425	0.7
	Total	**324,031**	**235,339**	**558,569**	**2,695**	**2,384**	**0**	**41,149**	**0**	**1,164,167**	**100.0**
Guinea-Pigs	Not altered	22,175	7,535	113,232	993	10	0	2,092	0	146,037	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**22,175**	**7,535**	**113,232**	**993**	**10**	**0**	**2,092**	**0**	**146,037**	**100.0**
Hamsters (Syrian)	Not altered	1,490	3,824	6,810	100	0	0	312	0	12,536	98.5
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	187	0	0	0	0	0	0	187	1.5
	Total	**1,490**	**4,011**	**6,810**	**100**	**0**	**0**	**312**	**0**	**12,723**	**100.0**
Hamsters (Chinese)	Not altered	3	120	59	0	0	0	5	0	187	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**3**	**120**	**59**	**0**	**0**	**0**	**5**	**0**	**187**	**100.0**
Mongolian gerbil	Not altered	1,494	2,183	1,480	109	0	10	109	0	5,385	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,494**	**2,183**	**1,480**	**109**	**0**	**10**	**109**	**0**	**5,385**	**100.0**
Other rodents	Not altered	15,233	464	9,224	0	169	77	285	0	25,452	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**15,233**	**464**	**9,224**	**0**	**169**	**77**	**285**	**0**	**25,452**	**100.0**
Rabbits	Not altered	23,398	11,800	94,315	204,998	331	0	1,959	0	336,801	92.4
	Non harmful	88	61	0	27,441	0	0	12	0	27,602	7.6
	Harmful	28	0	0	0	0	0	0	0	28	0.0
	Total	**23,514**	**11,861**	**94,315**	**232,439**	**331**	**0**	**1,971**	**0**	**364,431**	**100.0**
Cats	Not altered	750	1,133	1,372	10	0	0	73	0	3,338	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**750**	**1,133**	**1,372**	**10**	**0**	**0**	**73**	**0**	**3,338**	**100.0**
Dogs	Not altered	1,519	8,166	10,637	330	15	0	560	0	21,227	99.4
	Non harmful	0	12	0	0	0	0	0	0	12	0.1
	Harmful	104	16	0	0	0	0	0	0	120	0.6
	Total	**1,623**	**8,194**	**10,637**	**330**	**15**	**0**	**560**	**0**	**21,359**	**100.0**
Ferrets	Not altered	319	1,182	476	63	0	0	72	0	2,112	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**319**	**1,182**	**476**	**63**	**0**	**0**	**72**	**0**	**2,112**	**100.0**
Other carnivores	Not altered	876	618	756	20	123	121	0	0	2,514	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**876**	**618**	**756**	**20**	**123**	**121**	**0**	**0**	**2,514**	**100.0**
Horses, donkeys and cross-breeds	Not altered	1,754	1,570	320	9,618	6	0	356	0	13,624	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,754**	**1,570**	**320**	**9,618**	**6**	**0**	**356**	**0**	**13,624**	**100.0**

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Pigs	Not altered	18,182	32,394	12,697	460	608	2	10,995	36	75,374	99.3
	Non harmful	121	172	0	0	0	0	40	0	333	0.4
	Harmful	19	149	0	0	0	0	0	0	168	0.2
	Total	**18,322**	**32,715**	**12,697**	**460**	**608**	**2**	**11,035**	**36**	**75,875**	**100.0**
Goats	Not altered	1,144	728	121	46	0	0	229	0	2,268	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**1,144**	**728**	**121**	**46**	**0**	**0**	**229**	**0**	**2,268**	**100.0**
Sheep	Not altered	8,552	8,254	1,362	45,665	119	0	1,482	88	65,522	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	5	0	0	0	0	0	0	0	5	0.0
	Total	**8,557**	**8,254**	**1,362**	**45,665**	**119**	**0**	**1,482**	**88**	**65,527**	**100.0**
Cattle	Not altered	14,797	10,387	3,757	601	2,453	0	5,255	26	37,276	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**14,797**	**10,387**	**3,757**	**601**	**2,453**	**0**	**5,255**	**26**	**37,276**	**100.0**
Prosimians	Not altered	173	0	0	0	0	0	0	0	173	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**173**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**173**	**100.0**
Marmoset and tamarins	Not altered	182	162	215	86	0	0	1	0	646	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**182**	**162**	**215**	**86**	**0**	**0**	**1**	**0**	**646**	**100.0**
Squirrel monkey	Not altered	7	1	0	0	0	0	0	0	8	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**7**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**100.0**
Other species of new world monkeys (Ceboidea)	Not altered	3	0	0	0	0	0	0	0	3	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**100.0**
Cynomolgus monkey	Not altered	529	1,125	7,283	1,053	0	0	17	0	10,007	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**529**	**1,125**	**7,283**	**1,053**	**0**	**0**	**17**	**0**	**10,007**	**100.0**
Rhesus monkey	Not altered	250	334	11	29	0	0	4	0	628	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**250**	**334**	**11**	**29**	**0**	**0**	**4**	**0**	**628**	**100.0**
Vervets (Chlorocebus spp.)	Not altered	22	26	0	5	0	0	0	0	53	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**22**	**26**	**0**	**5**	**0**	**0**	**0**	**0**	**53**	**100.0**
Baboons	Not altered	10	36	0	0	0	0	0	0	46	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**10**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**46**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Not altered	14	21	0	0	0	0	0	0	35	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**14**	**21**	**0**	**0**	**0**	**0**	**0**	**0**	**35**	**100.0**
Other mammals	Not altered	5,013	21,540	0	1	94	274	121	0	27,043	99.9
	Non harmful	23	0	0	0	0	0	0	0	23	0.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**5,036**	**21,540**	**0**	**1**	**94**	**274**	**121**	**0**	**27,066**	**100.0**
Domestic fowl	Not altered	107,748	107,023	146,488	102,405	2,759	343	4,294	315	471,375	99.9
	Non harmful	637	0	0	0	0	0	0	0	637	0.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**108,385**	**107,023**	**146,488**	**102,405**	**2,759**	**343**	**4,294**	**315**	**472,012**	**100.0**

	Genetic status	Basic research	Translational and applied research	Regulatory use	Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Forensic enquiries	Total	%
Other birds	Not altered	57,356	13,092	5,004	22,821	2,567	696	810	0	102,346	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**57,356**	**13,092**	**5,004**	**22,821**	**2,567**	**696**	**810**	**0**	**102,346**	**100.0**
Reptiles	Not altered	6,267	117	0	0	8	70	100	0	6,562	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**6,267**	**117**	**0**	**0**	**8**	**70**	**100**	**0**	**6,562**	**100.0**
Rana	Not altered	798	108	91	0	200	0	2,301	0	3,498	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**798**	**108**	**91**	**0**	**200**	**0**	**2,301**	**0**	**3,498**	**100.0**
Xenopus	Not altered	13,688	3,454	653	210	902	0	390	0	19,297	90.0
	Non harmful	1,583	192	0	0	0	0	12	0	1,787	8.3
	Harmful	359	0	0	0	0	0	0	0	359	1.7
	Total	**15,630**	**3,646**	**653**	**210**	**902**	**0**	**402**	**0**	**21,443**	**100.0**
Other amphibians	Not altered	6,751	1,051	59	0	1,811	398	205	0	10,275	93.9
	Non harmful	671	0	0	0	0	0	0	0	671	6.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**7,422**	**1,051**	**59**	**0**	**1,811**	**398**	**205**	**0**	**10,946**	**100.0**
Zebra fish	Not altered	70,628	60,841	45,323	0	2,416	7	1,227	0	180,442	35.8
	Non harmful	254,763	38,893	0	0	0	133	454	0	294,243	58.4
	Harmful	28,945	503	50	0	0	0	0	0	29,498	5.9
	Total	**354,336**	**100,237**	**45,373**	**0**	**2,416**	**140**	**1,681**	**0**	**504,183**	**100.0**
Other fish	Not altered	328,729	90,734	126,690	49	105,023	63,410	3,512	0	718,147	99.3
	Non harmful	1,828	2,988	0	0	9	0	0	0	4,825	0.7
	Harmful	204	0	0	0	0	0	0	0	204	0.0
	Total	**330,761**	**93,722**	**126,690**	**49**	**105,032**	**63,410**	**3,512**	**0**	**723,176**	**100.0**
Cephalopods	Not altered	22	455	0	0	33	0	4	0	514	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**22**	**455**	**0**	**0**	**33**	**0**	**4**	**0**	**514**	**100.0**
All Species	**Harmful**	**302,000**	**127,348**	**1,771**	**0**	**0**	**378**	**701**	**8**	**432,206**	**4.5**
	Non harmful	**1,642,212**	**416,794**	**45,466**	**27,879**	**9**	**12,567**	**12,769**	**0**	**2,157,696**	**22.5**
	Not altered	**2,413,441**	**1,655,814**	**2,139,622**	**441,479**	**124,778**	**65,948**	**150,292**	**465**	**6,991,839**	**73.0**
	Total	**4,357,653**	**2,199,956**	**2,186,859**	**469,358**	**124,787**	**78,893**	**163,762**	**473**	**9,581,741**	**100.0**

Part 3: Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

Table 15: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2017)

	Severity	Basic research	Translational and applied research	Total	%
Mice	Non-recovery	23,615	382	23,997	4.9
	Mild	356,584	18,048	374,632	76.3
	Moderate	70,843	8,809	79,652	16.2
	Severe	12,014	422	12,436	2.5
	Total	**463,056**	**27,661**	**490,717**	**100.0**
Rats	Non-recovery	153	0	153	1.5
	Mild	6,613	523	7,136	71.6
	Moderate	1,036	685	1,721	17.3
	Severe	554	396	950	9.5
	Total	**8,356**	**1,604**	**9,960**	**100.0**
Rabbits	Non-recovery	102	133	235	49.5
	Mild	24	0	24	5.1
	Moderate	109	107	216	45.5
	Severe	0	0	0	0.0
	Total	**235**	**240**	**475**	**100.0**
Pigs	Non-recovery	2	6	8	3.5
	Mild	133	74	207	91.2
	Moderate	2	0	2	0.9
	Severe	10	0	10	4.4
	Total	**147**	**80**	**227**	**100.0**
Sheep	Non-recovery	0	0	0	0.0
	Mild	14	0	14	82.4
	Moderate	3	0	3	17.6
	Severe	0	0	0	0.0
	Total	**17**	**0**	**17**	**100.0**
Marmoset and tamarins	Non-recovery	0	0	0	0.0
	Mild	9	0	9	90.0
	Moderate	1	0	1	10.0
	Severe	0	0	0	0.0
	Total	**10**	**0**	**10**	**100.0**
Other mammals	Non-recovery	16	0	16	26.2
	Mild	34	0	34	55.7
	Moderate	11	0	11	18.0
	Severe	0	0	0	0.0
	Total	**61**	**0**	**61**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0.0
	Mild	620	27	647	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**620**	**27**	**647**	**100.0**
Xenopus	Non-recovery	0	0	0	0.0
	Mild	250	0	250	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**250**	**0**	**250**	**100.0**
Zebra fish	Non-recovery	1,018	40	1,058	0.7
	Mild	127,533	4,503	132,036	87.7
	Moderate	15,114	190	15,304	10.2
	Severe	2,198	0	2,198	1.5
	Total	**145,863**	**4,733**	**150,596**	**100.0**
Other fish	Non-recovery	0	0	0	0.0
	Mild	4,562	0	4,562	99.8
	Moderate	7	0	7	0.2
	Severe	0	0	0	0.0
	Total	**4,569**	**0**	**4,569**	**100.0**

	Severity	Basic research	Translational and applied research	Total	%
All Species	Non-recovery	24,906	561	25,467	3.9
	Mild	496,376	23,175	519,551	79.0
	Moderate	87,126	9,791	96,917	14.7
	Severe	14,776	818	15,594	2.4
	Total	623,184	34,345	657,529	100.0

Table 16: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2017)

	Reuse	Basic research	Translational and applied research	Total	%
Mice	Yes	1,895	225	2,120	0.4
	No	461,161	27,436	488,597	99.6
	Total	**463,056**	**27,661**	**490,717**	**100.0**
Rats	Yes	0	0	0	0.0
	No	8,356	1,604	9,960	100.0
	Total	**8,356**	**1,604**	**9,960**	**100.0**
Rabbits	Yes	0	0	0	0.0
	No	235	240	475	100.0
	Total	**235**	**240**	**475**	**100.0**
Pigs	Yes	0	3	3	1.3
	No	147	77	224	98.7
	Total	**147**	**80**	**227**	**100.0**
Sheep	Yes	0	0	0	0.0
	No	17	0	17	100.0
	Total	**17**	**0**	**17**	**100.0**
Marmoset and tamarins	Yes	0	0	0	0.0
	No	10	0	10	100.0
	Total	**10**	**0**	**10**	**100.0**
Other mammals	Yes	0	0	0	0.0
	No	61	0	61	100.0
	Total	**61**	**0**	**61**	**100.0**
Domestic fowl	Yes	0	0	0	0.0
	No	620	27	647	100.0
	Total	**620**	**27**	**647**	**100.0**
Xenopus	Yes	0	0	0	0.0
	No	250	0	250	100.0
	Total	**250**	**0**	**250**	**100.0**
Zebra fish	Yes	20,621	80	20,701	13.7
	No	125,242	4,653	129,895	86.3
	Total	**145,863**	**4,733**	**150,596**	**100.0**
Other fish	Yes	0	0	0	0.0
	No	4,569	0	4,569	100.0
	Total	**4,569**	**0**	**4,569**	**100.0**
All Species	**Yes**	**22,516**	**308**	**22,824**	**3.5**
	No	**600,668**	**34,037**	**634,705**	**96.5**
	Total	**623,184**	**34,345**	**657,529**	**100.0**

Table 17: Uses of animals for the creation of new genetically altered animal lines in basic research by species and type of research (2017)

	Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total	%
Mammals															
Rodents															
Mice	77,684	16,920	62,701	1,227	10,587	12,912	47,995	22,816	10,793	16,200	117,781	474	64,966	**463,056**	**74.3**
Rats	0	3,180	1,815	0	0	0	673	29	0	0	973	0	1,686	**8,356**	**1.3**
Guinea-Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Other rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Rabbits															
Rabbits	0	81	0	0	0	0	0	60	0	0	0	0	94	**235**	**0**
Farm animals															
Pigs	0	5	4	0	0	11	79	0	0	0	39	0	9	**147**	**0**
Sheep	0	0	16	1	0	0	0	0	0	0	0	0	0	**17**	**0**
Non-human primates															
Marmoset and tamarins	0	0	0	0	0	0	0	0	0	0	0	0	10	**10**	**0**
Other mammals															
Other mammals	0	0	61	0	0	0	0	0	0	0	0	0	0	**61**	**0**
Birds															
Domestic fowl	0	0	0	0	0	0	0	125	0	0	495	0	0	**620**	**0.1**
Amphibians															
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	250	**250**	**0**
Fish															
Zebra fish	4,109	45,549	28,686	0	109	3,728	10,786	4,140	5,787	2,549	19,260	6,917	14,243	**145,863**	**23.4**
Other fish	69	24	1	0	0	0	0	778	2,394	0	1,296	0	7	**4,569**	**0.7**
Totals															
Total	**81,862**	**65,759**	**93,284**	**1,228**	**10,696**	**16,651**	**59,533**	**27,948**	**18,974**	**18,749**	**139,844**	**7,391**	**81,265**	**623,184**	**100**
%	**13.1**	**10.6**	**15**	**0.2**	**1.7**	**2.7**	**9.6**	**4.5**	**3**	**3**	**22.4**	**1.2**	**13**	**100**	

Table 18.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species and type of research (Part 1) (2017)

	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders
Mammals								
Rodents								
Mice	9,346	490	2,074	2,866	263	2,544	305	2,265
Rats	44	0	149	971	0	0	408	0
Guinea-Pigs	0	0	0	0	0	0	0	0
Other rodents	0	0	0	0	0	0	0	0
Rabbits								
Rabbits	0	0	0	0	0	0	0	0
Farm animals								
Pigs	26	0	9	11	0	0	13	0
Sheep	0	0	0	0	0	0	0	0
Non-human primates								
Marmoset and tamarins	0	0	0	0	0	0	0	0
Other mammals								
Other mammals	0	0	0	0	0	0	0	0
Birds								
Domestic fowl	0	0	0	0	0	0	0	0
Amphibians								
Xenopus	0	0	0	0	0	0	0	0
Fish								
Zebra fish	0	730	1,480	242	0	0	155	0
Other fish	0	0	0	0	0	0	0	0
Totals								
Total	**9,416**	**1,220**	**3,712**	**4,090**	**263**	**2,544**	**881**	**2,265**
%	**27.8**	**3.6**	**11**	**12.1**	**0.8**	**7.5**	**2.6**	**6.7**

Table 18.2: Uses of animals for the creation of new genetically altered animal lines in basic translational and applied research by species and type of research (Part 2) (2017)

	Human Urogenital/Reproductive Disorders	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals										
Rodents										
Mice	654	67	4,469	502	1,816	0	0	0	**27,661**	**80.5**
Rats	0	15	0	0	0	17	0	0	**1,604**	**4.7**
Guinea-Pigs	0	0	0	0	0	0	0	0	**0**	**0**
Other rodents	0	0	0	0	0	0	0	0	**0**	**0**
Rabbits										
Rabbits	0	0	232	0	8	0	0	0	**240**	**0.7**
Farm animals										
Pigs	0	12	5	4	0	0	0	0	**80**	**0.2**
Sheep	0	0	0	0	0	0	0	0	**0**	**0**
Non-human primates										
Marmoset and tamarins	0	0	0	0	0	0	0	0	**0**	**0**
Other mammals										
Other mammals	0	0	0	0	0	0	0	0	**0**	**0**
Birds										
Domestic fowl	0	0	0	0	27	0	0	0	**27**	**0.1**
Amphibians										
Xenopus	0	0	0	0	0	0	0	0	**0**	**0**
Fish										
Zebra fish	0	1,074	0	40	0	0	502	510	**4,733**	**13.8**
Other fish	0	0	0	0	0	0	0	0	**0**	**0**
Totals										
Total	**654**	**1,168**	**4,706**	**546**	**1,851**	**17**	**502**	**510**	**34,345**	**100**
%	**1.9**	**3.4**	**13.7**	**1.6**	**5.4**	**0**	**1.5**	**1.5**	**100**	

Table 19: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, severity and genetic status (2017)

	Severity	Genetically altered with a harmful phenotype	Genetically altered without a harmful phenotype	Not genetically altered	Total	%
Mice	Non-recovery	417	225	71	713	0.1
	Mild	48,209	359,141	30,784	438,134	77.7
	Moderate	37,965	37,786	3,358	79,109	14.0
	Severe	22,525	23,197	106	45,828	8.1
	Total	**109,116**	**420,349**	**34,319**	**563,784**	**100.0**
Rats	Non-recovery	0	0	0	0	0.0
	Mild	2,271	816	590	3,677	54.1
	Moderate	830	755	391	1,976	29.1
	Severe	1,132	14	0	1,146	16.9
	Total	**4,233**	**1,585**	**981**	**6,799**	**100.0**
Dogs	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	0	0	0	0	0.0
	Severe	0	10	0	10	100.0
	Total	**0**	**10**	**0**	**10**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0	0.0
	Mild	0	242	26	268	73.0
	Moderate	93	0	0	93	25.3
	Severe	6	0	0	6	1.6
	Total	**99**	**242**	**26**	**367**	**100.0**
Xenopus	Non-recovery	0	0	0	0	0.0
	Mild	0	376	14	390	99.5
	Moderate	0	0	0	0	0.0
	Severe	0	1	1	2	0.5
	Total	**0**	**377**	**15**	**392**	**100.0**
Zebra fish	Non-recovery	0	1	26	27	0.0
	Mild	15,297	48,754	3,830	67,881	95.8
	Moderate	128	2,034	2	2,164	3.1
	Severe	127	637	4	768	1.1
	Total	**15,552**	**51,426**	**3,862**	**70,840**	**100.0**
Other fish	Non-recovery	0	0	0	0	0.0
	Mild	2	114	0	116	18.1
	Moderate	0	524	0	524	81.9
	Severe	0	0	0	0	0.0
	Total	**2**	**638**	**0**	**640**	**100.0**
All Species	**Non-recovery**	**417**	**226**	**97**	**740**	**0.1**
	Mild	**65,779**	**409,443**	**35,244**	**510,466**	**79.4**
	Moderate	**39,016**	**41,099**	**3,751**	**83,866**	**13.0**
	Severe	**23,790**	**23,859**	**111**	**47,760**	**7.4**
	Total	**129,002**	**474,627**	**39,203**	**642,832**	**100.0**

Table 20: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and genetic status (2017)

	Reuse	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	%
Mice	Yes	0	72	69	141	0.0
	No	34,319	420,277	109,047	563,643	100.0
	Total	**34,319**	**420,349**	**109,116**	**563,784**	**100.0**
Rats	Yes	0	0	0	0	0.0
	No	981	1,585	4,233	6,799	100.0
	Total	**981**	**1,585**	**4,233**	**6,799**	**100.0**
Dogs	Yes	0	0	0	0	0.0
	No	0	10	0	10	100.0
	Total	**0**	**10**	**0**	**10**	**100.0**
Domestic fowl	Yes	0	0	0	0	0.0
	No	26	242	99	367	100.0
	Total	**26**	**242**	**99**	**367**	**100.0**
Xenopus	Yes	4	193	0	197	50.3
	No	11	184	0	195	49.7
	Total	**15**	**377**	**0**	**392**	**100.0**
Zebra fish	Yes	149	463	0	612	0.9
	No	3,713	50,963	15,552	70,228	99.1
	Total	**3,862**	**51,426**	**15,552**	**70,840**	**100.0**
Other fish	Yes	0	0	0	0	0.0
	No	0	638	2	640	100.0
	Total	**0**	**638**	**2**	**640**	**100.0**
All Species	**Yes**	**153**	**728**	**69**	**950**	**0.1**
	No	**39,050**	**473,899**	**128,933**	**641,882**	**99.9**
	Total	**39,203**	**474,627**	**129,002**	**642,832**	**100.0**

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PART 3/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

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V.1. Introduction

Member States submitted statistical data to the Commission between 2015 and 2017 using the main categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU. The accompanying Member State narratives make reference to the numbers in these submissions.

However, the numbers contained in the Member State submission do not directly correlate with the compiled EU data.

Drawing from the Member State submissions, the EU report is based on a revised, improved, categorisation of data:

- **Numbers of animals** used for purposes of research, testing, routine production and education (including training) – Part 1 (III.1)
- **Details of all uses** (first and any subsequent reuse) of animals for the purposes of research, testing, routine production and education (including training) - Part 2 (III.2)
- Numbers and uses of animals for the **creation and maintenance of genetically altered animals** in the EU – Part 3 (III.3)

This has allowed for the presentation of a much clearer and precise picture of the numbers of animals and purposes for which animals are used in the EU.

To provide a possibility to refer back to the Member State data in a similar manner, the part V.3. of this Section C presents recalculation of the Member State data, for the year 2017, divided into the three categories above.

V.2. Member State narratives and data submissions 2015-2017

Member States annual submissions between years 2015 and 2017 are listed by Member State, first providing the Member State narrative for the respective year followed by the related data tables.

As stated above, these numbers do not directly correlate with numbers in the EU report in Part A but have been left here so that accurate presentation of the Member State submissions is provided, including correspondence with the related annual narratives.

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Austria

Austria: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Austria already collected statistical data on animals used in 2013 in the new format. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the years before 2013 can only be made with caution. The overall number of animals used in 2015 was 227.317 (2014: 209.183), this constitutes an increase of 8,7%, in comparison to 2013 this is an increase of 9%.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Significant increases in animal use were reported for translational research on infectious diseases and regulatory pyrogenicity testing. Significant decrease in animal use was observed for translational research in oncology and regulatory batch potency testing.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The percentages of actual severities were
Non-recovery: 4% (2014: 3%)
Mild: 60% (2014: 57%)
Moderate: 24% (2014: 30%)
Severe: 12% (2014: 10%)
These changes could not be considered as significant.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all the steps of the authorization processes, so that even with an increase in research activities the overall numbers of animals used have remained fairly constant.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Only small, not significant proportions were reported under the category “other”.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were observed or reported.

Austria: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	187413	82.45%
Rats	5162	2.27%
Guinea-Pigs	1858	0.82%
Hamsters (Syrian)	602	0.26%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	99	0.04%
Rabbits	15910	7%
Cats	34	0.01%
Dogs	111	0.05%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	94	0.04%
Pigs	1762	0.78%
Goats	7	0%
Sheep	115	0.05%
Cattle	632	0.28%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	515	0.23%
Domestic fowl	1623	0.71%
Other birds	465	0.2%
Reptiles		
Rana		
Xenopus	121	0.05%
Other Amphibians	616	0.27%
Zebra fish	9411	4.14%
Other Fish	767	0.34%
Cephalopods		
Total	**227317**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	216341	96.04%
Animals born in the EU but not at a registered breeder	4188	1.86%
Animals born in rest of Europe	61	0.03%
Animals born in rest of world	4678	2.08%
Total	**225268**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	89479	39.36%
Translational and applied research	74146	32.62%
Regulatory use and Routine production	31789	13.98%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	551	0.24%
Preservation of species	67	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1925	0.85%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	29360	12.92%
Total	**227317**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	15691	17.54%
Cardiovascular Blood and Lymphatic System	10313	11.53%
Nervous System	12922	14.44%
Respiratory System	739	0.83%
Gastrointestinal System including Liver	2525	2.82%
Musculoskeletal System	1816	2.03%
Immune System	19514	21.81%
Urogenital/Reproductive System	553	0.62%
Sensory Organs (skin, eyes and ears)	420	0.47%
Endocrine System/Metabolism	2055	2.3%
Multisystemic	8104	9.06%
Ethology / Animal Behaviour /Animal Biology	1343	1.5%
Other basic research	13484	15.07%
Total	**89479**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13389	18.06%
Human Infectious Disorders	42653	57.53%
Human Cardiovascular Disorders	7030	9.48%
Human Nervous and Mental Disorders	3885	5.24%
Human Respiratory Disorders	91	0.12%
Human Gastrointestinal Disorders including Liver	471	0.64%
Human Musculoskeletal Disorders	595	0.8%
Human Immune Disorders	2396	3.23%
Human Urogenital/Reproductive Disorders	167	0.23%
Human Sensory Organ Disorders (skin, eyes and ears)	262	0.35%
Human Endocrine/Metabolism Disorders	263	0.35%
Other Human Disorders	20	0.03%
Animal Diseases and Disorders	2874	3.88%
Animal Welfare		
Diagnosis of diseases	15	0.02%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	35	0.05%
Total	**74146**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	31413	98.82%
Other efficacy and tolerance testing	44	0.14%
Toxicity and other safety testing including pharmacology	151	0.48%
Routine production	181	0.57%
Total	**31789**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4708	14.99%
Pyrogenicity testing	14794	47.1%
Batch potency testing	11461	36.48%
Other quality controls	450	1.43%
Total	**31413**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	6	3.97%
Neurotoxicity	88	58.28%
Kinetics	48	31.79%
Safety testing in food and feed area	9	5.96%
Total	**151**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	6	100%
> 90 days		
Total	**6**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	181	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**181**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	31642	99.54%
Legislation on medicinal products for veterinary use and their residues	44	0.14%
Medical devices legislation	6	0.02%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		

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Testing by Legislation	Number of uses	Percentage
Feed legislation including legislation for the safety of target animals, workers and environment	9	0.03%
Cosmetics legislation		
Other legislation	88	0.28%
Total	**31789**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	27929	87.86%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	3860	12.14%
Total	**31789**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225268	99.1%
Yes	2049	0.9%
Total	**227317**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	8782	3.86%
Mild [up to and including]	136602	60.09%
Moderate	54896	24.15%
Severe	27037	11.89%
Total	**227317**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	215627	94.86%
Yes	11690	5.14%
Total	**227317**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	135911	59.79%
Genetically altered without a harmful phenotype	73220	32.21%
Genetically altered with a harmful phenotype	18186	8%
Total	**227317**	**100.00%**

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Austria: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In Austria the total number of animals used for scientific purposes in 2016 is 236.459 (2015: 227.317), which is an increase of 4.0% or in absolute numbers 9.142 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats. However, the overall numbers between 2013 and 2016 remained within the range of the last 10 years.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

A marked increase is observed in “Basic Research, Immune System” (from 19.514 animals to 29.555 animals). On the other hand, there is a decline in “Maintenance of colonies of established genetically altered animals, not used in other procedures” (from 29.360 animals to 18.905 animals).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of severity "severe" decreased from 12% to 7% compared to the previous year (also in absolute numbers: from 27.037 to 17.272). One possible reason for this could be the case-specific application of humane endpoints.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints. Thus, even with an increase in research activities the numbers of animals used have remained fairly constant, while at the same time the proportion of animals with “severe” suffering declined.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

“Other rodents” include i.a. the wood mouse (not Mus musculus), the edible dormouse and garden dormouse; “Other mammals” include i.a. llamas, “Other birds” i.a. turkeys, great tits and Eurasian blackcaps; “Other fish” mainly trouts and medaka.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as the production of antibodies.

6. Details on cases where the “severe” classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why “severe” classification was exceeded.

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Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

Austria: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	191896	81.15%
Rats	6344	2.68%
Guinea-Pigs	1785	0.75%
Hamsters (Syrian)	277	0.12%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	276	0.12%
Rabbits	14684	6.21%
Cats	12	0.01%
Dogs	177	0.07%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	43	0.02%
Pigs	4901	2.07%
Goats	2	0%
Sheep	423	0.18%
Cattle	386	0.16%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	150	0.06%
Domestic fowl	3307	1.4%
Other birds	1208	0.51%
Reptiles		
Rana		
Xenopus	148	0.06%
Other Amphibians	4	0%
Zebra fish	7960	3.37%
Other Fish	2476	1.05%
Cephalopods		
Total	**236459**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	224314	95.23%
Animals born in the EU but not at a registered breeder	7403	3.14%
Animals born in rest of Europe		

Place of birth	Number of animals	Percentage
Animals born in rest of world	3843	1.63%
Total	**235560**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	103605	43.82%
Translational and applied research	74336	31.44%
Regulatory use and Routine production	36202	15.31%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	191	0.08%
Preservation of species	563	0.24%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2657	1.12%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	18905	8%
Total	**236459**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	17191	16.59%
Cardiovascular Blood and Lymphatic System	11179	10.79%
Nervous System	9439	9.11%
Respiratory System	399	0.39%
Gastrointestinal System including Liver	1761	1.7%
Musculoskeletal System	2566	2.48%
Immune System	29555	28.53%
Urogenital/Reproductive System	469	0.45%
Sensory Organs (skin, eyes and ears)	1158	1.12%
Endocrine System/Metabolism	2033	1.96%
Multisystemic	10967	10.59%
Ethology / Animal Behaviour /Animal Biology	2842	2.74%
Other basic research	14046	13.56%

Basic Research	Number of uses	Percentage
Total	**103605**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	15369	20.68%
Human Infectious Disorders	35473	47.72%
Human Cardiovascular Disorders	7850	10.56%
Human Nervous and Mental Disorders	4748	6.39%
Human Respiratory Disorders	64	0.09%
Human Gastrointestinal Disorders including Liver	832	1.12%
Human Musculoskeletal Disorders	351	0.47%
Human Immune Disorders	1437	1.93%
Human Urogenital/Reproductive Disorders	8	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	47	0.06%
Human Endocrine/Metabolism Disorders	769	1.03%
Other Human Disorders	897	1.21%
Animal Diseases and Disorders	2637	3.55%
Animal Welfare	3848	5.18%
Diagnosis of diseases	6	0.01%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**74336**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	35884	99.12%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	72	0.2%
Routine production	246	0.68%
Total	**36202**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4228	11.78%
Pyrogenicity testing	13157	36.67%
Batch potency testing	17604	49.06%
Other quality controls	895	2.49%
Total	**35884**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Neurotoxicity	22	30.56%
Target animal safety	50	69.44%
Total	**72**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	246	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**246**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	36103	99.73%
Legislation on medicinal products for veterinary use and their residues	50	0.14%
Medical devices legislation	27	0.07%

Testing by Legislation	Number of uses	Percentage
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	22	0.06%
Total	**36202**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	31134	86%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	5068	14%
Total	**36202**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235560	99.62%
Yes	899	0.38%
Total	**236459**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	5815	2.46%
Mild [up to and including]	148333	62.73%
Moderate	65039	27.51%
Severe	17272	7.3%
Total	**236459**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	222857	94.25%
Yes	13602	5.75%
Total	**236459**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	138680	58.65%
Genetically altered without a harmful phenotype	80249	33.94%
Genetically altered with a harmful phenotype	17530	7.41%
Total	**236459**	**100.00%**

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Austria: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In Austria the total number of animals used for scientific purposes in 2017 is 264.071 (2016: 236.459), which is an increase of 11.7% or in absolute numbers 27.612 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The total number of fish (zebra fish and other fish) used for scientific purposes in 2017 is 20.927 (2016: 10.436). Zebra fish were mainly used for the purpose “Basic Research, Other” in particular cell and developmental biology.

With regard to the categories of purposes, a marked increase is observed in “Basic Research, Oncology” (from 17.191 animals to 25.406 animals used in 2017). For Maintenance of colonies of established genetically altered animals, not used in other procedures” a decrease was reported in 2016, whereas for 2017 an increase is observed in this category (from 18.905 animals to 29.360 animals).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

No significant changes are observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

“Other rodents” include i.a. the common vole and the wood mouse; “Other mammals” include i.a. the brown hare and wild boar, “Other birds” i.a. reed buntings and Eurasian blackcaps; “Other fish” include i.a. trouts.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as cell and developmental biology and imaging.

6. Details on cases where the “severe” classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why “severe” classification was exceeded.

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Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

Austria: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	212913	80.63%
Rats	6038	2.29%
Guinea-Pigs	1154	0.44%
Hamsters (Syrian)	8	0%
Hamsters (Chinese)		
Mongolian gerbil	41	0.02%
Other Rodents	998	0.38%
Rabbits	10388	3.93%
Cats	61	0.02%
Dogs	203	0.08%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	521	0.2%
Pigs	2040	0.77%
Goats	22	0.01%
Sheep	149	0.06%
Cattle	908	0.34%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	102	0.04%
Domestic fowl	3895	1.47%
Other birds	1819	0.69%
Reptiles		
Rana		
Xenopus	972	0.37%
Other Amphibians	912	0.35%
Zebra fish	16297	6.17%
Other Fish	4630	1.75%
Cephalopods		
Total	**264071**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	247185	93.95%
Animals born in the EU but not at a registered breeder	11909	4.53%
Animals born in rest of Europe	99	0.04%

Place of birth	Number of animals	Percentage
Animals born in rest of world	3902	1.48%
Total	**263095**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	127667	48.35%
Translational and applied research	77138	29.21%
Regulatory use and Routine production	26569	10.06%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	198	0.07%
Preservation of species	30	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3108	1.18%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	29361	11.12%
Total	**264071**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	25406	19.9%
Cardiovascular Blood and Lymphatic System	10272	8.05%
Nervous System	16591	13%
Respiratory System	316	0.25%
Gastrointestinal System including Liver	2229	1.75%
Musculoskeletal System	4947	3.87%
Immune System	25283	19.8%
Urogenital/Reproductive System	1128	0.88%
Sensory Organs (skin, eyes and ears)	1208	0.95%
Endocrine System/Metabolism	1694	1.33%
Multisystemic	12805	10.03%
Ethology / Animal Behaviour /Animal Biology	5799	4.54%
Other basic research	19989	15.66%

Basic Research	Number of uses	Percentage
Total	**127667**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14506	18.81%
Human Infectious Disorders	42202	54.71%
Human Cardiovascular Disorders	5109	6.62%
Human Nervous and Mental Disorders	5487	7.11%
Human Respiratory Disorders	285	0.37%
Human Gastrointestinal Disorders including Liver	151	0.2%
Human Musculoskeletal Disorders	260	0.34%
Human Immune Disorders	785	1.02%
Human Urogenital/Reproductive Disorders	201	0.26%
Human Sensory Organ Disorders (skin, eyes and ears)	300	0.39%
Human Endocrine/Metabolism Disorders	1138	1.48%
Other Human Disorders	576	0.75%
Animal Diseases and Disorders	4816	6.24%
Animal Welfare	542	0.7%
Diagnosis of diseases	715	0.93%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	65	0.08%
Total	**77138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25823	97.19%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	740	2.79%
Routine production	6	0.02%
Total	**26569**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2700	10.46%
Pyrogenicity testing	9125	35.34%
Batch potency testing	13554	52.49%
Other quality controls	444	1.72%
Total	**25823**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	43	5.81%
Neurotoxicity	32	4.32%
Target animal safety	665	89.86%
Total	**740**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	43	100%
> 90 days		
Total	**43**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	6	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**6**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25870	97.37%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation	2	0.01%

Testing by Legislation	Number of uses	Percentage
Industrial chemicals legislation		
Plant protection product legislation	665	2.5%
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	32	0.12%
Total	**26569**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23037	86.71%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	3532	13.29%
Total	**26569**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	263095	99.63%
Yes	976	0.37%
Total	**264071**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	5153	1.95%
Mild [up to and including]	175022	66.28%
Moderate	62516	23.67%
Severe	21380	8.1%
Total	**264071**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	241513	91.46%
Yes	22558	8.54%
Total	**264071**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	145931	55.26%
Genetically altered without a harmful phenotype	82509	31.25%
Genetically altered with a harmful phenotype	35631	13.49%
Total	**264071**	**100.00%**

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Belgium

Belgium: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2014 (660.261 animals used), there is a decrease of 14,95 % in the number of animals used for scientific purposes in 2015 (561.551 animals used).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The use of animals in the specific areas is similar to the figures of 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 more animals were reported in the 'severe' category [2014: severe (14.82%), moderate (28.23%), mild (53.02%) and non-recovery (3.93%); 2015: severe (16.68%), moderate (22.14%), mild (56.69%) and non-recovery (4.49%)]. This trend is mostly due to a better reporting of the actual severities by the users and stricter controls by the ethical committees and the government.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests
- Collaboration with the university board to promote the development and promotion of alternative methods.
- Collaboration between the different regions and other member states to promote the 3R principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

40.67% of the fishes are reported under the "other" category. They are mostly *Clarias gariepinus* and *Dicentrarchus labrax.* 36.67% of the amphibians reported under the "other" category are *Salamandridae* (in order of importance: *Lissotriton helveticus*, *Ichthyosaura alpestris*, *Salamandra salamandra*) and *Ranidae* (in order of importance: *Lithobates catesbeianus*, *Litoria caerulea*, *Alytes obstetricans*). 18.10% of the birds are reported under the "other" category. They are mostly *Paridae, Fringillidae, Passeridae, Coturnix, Meleagrididae, Estrildida* and *Laridae*.

19.73% of the regulatory routine production – toxicity and safety testing is reported as "other" toxicity and safety testing. This concerns mostly immunogenicity and psychopharmacology tests.

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6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no exceeding of the ‘severe’ classification reported in 2015.

Belgium: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	331692	59.07%
Rats	33686	6%
Guinea-Pigs	17363	3.09%
Hamsters (Syrian)	2246	0.4%
Hamsters (Chinese)		
Mongolian gerbil	111	0.02%
Other Rodents	200	0.04%
Rabbits	43304	7.71%
Cats	82	0.01%
Dogs	1850	0.33%
Ferrets	5	0%
Other carnivores		
Horses, donkeys and cross-breeds	115	0.02%
Pigs	3391	0.6%
Goats	96	0.02%
Sheep	417	0.07%
Cattle	598	0.11%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	5	0%
Rhesus monkey	41	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	131	0.02%
Domestic fowl	18350	3.27%
Other birds	4055	0.72%
Reptiles	133	0.02%
Rana		
Xenopus	855	0.15%
Other Amphibians	495	0.09%
Zebra fish	60711	10.81%
Other Fish	41619	7.41%
Cephalopods		
Total	**561551**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	496746	91.89%
Animals born in the EU but not at a registered breeder	36621	6.77%
Animals born in rest of Europe	2693	0.5%
Animals born in rest of world	4501	0.83%
Total	**540561**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	5	50%
Animals born in rest of Europe		
Animals born in Asia	5	50%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**10**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	10	100%
Self-sustaining colony		
Total	**10**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	309245	55.07%
Translational and applied research	94736	16.87%
Regulatory use and Routine production	146804	26.14%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	377	0.07%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8426	1.5%
Forensic enquiries	36	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1927	0.34%
Total	**561551**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	42541	13.76%
Cardiovascular Blood and Lymphatic System	19624	6.35%
Nervous System	48985	15.84%
Respiratory System	7410	2.4%
Gastrointestinal System including Liver	15356	4.97%
Musculoskeletal System	18962	6.13%
Immune System	59121	19.12%
Urogenital/Reproductive System	20248	6.55%

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Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	4820	1.56%
Endocrine System/Metabolism	30242	9.78%
Multisystemic	15254	4.93%
Ethology / Animal Behaviour /Animal Biology	17519	5.67%
Other basic research	9163	2.96%
Total	**309245**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	16760	17.69%
Human Infectious Disorders	21894	23.11%
Human Cardiovascular Disorders	1085	1.15%
Human Nervous and Mental Disorders	17936	18.93%
Human Respiratory Disorders	4176	4.41%
Human Gastrointestinal Disorders including Liver	971	1.02%
Human Musculoskeletal Disorders	181	0.19%
Human Immune Disorders	2558	2.7%
Human Urogenital/Reproductive Disorders	433	0.46%
Human Sensory Organ Disorders (skin, eyes and ears)	2880	3.04%
Human Endocrine/Metabolism Disorders	1359	1.43%
Other Human Disorders	62	0.07%
Animal Diseases and Disorders	6235	6.58%
Animal Welfare	165	0.17%
Diagnosis of diseases	7256	7.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	10785	11.38%
Total	**94736**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	89897	61.24%
Other efficacy and tolerance testing	7066	4.81%
Toxicity and other safety testing including pharmacology	9705	6.61%
Routine production	40136	27.34%
Total	**146804**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	13136	14.61%
Pyrogenicity testing		
Batch potency testing	74356	82.71%
Other quality controls	2405	2.68%
Total	**89897**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	990	10.2%
Skin irritation/corrosion	158	1.63%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Repeated dose toxicity	1380	14.22%
Genotoxicity	126	1.3%
Reproductive toxicity	349	3.6%
Neurotoxicity	183	1.89%
Kinetics	671	6.91%
Pharmaco-dynamics (incl safety pharmacology)	1548	15.95%
Ecotoxicity	871	8.97%
Safety testing in food and feed area	1506	15.52%
Target animal safety	8	0.08%
Other toxicity/safety testing	1915	19.73%
Total	**9705**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	990	100%
Total	**990**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1380	100%
29 - 90 days		
> 90 days		
Total	**1380**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	871	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**871**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	39961	99.56%
Monoclonal antibody by mouse ascites method		
Other product types	175	0.44%
Total	**40136**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	120283	81.93%
Legislation on medicinal products for veterinary use and their residues	18724	12.75%
Medical devices legislation	552	0.38%
Industrial chemicals legislation		
Plant protection product legislation	136	0.09%
Biocides legislation		
Food legislation including food contact material	1336	0.91%
Feed legislation including legislation for the safety of target animals, workers and environment	332	0.23%
Cosmetics legislation		
Other legislation	5441	3.71%
Total	**146804**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	130212	88.7%
Legislation satisfying national requirements only [within EU]	871	0.59%
Legislation satisfying Non-EU requirements only	15721	10.71%
Total	**146804**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	540571	96.26%
Yes	20980	3.74%
Total	**561551**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	25221	4.49%
Mild [up to and including]	318327	56.69%
Moderate	124343	22.14%
Severe	93660	16.68%
Total	**561551**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	539762	96.12%
Yes	21789	3.88%
Total	**561551**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	424438	75.58%
Genetically altered without a harmful phenotype	124304	22.14%
Genetically altered with a harmful phenotype	12809	2.28%
Total	**561551**	**100.00%**

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Belgium: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2015 (561.551 animals used), there is a decrease of 4.75 % in the number of animals used for scientific purposes in 2016 (534.854 animals used).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The use of animals in the specific areas is similar to the figures of 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There were no significant changes in actual severities.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests.
- Collaboration with the university board to promote the development and promotion of alternative methods.
- Collaboration between the different regions and other member states to promote the 3R principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

40.12% of the fishes are reported under the “other” category. They are mostly Cyprinidae, Cichlidae, Salmonidae, Percidae, Soleidae, Pleuronectidae and Aplocheilidae.

37,28% of the amphibians reported under the “other” category are mostly Ranidae (Lithobates catesbeianus), Salamandridae (in order of importance: Lissotriton helveticus, Pleurodeles waltl, Ichthyosaura alpestris) and Bombinatoridae (Bombina orientalis).

14.65% of the birds are reported under the “other” category. They are Paridae, Fringillidae, Meleagrididae, Phasianidae, Passeridae, Pycnonotidae, Estrildida, Laridae, Columbidae and Psittacidae.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the ‘severe’ classification was exceeded.

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Belgium: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	336052	62.83%
Rats	30337	5.67%
Guinea-Pigs	16223	3.03%
Hamsters (Syrian)	1880	0.35%
Hamsters (Chinese)		
Mongolian gerbil	118	0.02%
Other Rodents	175	0.03%
Rabbits	48036	8.98%
Cats	123	0.02%
Dogs	1529	0.29%
Ferrets	13	0%
Other carnivores		
Horses, donkeys and cross-breeds	231	0.04%
Pigs	3630	0.68%
Goats	101	0.02%
Sheep	581	0.11%
Cattle	1279	0.24%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	40	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	153	0.03%
Domestic fowl	26230	4.9%
Other birds	4504	0.84%
Reptiles	172	0.03%
Rana		
Xenopus	769	0.14%
Other Amphibians	457	0.09%
Zebra fish	37256	6.97%
Other Fish	24965	4.67%
Cephalopods		
Total	**534854**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	494820	93.94%
Animals born in the EU but not at a registered breeder	26817	5.09%
Animals born in rest of Europe	48	0.01%
Animals born in rest of world	5034	0.96%
Total	**526719**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	4	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**4**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	4	100%
Self-sustaining colony		
Total	**4**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	283739	53.05%
Translational and applied research	105760	19.77%
Regulatory use and Routine production	132925	24.85%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1006	0.19%
Preservation of species	6	0%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8819	1.65%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2599	0.49%
Total	**534854**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	54616	19.25%
Cardiovascular Blood and Lymphatic System	14443	5.09%
Nervous System	56699	19.98%
Respiratory System	6121	2.16%
Gastrointestinal System including Liver	19837	6.99%
Musculoskeletal System	5877	2.07%
Immune System	50140	17.67%
Urogenital/Reproductive System	11536	4.07%
Sensory Organs (skin, eyes and ears)	3772	1.33%
Endocrine System/Metabolism	18300	6.45%
Multisystemic	10342	3.64%
Ethology / Animal Behaviour /Animal Biology	19464	6.86%
Other basic research	12592	4.44%
Total	**283739**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	18857	17.83%
Human Infectious Disorders	18443	17.44%
Human Cardiovascular Disorders	920	0.87%
Human Nervous and Mental Disorders	22383	21.16%
Human Respiratory Disorders	3243	3.07%
Human Gastrointestinal Disorders including Liver	1328	1.26%
Human Musculoskeletal Disorders	1047	0.99%
Human Immune Disorders	2329	2.2%
Human Urogenital/Reproductive Disorders	284	0.27%
Human Sensory Organ Disorders (skin, eyes and ears)	3290	3.11%
Human Endocrine/Metabolism Disorders	2634	2.49%
Other Human Disorders	232	0.22%
Animal Diseases and Disorders	12467	11.79%
Animal Welfare	1514	1.43%
Diagnosis of diseases	6481	6.13%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	10308	9.75%
Total	**105760**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	82222	61.86%
Other efficacy and tolerance testing	3345	2.52%
Toxicity and other safety testing including pharmacology	5467	4.11%
Routine production	41891	31.51%
Total	**132925**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	12844	15.62%
Pyrogenicity testing		
Batch potency testing	66345	80.69%
Other quality controls	3033	3.69%
Total	**82222**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	392	7.17%
Carcinogenicity		
Eye irritation/corrosion		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	964	17.63%
Genotoxicity	83	1.52%
Developmental toxicity	1697	31.04%
Neurotoxicity	30	0.55%
Kinetics	465	8.51%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	358	6.55%
Safety testing in food and feed area	1451	26.54%
Target animal safety	8	0.15%
Other toxicity/safety testing	19	0.35%
Total	**5467**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	392	100%
Total	**392**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	864	89.63%
29 - 90 days	92	9.54%
> 90 days	8	0.83%
Total	**964**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	262	73.18%
Chronic toxicity	96	26.82%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**358**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	41781	99.74%
Monoclonal antibody by mouse ascites method		
Other product types	110	0.26%
Total	**41891**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	115307	86.75%
Legislation on medicinal products for veterinary use and their residues	15187	11.43%
Medical devices legislation	1299	0.98%
Industrial chemicals legislation	195	0.15%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	668	0.5%
Feed legislation including legislation for the safety of target animals, workers and environment	159	0.12%
Cosmetics legislation		
Other legislation	110	0.08%
Total	**132925**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	118429	89.09%
Legislation satisfying national requirements only [within EU]	19	0.01%
Legislation satisfying Non-EU requirements only	14477	10.89%
Total	**132925**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	526723	98.48%
Yes	8131	1.52%
Total	**534854**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21229	3.97%
Mild [up to and including]	297600	55.64%
Moderate	119243	22.29%
Severe	96782	18.1%
Total	**534854**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	513065	95.93%
Yes	21789	4.07%
Total	**534854**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	408773	76.43%
Genetically altered without a harmful phenotype	108899	20.36%
Genetically altered with a harmful phenotype	17182	3.21%
Total	**534854**	**100.00%**

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Belgium: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2016 (534.854 animals used), there is an increase of 1.54% in the number of animals used for scientific purposes in 2017 (543.074 animals used) but still a decrease of 3.29% compared to 2015 (561.551 animals used). The increase in 2017 is the result of an increased use of poultry merely in translational and applied research (animal diseases and disorders) and for forensic enquiries.

Number of use in 2017	Number of use in 2016	Number of use in 2015
543074	534854	561551

Since 2015 the numbers of re-used animals continues to decline: 3.74% of all uses in 2015, 1.52% in 2016 and 0.93% in 2017.

Re-Use	Number of use in 2017	Number of use in 2016	Number of use in 2015
No	538043	526723	540571
Yes	5031	8131	20980
Total uses	**543074**	**534854**	**561551**

There is a significant increase in the use of birds (108.94% compared with the use of birds in 2015). This is due to an increase in the area of Animal Diseases and Disorders and Regulatory use and Routine production (Legislation on medicinal products for veterinary use and their residues). The fish decreased with 48,73% compared to 2015. No apparent reason was noted.

Species	Number of use in 2017	Number of use in 2016	Number of use in 2015
Mammals	442378	440501	435333
Birds	46812	30734	22405
Fish	52462	62221	102330
Amphibians	1241	1226	1350
Reptiles	181	172	133
Cephalopods	0	0	0

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Total uses	**543074**	**534854**	**561551**

In the mammals the use of rabbits and Artiodactyla increased. The use of rabbits has increased in the Legislation on medicinal products for human use area. This is reflected in an increase of 33.68% compared to 2015. The use of Artiodactyla augmented (61.53% more Artiodactyla used compared to 2015). This is due to an increase in Basic research (this was caused by zootechnics (selection)), Translational and applied research (Animal Diseases and Disorders) and Protection of the natural environment in the interests of the health or welfare of human beings or animals. The use of all other species remained unchanged.

Mammals	Number of use in 2017	Number of use in 2016	Number of use in 2015
Rodents	374857	384785	385298
Rabbits	57888	48036	43304
Carnivores	1943	1665	1937
Equidae	234	231	115
Artiodactyla	7272	5591	4502
Non-human primates	44	40	46
Other mammals	140	153	131
Total uses	**442378**	**440501**	**435333**

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Between 2015 and 2017, basic research diminished with 11,79%. This was in particular due to decreases in the area of Musculoskeletal System, Urogenital/Reproductive System, Multisystemic research, Endocrine System/Metabolism and Respiratory System. However, the research in the domain of the Immune System and Oncology significantly increased between 2015 and 2017.
During the same time period Translational and applied research augmented with 23.77%. We noted a significant increase in Animal Welfare (3,525 animals in 2017 compared to 165 in 2015), Animal Diseases and Disorders, Human Endocrine/Metabolism Disorders, Human Sensory Organ Disorders (skin, eyes and ears), Human Nervous and Mental Disorders and Non-regulatory toxicology and ecotoxicology. A decrease was noted in Diagnosis of diseases and Human Infectious Disorders.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Within the actual severities classification we note that the category "severe" decreased from 18.10% in 2016 to 15.61% in 2017.
This is due to a diminution of quality control research (incl. batch safety and potency testing). This percentage is still higher than the European average of 10% but in Belgium a lot of basic research was done with in particular research in the field of Oncology, Immune system and Nervous system. Another important area in the research concerns Translational and applied research with again Human Nervous and Mental Disorders, Human Infectious Disorders and Human Cancer as the most important domains. Since, according to the legislation, tumours leading to metastases, tumours that lead to cachexia, invasive bone tumours, ulcerating tumours, loss of immunity, etc. (research that is often done in Belgium) should be classified as "severe", this can lead to an increase in this category.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests:
    - Thyroid hormone disruptors: There is a wide-variety of environmental contaminants that have the potential to cause thyroid hormone disruption[1]. Exposure to specific environmental toxins, including polychlorinated biphenyls, dioxins, phthalates, polybrominated diphenyl ethers (PBDEs), and other halogenated compounds, has been shown to interfere with the production, transportation, and/or metabolism of thyroid hormones by a variety of mechanisms. Some chemicals, with structural similarity to thyroid hormones, have been shown to bind to thyroid receptors with both agonist and antagonist effects on thyroid hormone signalling. Thyroid hormone disruption can therefore cause severe adverse effects on *e.g*. brain development, growth and metabolism.

      Validated and internationally recognised tests methods are essential in assessing the potential of chemicals to interact with the hormonal system and cause adverse effects. Non-animal test methods are needed for efficient testing and screening of substances. In 2014, OECD published a scoping document on *in vitro* and *ex vivo* assays for the identification of modulators of thyroid hormone signalling (OECD, 2014). Several key biological mechanisms of thyroid system disruption were reviewed and the corresponding methods evaluated for their state of readiness as candidates to enter the validation process. Relevant *in vitro* and *ex vivo* methods were identified and recommendations were given for their development/use. Eighteen methods were reported that cover the possible sites of action in the hypothalamic-pituitary-thyroid (HPT) axis. The research is carried out by EU-Netval facilities. By funding this research we enable our EU NETVAL facility to take part of this study.

[1] http://www.oecd.org/chemicalsafety/oecd-encourages-development-of-non-animal-test-methods-for-detection-of-thyroid-disruptors.htm

- Differentiation of human skin-derived stem cells towards hepatic cells: new source for the "in vitro study" of liver toxicity of drugs. Liver toxicity is one of the most important research elements in drug development. In addition, liver toxicity is the main reason for withdrawing medicines from the market. Presently, pre-clinical drug safety tests are carried out by "in vivo studies", i.e. studies on laboratory animals. In addition to the ethical concerns and the high costs associated with these in vivo studies, it is important to note the relatively low correlation between the results of animals on humans (less than 60% of the results of tests on animals apply to humans). By funding the project, we contribute to research that will lead in the long term to the reduction of the number of laboratory animals that are used in the context of drug development.

- Collaboration with the university board to promote the development and promotion of alternative methods (for example, WALCOPA project in Wallonia).

- Collaboration between the different regions and other member states to promote the 3R principle.

- Establishment of RE-place: The RE-Place project will create a database that brings together all existing expertise on alternative methods for animal testing in the Flemish and Brussels regions. The RE-Place website will be expanded in a next phase into a platform where researchers can find more information about alternative methods for animal testing and share their research methodology with the rest of the research community. By charting and making known generally the available and developing alternative methods for animal testing, not only researchers but also the general public and the political world will be better informed about the expertise in their own region. In the long term, all collected information will be integrated at European level.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

1. Other fish
   45.80% of the fishes are reported under the “other” category.
   They are mostly Cichlidae (*Oreochromis niloticus*) (31.21% of other fish), Salmonidae (*Salmo salar and Oncorhynchus mykiss*) (18.85% of other fish), Anguillidae (*Anguilla anguilla*) (18.75% of other fish), Cyprinidae (*Cyprinus carpio carpio and Cyprinus carpio*) (10.27% of other fish), Nothobranchiidae (*Nothobranchius furzeri*) (7.79% of other fish) and Moronidae (*Dicentrarchus labrax*) (5.70% of other fish).

Other Fish	Number of uses
Oreochromis niloticus	7499
Anguilla anguilla	4506
Salmo salar	2012

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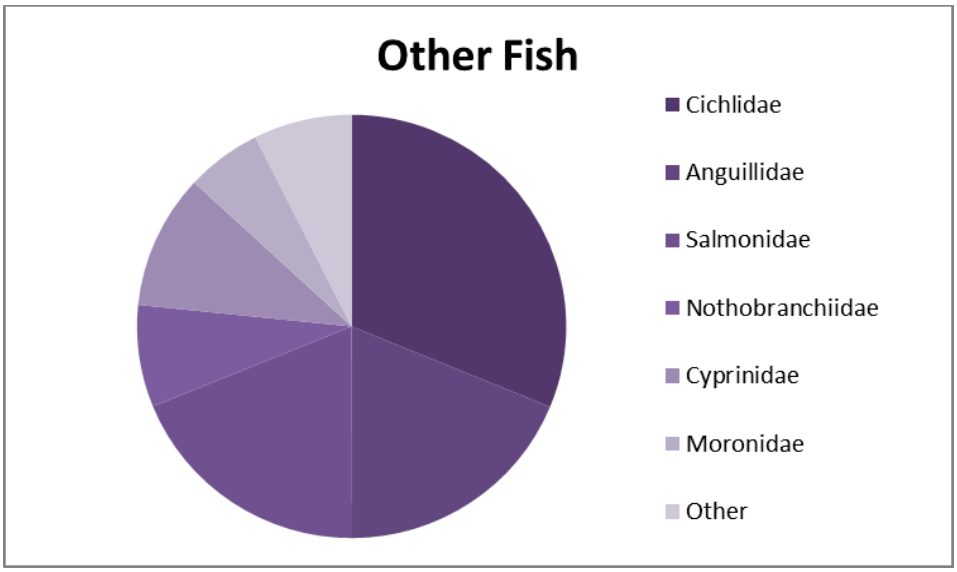
Oncorhynchus mykiss	2522
Nothobranchius furzeri	1871
Cyprinus carpio carpio	1814
Dicentrarchus labrax	1370
Cyprinus carpio	654
Scortum barcoo	648
Poecilia reticulata	300
Pleuronectes platessa	229
Lota lota	144
Gasterosteus aculeatus	82
Clarias gariepinus	50
Kryptolebias marmoratus	50
Limanda limanda	48
Gadus morhua	47
Pseudotropheus saulosi	25
Synodontis grandiops	20
Microsynodontis batesii	12
Myloplus schomburgkii	8
Catoprion mento	7
Metynnis hypsauchen	7
Pseudotropheus estherae	7
Pygopristis denticulata	7
Serrasalmus spilopleura	7
Ophthalmotilapia ventralis	6
Synodontis nigriventris	6
Maylandia zebra	5
Mochokiella paynei	5
Pygocentrus cariba	5
Pygocentrus nattereri	5
Pygocentrus piraya	5
Botia morleti	3
Myloplus rubripinnis	3
Pantodon buchholzi	3
Piaractus brachypomus	3
Synodontis acanthomias	3
Synodontis brichardi	3
Synodontis contractus	3
Synodontis elongatus	3
Synodontis flavitaeniatus	3
Synodontis lucipinnis	3
Synodontis notatus	3
Botia modesta	2
Serrasalmus manueli	2

Colossoma macropomum	1
Malapterurus electricus	1
Metynnis lippincottianus	1
Ophthalmotilapia nasuta	1
Platydoras hancockii	1
Synodontis eupterus	1
Synodontis schall	1
Total uses:	**24027**

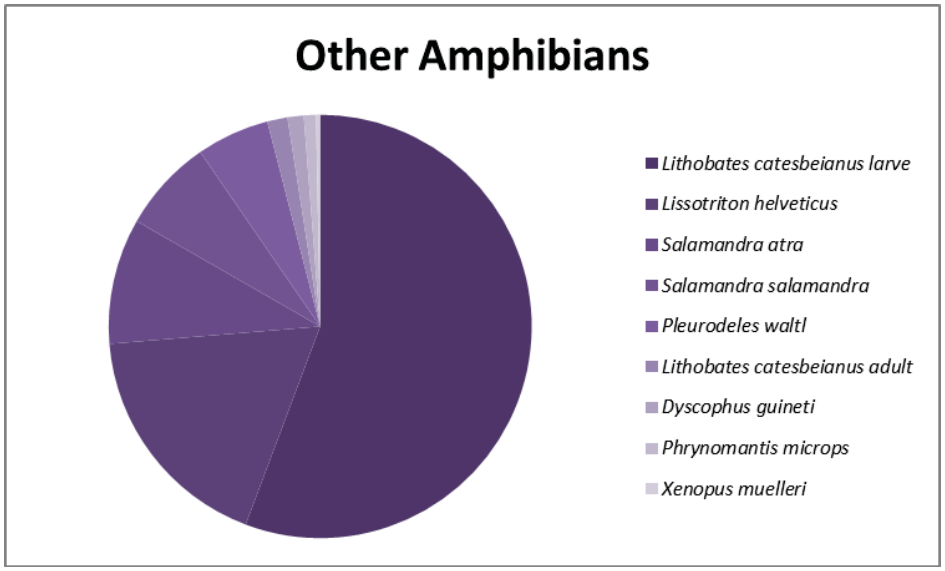


2. Other amphibians

   26.03% of the amphibians are reported under the "other" category.

   They are mostly Ranidae (*Lithobates catesbeianus larva + adult*) (57.27% of other amphibians) and Salamandridae (in order of importance: *Lissotriton helveticus, Salamandra atra, Salamandra salamandra, Pleurodeles waltl*) (40.24% of other amphibians).

Other Amphibians	Number of uses
Lithobates catesbeianus larve	180
Lissotriton helveticus	58
Salamandra atra	31
Salamandra salamandra	23
Pleurodeles waltl	18
Lithobates catesbeianus adult	5
Dyscophus guineti	4
Phrynomantis microps	3
Xenopus muelleri	1
Total uses:	**323**



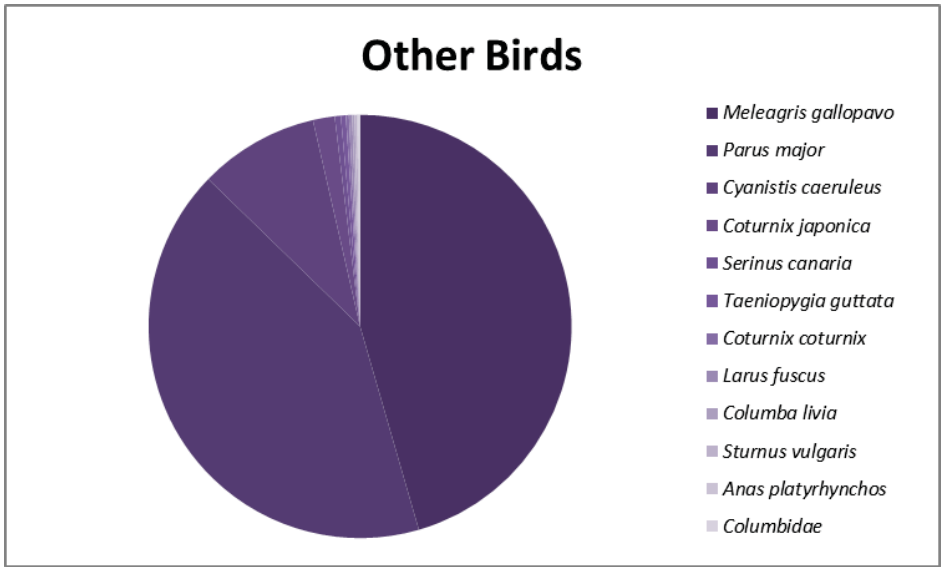
3. Other birds

   15.25% of the birds are reported under the "other" category.

   They are mostly Paridae (*Parus major and Cyanistis caeruleus*) (50.89% of other birds) and Phasianidae (*Meleagris gallopavo, Coturnix japonica, Coturnix coturnix*) (47.42% of other birds).

   The other birds are members of Fringillidae (*Serinus canaria*), Estrildidae (*Taeniopygia guttata*), Laridae (*Larus fuscus*), Columbidae (Columba livia), Sturnidae (Sturnus vulgaris) and the Anatidae (*Anas platyrhynchos*).

Other Birds	Number of uses
Meleagris gallopavo	3249
Parus major	2979
Cyanistis caeruleus	654
Coturnix japonica	119
Serinus canaria	33
Taeniopygia guttata	27
Coturnix coturnix	17
Larus fuscus	17
Columba livia	14
Sturnus vulgaris	13
Anas platyrhynchos	8
Columbidae	8
Total uses:	**7138**



6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

As in previous years, there were no cases in which the 'severe' classification was exceeded.

Belgium: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	334054	61.51%
Rats	23826	4.39%
Guinea-Pigs	15541	2.86%
Hamsters (Syrian)	1147	0.21%
Hamsters (Chinese)		
Mongolian gerbil	174	0.03%
Other Rodents	115	0.02%
Rabbits	57888	10.66%
Cats	61	0.01%
Dogs	1856	0.34%
Ferrets	26	0%
Other carnivores		
Horses, donkeys and cross-breeds	234	0.04%
Pigs	4970	0.92%
Goats	78	0.01%
Sheep	666	0.12%
Cattle	1558	0.29%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	44	0.01%

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Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	140	0.03%
Domestic fowl	39674	7.31%
Other birds	7138	1.31%
Reptiles	181	0.03%
Rana		
Xenopus	918	0.17%
Other Amphibians	323	0.06%
Zebra fish	28435	5.24%
Other Fish	24027	4.42%
Cephalopods		
Total	**543074**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	511268	95.03%
Animals born in the EU but not at a registered breeder	22269	4.14%
Animals born in rest of Europe	903	0.17%
Animals born in rest of world	3594	0.67%
Total	**538034**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	9	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**9**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	9	100%
Self-sustaining colony		
Total	**9**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	272795	50.23%
Translational and applied research	117258	21.59%
Regulatory use and Routine production	141853	26.12%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	706	0.13%
Preservation of species	151	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8051	1.48%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2260	0.42%
Total	**543074**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	58087	21.29%
Cardiovascular Blood and Lymphatic System	13462	4.93%
Nervous System	42974	15.75%
Respiratory System	3583	1.31%
Gastrointestinal System including Liver	16775	6.15%
Musculoskeletal System	4967	1.82%
Immune System	70105	25.7%
Urogenital/Reproductive System	5852	2.15%
Sensory Organs (skin, eyes and ears)	4785	1.75%
Endocrine System/Metabolism	14861	5.45%
Multisystemic	5600	2.05%
Ethology / Animal Behaviour /Animal Biology	14701	5.39%
Other basic research	17043	6.25%
Total	**272795**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	12720	10.85%
Human Infectious Disorders	15691	13.38%
Human Cardiovascular Disorders	1573	1.34%
Human Nervous and Mental Disorders	28936	24.68%
Human Respiratory Disorders	5945	5.07%
Human Gastrointestinal Disorders including Liver	977	0.83%
Human Musculoskeletal Disorders	783	0.67%
Human Immune Disorders	2039	1.74%
Human Urogenital/Reproductive Disorders	503	0.43%
Human Sensory Organ Disorders (skin, eyes and ears)	5441	4.64%
Human Endocrine/Metabolism Disorders	3722	3.17%
Other Human Disorders	40	0.03%
Animal Diseases and Disorders	17960	15.32%
Animal Welfare	3525	3.01%
Diagnosis of diseases	4292	3.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	13111	11.18%
Total	**117258**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68615	48.37%
Other efficacy and tolerance testing	17201	12.13%
Toxicity and other safety testing including pharmacology	4133	2.91%
Routine production	51904	36.59%
Total	**141853**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	8016	11.68%
Pyrogenicity testing		
Batch potency testing	57716	84.12%
Other quality controls	2883	4.2%
Total	**68615**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1037	25.09%
Carcinogenicity		
Eye irritation/corrosion		
Genotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	672	16.26%
Reproductive toxicity	290	7.02%
Developmental toxicity	11	0.27%
Neurotoxicity	20	0.48%
Kinetics	399	9.65%
Ecotoxicity	1418	34.31%
Safety testing in food and feed area	150	3.63%
Target animal safety	136	3.29%
Total	**4133**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	4.82%
Other lethal methods		
Non lethal methods	987	95.18%
Total	**1037**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	505	75.15%
29 - 90 days	42	6.25%
> 90 days	125	18.6%
Total	**672**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1202	84.77%
Chronic toxicity	216	15.23%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1418**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	51804	99.81%
Monoclonal antibody by mouse ascites method		
Other product types	100	0.19%
Total	**51904**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	113897	80.29%
Legislation on medicinal products for veterinary use and their residues	25559	18.02%
Medical devices legislation	779	0.55%
Industrial chemicals legislation	216	0.15%
Plant protection product legislation	52	0.04%
Biocides legislation		
Food legislation including food contact material	74	0.05%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1276	0.9%
Total	**141853**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	128208	90.38%
Legislation satisfying national requirements only [within EU]	50	0.04%
Legislation satisfying Non-EU requirements only	13595	9.58%
Total	**141853**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	538043	99.07%
Yes	5031	0.93%
Total	**543074**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	26546	4.89%
Mild [up to and including]	297189	54.72%
Moderate	134577	24.78%
Severe	84762	15.61%
Total	**543074**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	513454	94.55%
Yes	29620	5.45%
Total	**543074**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	402289	74.08%
Genetically altered without a harmful phenotype	118326	21.79%
Genetically altered with a harmful phenotype	22459	4.14%
Total	**543074**	**100.00%**

Bulgaria

Bulgaria: Narrative 2015 - no narrative submitted

No narrative submitted by the Member State

Bulgaria : Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2381	25.17%
Rats	1753	18.53%
Guinea-Pigs	105	1.11%
Hamsters (Syrian)	404	4.27%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	365	3.86%
Cats	46	0.49%
Dogs	10	0.11%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	4	0.04%
Pigs	50	0.53%
Goats	7	0.07%
Sheep	320	3.38%
Cattle	26	0.27%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	1025	10.84%
Other birds	24	0.25%
Reptiles		
Rana	2920	30.87%
Xenopus		
Other Amphibians	20	0.21%
Zebra fish		
Other Fish		
Cephalopods		
Total	**9460**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	8850	99.55%
Animals born in the EU but not at a registered breeder	40	0.45%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**8890**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	4930	52.11%
Translational and applied research	322	3.4%
Regulatory use and Routine production	1000	10.57%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3208	33.91%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9460**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1480	30.02%
Cardiovascular Blood and Lymphatic System	20	0.41%
Nervous System	950	19.27%
Respiratory System		
Gastrointestinal System including Liver	242	4.91%
Musculoskeletal System		
Immune System	1	0.02%
Urogenital/Reproductive System	3	0.06%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	84	1.7%
Endocrine System/Metabolism	284	5.76%
Multisystemic	624	12.66%
Ethology / Animal Behaviour /Animal Biology	1204	24.42%
Other basic research	38	0.77%
Total	**4930**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	100	31.06%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders	4	1.24%
Animal Welfare		
Diagnosis of diseases	218	67.7%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**322**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	850	85%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	150	15%
Total	**1000**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	700	82.35%
Pyrogenicity testing	150	17.65%
Batch potency testing		
Other quality controls		
Total	**850**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	33.33%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Neurotoxicity	100	66.67%
Total	**150**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	100%
Other lethal methods		
Non lethal methods		
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	900	90%
Legislation on medicinal products for veterinary use and their residues	100	10%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**1000**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1000	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**1000**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	8890	93.97%
Yes	570	6.03%
Total	**9460**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	815	8.62%
Mild [up to and including]	3933	41.58%
Moderate	2508	26.51%
Severe	2204	23.3%
Total	**9460**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9460	100%
Yes		
Total	**9460**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	9460	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**9460**	**100.00%**

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Bulgaria: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

Bulgaria: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2015	21.19%
Rats	2047	21.53%
Guinea-Pigs	1860	19.56%
Hamsters (Syrian)	30	0.32%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	689	7.25%
Cats		
Dogs	60	0.63%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	300	3.16%
Cattle	6	0.06%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	100	1.05%
Other birds		
Reptiles		
Rana	2400	25.24%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**9507**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	9267	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**9267**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	6033	63.46%
Translational and applied research	691	7.27%
Regulatory use and Routine production	180	1.89%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2603	27.38%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9507**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	30	0.5%
Cardiovascular Blood and Lymphatic System		
Nervous System	1529	25.34%
Respiratory System	60	0.99%
Gastrointestinal System including Liver	572	9.48%
Musculoskeletal System	5	0.08%
Immune System	2936	48.67%
Urogenital/Reproductive System	40	0.66%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	10	0.17%
Endocrine System/Metabolism	270	4.48%
Multisystemic	563	9.33%
Ethology / Animal Behaviour /Animal Biology		
Other basic research	18	0.3%
Total	**6033**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	331	47.9%
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	30	4.34%
Other Human Disorders	74	10.71%
Animal Diseases and Disorders	256	37.05%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**691**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	130	72.22%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	50	27.78%
Total	**180**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	130	100%
Total	**130**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	100%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total	50	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	100%
Other lethal methods		
Non lethal methods		
Total	50	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	180	100%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**180**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	180	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**180**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	9267	97.48%
Yes	240	2.52%
Total	**9507**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1474	15.5%
Mild [up to and including]	4016	42.24%
Moderate	1762	18.53%
Severe	2255	23.72%
Total	**9507**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9507	100%
Yes		
Total	**9507**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	9507	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**9507**	**100.00%**

Bulgaria: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

Bulgaria: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	989	11.39%
Rats	1892	21.79%
Guinea-Pigs	1841	21.21%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	568	6.54%
Cats	30	0.35%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	20	0.23%
Goats		
Sheep	340	3.92%
Cattle	15	0.17%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	680	7.83%
Other birds		
Reptiles		
Rana	2306	26.56%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**8681**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	8651	99.65%
Animals born in the EU but not at a registered breeder	30	0.35%

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Place of birth	Number of animals	Percentage
Animals born in rest of Europe		
Animals born in rest of world		
Total	8681	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2246	25.87%
Translational and applied research	19	0.22%
Regulatory use and Routine production	4126	47.53%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2290	26.38%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	8681	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	1651	73.51%
Respiratory System		
Gastrointestinal System including Liver	11	0.49%
Musculoskeletal System	74	3.29%
Immune System	42	1.87%
Urogenital/Reproductive System	45	2%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	56	2.49%
Multisystemic	62	2.76%
Ethology / Animal Behaviour /Animal Biology	235	10.46%

Basic Research	Number of uses	Percentage
Other basic research	70	3.12%
Total	2246	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	19	100%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	19	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2843	68.9%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	238	5.77%
Routine production	1045	25.33%
Total	4126	100.00%

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2843	100%
Batch potency testing		
Other quality controls		
Pyrogenicity testing		
Total	2843	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	38	15.97%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Pharmaco-dynamics (incl safety pharmacology)	150	63.03%
Ecotoxicity	50	21.01%
Total	**238**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	38	100%
Other lethal methods		
Non lethal methods		
Total	**38**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	50	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**50**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	1045	100%
Total	**1045**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3081	74.67%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		

Testing by Legislation	Number of uses	Percentage
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1045	25.33%
Total	**4126**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4126	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**4126**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	8681	100%
Yes		
Total	**8681**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	4547	52.38%
Moderate	3869	44.57%
Severe	265	3.05%
Total	**8681**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	8681	100%
Yes		
Total	**8681**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	8681	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**8681**	**100.00%**

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Croatia

Croatia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

There is an overall decrease in the total number of uses but increase in the use of not genetically altered animals, increase of uses in basic research and decrease in uses for regulatory and routine production. The number of uses for higher education or training for the acquisition, maintenance or improvement of vocational skills is less in number even though it is higher in percentage. There is a significant decrease in testing by legislation and regulatory use and routine production but slightly increase in basic research.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is decrease in 2015 in:
- uses (7,53% (1958)) in 2015 when we compare data from 2015 with the data from 2014:
  - -Testing by legislation – decrease in total – 45,99% (3899)
    - Legislation on medicinal products for human use – 52,73% (1760)
    - Food legislation including food contact material – from 32,87 % in 2014 to 8,40% in 2015
  - Regulatory use and production – decrease in total 45,99 % (3899):
    - Quality control (incl. batch safety and potency testing) – 60,67% (1876)
    - Toxicity and other safety testing including pharmacology – 2091 uses less
    - Other quality controls uses (they are specified as a use for Registration purpose (use of European viper venom antiserum, Equine on dogs), as a method of validation and use of cock RBCs) in number of uses and also in percentage in 2015 – 33,89% (1993)

There is increase in 2015 in:
- Regulatory use and Routine production:
  - – Routine production - 68 uses in 2015 (in 2014 such uses were not reported)
  - Toxicity and other safety testing including pharmacology:
    - Repeated dose toxicity – 80 uses (in 2014 such uses were not reported)

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Severity of procedures	**2014**		**2015**	
	number	**%**	**number**	**%**
Non-recovery	6543	25,17	3714	16,13

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Mild (up to and including)	13 915	53,52	9 273	40,26
Moderate	4 551	17,51	7 994	34,71
Severe	989	3,80	2 051	8,91
Total number	25 998	100	23 032	100

In 2015 (when we compare with 2014) there is:

- an increase of Non-recovery procedures in Basic research but in total it is decrease of Non-recovery procedures (in 2014 it was reported 2659 uses in Basic research, 3445 in Regulatory use and Routine production, 359 in education and 60 in Translation and applied research and in 2015 it was reported 3236 uses in Basic research, nothing in Regulatory use and Routine production, 361 in education and 117 in Translation and applied research)
- an decrease of mild procedures in total
- an increase of moderate procedures in Basic research mainly and in total and
- an increase of severe procedures in Regulatory use and Routine production (in 2014 it was reported 903 uses in Basic research, nothing in Regulatory use and Routine production, 78 in Translation and applied research and 8 in education and in 2015 it was reported 908 uses in Basic research, 1078 in Regulatory use and Routine production and 67 in Translation and applied research)

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- 22 October 2015, 2nd Workshop of the Croatian Society for Laboratory Animal Science, international participation, Implementation of 3R principles, Zagreb, Croatia - for users, breeders, suppliers
- 10th October 2015, 2nd Symposium of Croatian Society for the Science of Laboratory Animals 'Experimental Animals in Scientific Research", Zagreb, Croatia - for users, breeders, suppliers
- 25th March 2015, Scientific Forum, Application and evaluation of projects and experiments using animal models for scientific purposes, Zagreb - for users, breeders, suppliers

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

See point 2.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The exceeded 'severe' classification was not authorised and also not reported.

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Croatia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	16197	70.32%
Rats	5374	23.33%
Guinea-Pigs	264	1.15%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	472	2.05%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	26	0.11%
Pigs	1	0%
Goats		
Sheep	44	0.19%
Cattle	28	0.12%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	626	2.72%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**23032**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	22347	97.65%
Animals born in the EU but not at a registered breeder	538	2.35%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**22885**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	18073	78.47%
Translational and applied research	421	1.83%
Regulatory use and Routine production	3321	14.42%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1217	5.28%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**23032**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	447	2.47%
Cardiovascular Blood and Lymphatic System	412	2.28%
Nervous System	1619	8.96%
Respiratory System	4426	24.49%
Gastrointestinal System including Liver	565	3.13%
Musculoskeletal System	217	1.2%
Immune System	4177	23.11%
Urogenital/Reproductive System	424	2.35%
Sensory Organs (skin, eyes and ears)	431	2.38%
Endocrine System/Metabolism	873	4.83%
Multisystemic	2223	12.3%
Ethology / Animal Behaviour /Animal Biology	28	0.15%
Other basic research	2231	12.34%
Total	**18073**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	92	21.85%
Human Nervous and Mental Disorders	108	25.65%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	185	43.94%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1	0.24%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	35	8.31%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**421**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2894	87.14%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	359	10.81%
Routine production	68	2.05%
Total	**3321**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	569	19.66%
Pyrogenicity testing	63	2.18%
Batch potency testing	1236	42.71%
Other quality controls	1026	35.45%
Total	**2894**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	80	22.28%
Safety testing in food and feed area	279	77.72%
Total	**359**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	80	100%
29 - 90 days		
> 90 days		
Total	**80**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	68	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**68**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1964	59.14%
Legislation on medicinal products for veterinary use and their residues	1078	32.46%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	279	8.4%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**3321**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3321	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**3321**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	22885	99.36%
Yes	147	0.64%
Total	**23032**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3714	16.13%
Mild [up to and including]	9273	40.26%
Moderate	7994	34.71%
Severe	2051	8.91%
Total	**23032**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	23032	100%
Yes		
Total	**23032**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	21756	94.46%
Genetically altered without a harmful phenotype	1143	4.96%
Genetically altered with a harmful phenotype	133	0.58%
Total	**23032**	**100.00%**

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Croatia: Narrative 2016

This report shows statistical data on the number of animals used for scientific purposes during the year 2016. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

1. General information on any changes in trends observed since the previous reporting period.
Data for 2016, in comparison with data from 2014 and 2015:

Purpose	**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**
Total number of animals used for scientific purposes	21,901	100	23,032	100	25,998	100
Basic research	19,183	87.59	18,073	78.47	15,024	57.79
Testing by legislation	988	4.51	3,321	14.42	7,220	27.77
Number of genetically altered animals with a harmful phenotype	129	0.59	133	0.58	3,930	15.12

Compared to the data for 2014 and 2015, the data for 2016 shows:

- an overall decrease in the total number of animals used for scientific purposes
- an increase in number of animals used for basic research and
- a decrease in number of genetically altered animals with a harmful phenotype used for scientific purposes.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

When data from 2016 are compared with data from 2015 and 2014, the following is apparent:

- a significant decrease in number of animals used for regulatory use and routine production
- a significant decrease in number of animals used for testing by legislation
- a decrease in number of animals used in non-recovery and mild procedures and significant decrease in number of animals used in severe procedures while the number of animals used in moderate procedures is significantly higher.
- a significant decrease in number of animals used for regulatory use and routine production (Quality control including batch safety and potency testing).

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3. Information on any changes in trends in actual severities and analysis of the reasons thereof. Compared to the data for 2014 and 2015, the data for 2016 shows:

Severity of procedures	2016		2015		2014	
	number	%	number	%	number	%
Non-recovery	3,220	14.70	3,714	16.13	6,543	25.17
Mild (up to and including)	6,875	31.31	9,273	40.26	13,915	53.52
Moderate	11,394	52.03	7,994	34.71	4,551	17.51
Severe	430	1.96	2,051	8.91	989	3.80
Total number	21,901	100	23,032	100	25,998	100

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- 26 – 29th October 2016, Implementation of legislation on the protection of animals used for scientific purposes, Croatian Veterinary Days 2016, Croatia, Scientific – Proffesional conference with International participation – for veterinary inspectors
- 24th October 2016, Workshop "Best practice and alternatives to animal experiments in education and training", Co-organisers Ministry of Agriculture, Animal Friends Croatia and InterNICHE, Zagreb – for users, breeders, suppliers
- 4th October 2016, Training "Implementation of legislation on the protection of animals in experiments", Medicin School of the University of Rijeka, Croatia - for users, breeders, suppliers
- 3 May 2016, Presentation on education and training in implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes, Zagreb - for users, breeders, suppliers
- Workshop "Animal Experiment Design" organised by *Croatian Laboratory Animal Science Association (CroLASA)*.

5. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The exceeded 'severe' classification was not authorised and also not reported.

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Croatia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	14976	68.38%
Rats	5762	26.31%
Guinea-Pigs	71	0.32%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	704	3.21%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	27	0.12%
Pigs	2	0.01%
Goats		
Sheep	49	0.22%
Cattle	50	0.23%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	260	1.19%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**21901**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	21701	99.59%
Animals born in the EU but not at a registered breeder	89	0.41%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**21790**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	19183	87.59%
Translational and applied research	456	2.08%
Regulatory use and Routine production	988	4.51%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1203	5.49%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	71	0.32%
Total	**21901**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	708	3.69%
Cardiovascular Blood and Lymphatic System	510	2.66%
Nervous System	1613	8.41%
Respiratory System	4564	23.79%
Gastrointestinal System including Liver	663	3.46%
Musculoskeletal System	122	0.64%
Immune System	3861	20.13%
Urogenital/Reproductive System	146	0.76%
Sensory Organs (skin, eyes and ears)	1652	8.61%
Endocrine System/Metabolism	397	2.07%
Multisystemic	2673	13.93%
Ethology / Animal Behaviour /Animal Biology	88	0.46%
Other basic research	2186	11.4%
Total	**19183**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	70	15.35%
Human Infectious Disorders		
Human Cardiovascular Disorders	119	26.1%
Human Nervous and Mental Disorders	60	13.16%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	37	8.11%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	120	26.32%
Other Human Disorders		
Animal Diseases and Disorders	50	10.96%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**456**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	831	84.11%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	98	9.92%
Routine production	59	5.97%
Total	**988**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	210	25.27%
Pyrogenicity testing	67	8.06%
Batch potency testing	194	23.35%
Other quality controls	360	43.32%
Total	**831**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	88	89.8%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	4	4.08%
Kinetics	6	6.12%
Total	**98**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	88	100%
Total	**88**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4	100%
29 - 90 days		
> 90 days		
Total	**4**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	59	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**59**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	618	62.55%
Legislation on medicinal products for veterinary use and their residues	364	36.84%
Medical devices legislation	6	0.61%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**988**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	988	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**988**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	21790	99.49%
Yes	111	0.51%
Total	**21901**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3220	14.7%
Mild [up to and including]	6857	31.31%
Moderate	11394	52.03%
Severe	430	1.96%
Total	**21901**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	21901	100%
Yes		
Total	**21901**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19422	88.68%
Genetically altered without a harmful phenotype	2350	10.73%
Genetically altered with a harmful phenotype	129	0.59%
Total	**21901**	**100.00%**

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Croatia: Narrative 2017

This report shows statistical data on the number of animals used for scientific purposes during the year 2017. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

1. General information on any changes in trends observed since the previous reporting periods.

1) Animal Species used for scientific procedures

Data for 2017, 2016, 2015 and 2014:

Animal Species	**2017**		**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**	**number**	**%**
Mice	19,806	69.41	14,976	68.38	16,197	70.32	19,427	74.72
Rats	7,700	26.99	5,762	26.31	5,374	23.33	4,962	19.09
Guinea Pigs	21	0.07	71	0.32	264	1.15	488	1.88
Rabbits	426	1,49	704	3.21	472	2.05	331	1.27
Horses, donkeys and cross-breeds	25	0.09	27	0.12	26	0.11	0	0
Pigs	2	0.01	2	0.01	1	0.00	0	0
Sheep	39	0.14	49	0.22	44	0.19	18	0.07
Cattle	30	0.11	50	0.23	28	0.12	0	0
Domestic fowl	255	0.89	260	1.19	626	2.72	772	2.97
Zebra fish	230	0.81	0	0	0	0	0	0
SUMMARY	28,534	100	21,901	100	23,032	100	25,998	100

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

- an overall decrease in the total number of animals used for scientific purposes and most in mice and rats
- Zebra fish as new animal model has been reported

2) Information on any changes in trends in Purpose

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

Purpose	**2017**		**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**	**number**	**%**
Total number of animals used for scientific purposes	28,534	100	21,901	100	23,032	100	25,998	100

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Basic research	22,067	77.36	19,183	87.59	18,073	78.47	15,024	57.79
Translational and applied research	2,761	9,68	456	2,08	421	1.83	671	2.58
Regulatory use and routine production	2,182	7.65	988	4.51	3,321	14.42	7,220	27.77
Higher education or training for acquisition, maintenance or improvement of vocational skills	1,428	5,01	1,203	5,49	1,217	5.28	0	0
Maintenance of colonies of established genetically altered animals, not used in other procedures	96	0,34	71	0,32	0	0	0	0

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

- an increase in the total number of animals used for basic and translational/applied research and regulatory use and routine production
- in 2017 and 2016 the data for maintenance of colonies of established genetically altered animals, not used in other procedures have been reported.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

When data from 2017 are compared with the data from 2016, 2015 and 2014, the following is apparent:

- a significant increase in the total number of animals used for translational/applied research and regulatory use and routine production
- an overall decrease in the total number of rabbits and domestic fowl used for scientific purposes
- increase of number of animals not used for creation of new GL
- for the first time use of animals for use for creation of new GL reported
- increase of number of not genetically altered animals and genetically altered animals without a harmful phenotype
- decrease of number of animals genetically altered with a harmful phenotype
- no animals in pyrogenicity testing are reported

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

Severity of procedures	2017		2016		2015		2014	
	number	%	number	%	number	%	number	%
Non-recovery	3,005	10.53	3,220	14.70	3,714	16.13	6,543	25.17
Mild (up to and including)	8,338	29.22	6,875	31.31	9,273	40.26	13,915	53.52
Moderate	11,593	40.63	11,394	52.03	7,994	34.71	4,551	17.51
Severe	5,598	19.62	430	1.96	2,051	8.91	989	3.80
Total number	28,534	100	21,901	100	23,032	100	25,998	100

- an increase in number of animals used in mild and severe procedures but in percentage there is a decrease in all categories except in “severe” where the significant increase is reported

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

- 2nd Workshop “Animal Experiment Design” organised by *Croatian Laboratory Animal Science Association (CroLASA), 19-20 October 2017*

- Workshop "How to submit an experiment on animals for approval", 2017

5. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

The exceeded 'severe' classification was not authorised and also not reported.

Croatia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	19806	69.41%
Rats	7700	26.99%
Guinea-Pigs	21	0.07%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	426	1.49%
Cats		

Animal Species	Number of animals	Percentage
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	25	0.09%
Pigs	2	0.01%
Goats		
Sheep	39	0.14%
Cattle	30	0.11%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	255	0.89%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	230	0.81%
Other Fish		
Cephalopods		
Total	**28534**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	28292	99.51%
Animals born in the EU but not at a registered breeder	60	0.21%
Animals born in rest of Europe		
Animals born in rest of world	79	0.28%
Total	**28431**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	22067	77.34%
Translational and applied research	2761	9.68%
Regulatory use and Routine production	2182	7.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1428	5%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	96	0.34%
Total	**28534**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1345	6.1%
Cardiovascular Blood and Lymphatic System	378	1.71%
Nervous System	1428	6.47%
Respiratory System	5721	25.93%
Gastrointestinal System including Liver	2069	9.38%
Musculoskeletal System	30	0.14%
Immune System	3764	17.06%
Urogenital/Reproductive System	234	1.06%
Sensory Organs (skin, eyes and ears)	688	3.12%
Endocrine System/Metabolism	384	1.74%
Multisystemic	4582	20.76%
Ethology / Animal Behaviour /Animal Biology	122	0.55%
Other basic research	1322	5.99%
Total	**22067**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	230	8.33%
Human Infectious Disorders	1394	50.49%
Human Cardiovascular Disorders	510	18.47%
Human Nervous and Mental Disorders	214	7.75%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	28	1.01%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	60	2.17%
Other Human Disorders		
Animal Diseases and Disorders	30	1.09%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	295	10.68%
Total	**2761**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1585	72.64%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	556	25.48%
Routine production	41	1.88%
Total	**2182**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	262	16.53%
Pyrogenicity testing		
Batch potency testing	128	8.08%
Other quality controls	1195	75.39%
Total	**1585**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	556	100%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total	**556**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	556	100%
Total	**556**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	41	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**41**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1799	82.45%
Legislation on medicinal products for veterinary use and their residues	383	17.55%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**2182**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2182	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2182**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	28431	99.64%
Yes	103	0.36%
Total	**28534**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3005	10.53%
Mild [up to and including]	8338	29.22%
Moderate	11593	40.63%
Severe	5598	19.62%
Total	**28534**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	28304	99.19%
Yes	230	0.81%
Total	**28534**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	26027	91.21%
Genetically altered without a harmful phenotype	2452	8.59%
Genetically altered with a harmful phenotype	55	0.19%
Total	**28534**	**100.00%**

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Cyprus

Cyprus: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a significant increase in the use of animals in 2015 (almost doubled) due to the improvement of the economic situation in Cyprus that resulted in increased funds for research.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1141	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		

Animal Species	Number of animals	Percentage
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	1141	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1141	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	1141	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		

NHP Generation	Number of animals	Percentage
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	685	60.04%
Translational and applied research	456	39.96%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	1141	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	126	18.39%
Cardiovascular Blood and Lymphatic System		
Nervous System	476	69.49%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	83	12.12%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	685	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	215	47.15%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	241	52.85%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		

Translational and applied research	Number of uses	Percentage
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	456	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

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First uses and re-uses

Re-use	Number of uses	Percentage
No	1141	100%
Yes		
Total	**1141**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	110	9.64%
Mild [up to and including]	700	61.35%
Moderate	331	29.01%
Severe		
Total	**1141**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1141	100%
Yes		
Total	**1141**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	607	53.2%
Genetically altered without a harmful phenotype	434	38.04%
Genetically altered with a harmful phenotype	100	8.76%
Total	**1141**	**100.00%**

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Cyprus: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a slight expected increase in the number of animal use in 2016 due to the further improvement of the economic situation in Cyprus.

-

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1448	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		

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Animal Species	Number of animals	Percentage
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	1448	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1448	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	1448	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		

NHP Generation	Number of animals	Percentage
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	927	64.02%
Translational and applied research	521	35.98%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	1448	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	108	11.65%
Cardiovascular Blood and Lymphatic System		
Nervous System	350	37.76%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	250	26.97%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	180	19.42%
Endocrine System/Metabolism	39	4.21%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	927	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	404	77.54%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	117	22.46%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		

Translational and applied research	Number of uses	Percentage
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	521	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	1448	100%
Yes		

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Re-use	Number of uses	Percentage
Total	**1448**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	1244	85.91%
Moderate	204	14.09%
Severe		
Total	**1448**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1448	100%
Yes		
Total	**1448**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	789	54.49%
Genetically altered without a harmful phenotype	659	45.51%
Genetically altered with a harmful phenotype		
Total	**1448**	**100.00%**

Cyprus: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In general there were no significant changes in the numbers of animals used since the previous reporting periods.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1209	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		

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Animal Species	Number of animals	Percentage
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	1209	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1209	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	1209	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		

NHP Generation	Number of animals	Percentage
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	839	69.4%
Translational and applied research	370	30.6%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	1209	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	129	15.38%
Cardiovascular Blood and Lymphatic System	17	2.03%
Nervous System	368	43.86%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	275	32.78%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	50	5.96%
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	839	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	370	100%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		

Translational and applied research	Number of uses	Percentage
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	370	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	1209	100%
Yes		

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Re-use	Number of uses	Percentage
Total	**1209**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	1197	99.01%
Moderate	12	0.99%
Severe		
Total	**1209**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1209	100%
Yes		
Total	**1209**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	623	51.53%
Genetically altered without a harmful phenotype	586	48.47%
Genetically altered with a harmful phenotype		
Total	**1209**	**100.00%**

Czechia

Czechia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In 2015 statistical data there are no changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2015 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2015 statistical data.

Czechia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	73415	31.94%
Rats	24200	10.53%
Guinea-Pigs	1008	0.44%
Hamsters (Syrian)	48	0.02%
Hamsters (Chinese)		
Mongolian gerbil	18	0.01%
Other Rodents	988	0.43%
Rabbits	4840	2.11%
Cats	341	0.15%

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Animal Species	Number of animals	Percentage
Dogs	1135	0.49%
Ferrets	154	0.07%
Other carnivores	10	0%
Horses, donkeys and cross-breeds	113	0.05%
Pigs	2118	0.92%
Goats	318	0.14%
Sheep	1468	0.64%
Cattle	1941	0.84%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	6	0%
Rhesus monkey	51	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	36	0.02%
Domestic fowl	22962	9.99%
Other birds	3003	1.31%
Reptiles	453	0.2%
Rana	100	0.04%
Xenopus	135	0.06%
Other Amphibians	675	0.29%
Zebra fish	2729	1.19%
Other Fish	87604	38.11%
Cephalopods		
Total	**229869**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	197689	87.69%
Animals born in the EU but not at a registered breeder	27419	12.16%
Animals born in rest of Europe		
Animals born in rest of world	334	0.15%
Total	**225442**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		

NHP Generation	Number of animals	Percentage
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	85456	37.18%
Translational and applied research	26835	11.67%
Regulatory use and Routine production	61272	26.66%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	40441	17.59%
Preservation of species	176	0.08%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	15673	6.82%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	16	0.01%
Total	**229869**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	12911	15.11%
Cardiovascular Blood and Lymphatic System	7180	8.4%
Nervous System	13447	15.74%
Respiratory System	314	0.37%
Gastrointestinal System including Liver	1862	2.18%
Musculoskeletal System	509	0.6%
Immune System	11136	13.03%
Urogenital/Reproductive System	8142	9.53%
Sensory Organs (skin, eyes and ears)	549	0.64%
Endocrine System/Metabolism	3889	4.55%
Multisystemic	5835	6.83%
Ethology / Animal Behaviour /Animal Biology	8909	10.43%
Other basic research	10773	12.61%
Total	**85456**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1631	6.08%
Human Infectious Disorders	541	2.02%
Human Cardiovascular Disorders	426	1.59%
Human Nervous and Mental Disorders	803	2.99%
Human Respiratory Disorders	12	0.04%
Human Gastrointestinal Disorders including Liver	45	0.17%
Human Musculoskeletal Disorders	79	0.29%
Human Immune Disorders	219	0.82%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	30	0.11%
Human Endocrine/Metabolism Disorders	1183	4.41%
Other Human Disorders	60	0.22%

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	7189	26.79%
Animal Welfare	7541	28.1%
Diagnosis of diseases	6913	25.76%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	163	0.61%
Total	**26835**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	11354	18.53%
Other efficacy and tolerance testing	219	0.36%
Toxicity and other safety testing including pharmacology	29613	48.33%
Routine production	20086	32.78%
Total	**61272**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1742	15.34%
Pyrogenicity testing	72	0.63%
Batch potency testing	9354	82.39%
Other quality controls	186	1.64%
Total	**11354**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3091	10.44%
Skin irritation/corrosion	12	0.04%
Skin sensitisation	568	1.92%
Eye irritation/corrosion	9	0.03%
Repeated dose toxicity	1532	5.17%
Carcinogenicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Target animal safety		
Genotoxicity	109	0.37%
Reproductive toxicity	1256	4.24%
Developmental toxicity	658	2.22%
Kinetics	554	1.87%
Ecotoxicity	21394	72.25%
Safety testing in food and feed area	72	0.24%
Other toxicity/safety testing	358	1.21%
Total	**29613**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1650	53.38%
Other lethal methods	1435	46.43%
Non lethal methods	6	0.19%
Total	**3091**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	782	51.04%
29 - 90 days	540	35.25%
> 90 days	210	13.71%
Total	**1532**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	19257	90.01%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	2137	9.99%
Total	**21394**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	899	4.48%
Monoclonal antibody by mouse ascites method		
Other product types	19187	95.52%
Total	**20086**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3476	5.67%
Legislation on medicinal products for veterinary use and their residues	29178	47.62%
Medical devices legislation	1320	2.15%
Industrial chemicals legislation	2685	4.38%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	817	1.33%
Feed legislation including legislation for the safety of target animals, workers and environment	12	0.02%
Cosmetics legislation		
Other legislation	23784	38.82%
Total	**61272**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	49869	81.39%
Legislation satisfying national requirements only [within EU]	11403	18.61%
Legislation satisfying Non-EU requirements only		
Total	**61272**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225442	98.07%
Yes	4427	1.93%
Total	**229869**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21573	9.38%
Mild [up to and including]	124277	54.06%
Moderate	60578	26.35%
Severe	23441	10.2%
Total	**229869**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	221507	96.36%
Yes	8362	3.64%
Total	**229869**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	204049	88.77%
Genetically altered without a harmful phenotype	24009	10.44%
Genetically altered with a harmful phenotype	1811	0.79%
Total	**229869**	**100.00%**

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Czechia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In 2016 statistical data there are no changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2016 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2016 statistical data.

Czechia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	78249	32.92%
Rats	30323	12.76%
Guinea-Pigs	1202	0.51%
Hamsters (Syrian)	82	0.03%
Hamsters (Chinese)		
Mongolian gerbil	30	0.01%
Other Rodents	1122	0.47%
Rabbits	6834	2.88%
Cats	240	0.1%
Dogs	797	0.34%
Ferrets	42	0.02%

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Animal Species	Number of animals	Percentage
Other carnivores	53	0.02%
Horses, donkeys and cross-breeds	155	0.07%
Pigs	2173	0.91%
Goats	48	0.02%
Sheep	1032	0.43%
Cattle	2978	1.25%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	9	0%
Rhesus monkey	26	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	37	0.02%
Domestic fowl	27261	11.47%
Other birds	3124	1.31%
Reptiles	915	0.39%
Rana		
Xenopus	58	0.02%
Other Amphibians	819	0.34%
Zebra fish	4495	1.89%
Other Fish	75558	31.79%
Cephalopods		
Total	**237662**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	212176	90.81%
Animals born in the EU but not at a registered breeder	21429	9.17%
Animals born in rest of Europe		
Animals born in rest of world	51	0.02%
Total	**233656**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		

NHP Generation	Number of animals	Percentage
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	87751	36.92%
Translational and applied research	25941	10.92%
Regulatory use and Routine production	74739	31.45%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	32752	13.78%
Preservation of species	228	0.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	16143	6.79%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	108	0.05%
Total	**237662**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	11267	12.84%
Cardiovascular Blood and Lymphatic System	12055	13.74%
Nervous System	12066	13.75%
Respiratory System	1511	1.72%
Gastrointestinal System including Liver	2348	2.68%
Musculoskeletal System	46	0.05%
Immune System	7811	8.9%
Urogenital/Reproductive System	9041	10.3%
Sensory Organs (skin, eyes and ears)	750	0.85%
Endocrine System/Metabolism	4128	4.7%
Multisystemic	4223	4.81%
Ethology / Animal Behaviour /Animal Biology	7278	8.29%
Other basic research	15227	17.35%
Total	**87751**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3288	12.67%
Human Infectious Disorders	905	3.49%
Human Cardiovascular Disorders	969	3.74%
Human Nervous and Mental Disorders	674	2.6%
Human Respiratory Disorders	12	0.05%
Human Gastrointestinal Disorders including Liver	137	0.53%
Human Musculoskeletal Disorders	93	0.36%
Human Immune Disorders	368	1.42%
Human Urogenital/Reproductive Disorders	551	2.12%
Human Sensory Organ Disorders (skin, eyes and ears)	39	0.15%
Human Endocrine/Metabolism Disorders	1191	4.59%
Other Human Disorders	107	0.41%
Animal Diseases and Disorders	5469	21.08%
Animal Welfare	3611	13.92%

Translational and applied research	Number of uses	Percentage
Diagnosis of diseases	8227	31.71%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	300	1.16%
Total	**25941**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	17569	23.51%
Other efficacy and tolerance testing	316	0.42%
Toxicity and other safety testing including pharmacology	36408	48.71%
Routine production	20446	27.36%
Total	**74739**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1574	8.96%
Pyrogenicity testing	51	0.29%
Batch potency testing	15636	89%
Other quality controls	308	1.75%
Total	**17569**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	14946	41.05%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation	570	1.57%
Eye irritation/corrosion	3	0.01%
Repeated dose toxicity	958	2.63%
Reproductive toxicity	5497	15.1%
Developmental toxicity	127	0.35%
Kinetics	511	1.4%
Ecotoxicity	13552	37.22%
Safety testing in food and feed area	40	0.11%
Target animal safety	12	0.03%
Other toxicity/safety testing	192	0.53%
Total	**36408**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	12250	81.96%
Other lethal methods	2668	17.85%
Non lethal methods	28	0.19%
Total	**14946**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	538	56.16%
29 - 90 days	420	43.84%
> 90 days		
Total	**958**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	12132	89.52%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	1420	10.48%
Total	**13552**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	838	4.1%
Monoclonal antibody by mouse ascites method		
Other product types	19608	95.9%
Total	**20446**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3069	4.11%
Legislation on medicinal products for veterinary use and their residues	35721	47.79%
Medical devices legislation	1110	1.49%
Industrial chemicals legislation	6746	9.03%
Plant protection product legislation		
Biocides legislation	5	0.01%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	28088	37.58%
Total	**74739**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	51716	69.2%
Legislation satisfying national requirements only [within EU]	23023	30.8%
Legislation satisfying Non-EU requirements only		
Total	**74739**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	233656	98.31%
Yes	4006	1.69%
Total	**237662**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	23268	9.79%
Mild [up to and including]	87633	36.87%
Moderate	77641	32.67%
Severe	49120	20.67%
Total	**237662**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	224531	94.47%
Yes	13131	5.53%
Total	**237662**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	205032	86.27%
Genetically altered without a harmful phenotype	30738	12.93%
Genetically altered with a harmful phenotype	1892	0.8%
Total	**237662**	**100.00%**

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Czechia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In the last three years appears trend increasing number of animal used for preservation of species, in year 2017 is the number of these animals more significant than 2 years ago. In 2017 statistical data there are no other changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in trends in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2017 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2017 statistical data.

Czechia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	82219	34.02%
Rats	26967	11.16%
Guinea-Pigs	1383	0.57%
Hamsters (Syrian)	15	0.01%
Hamsters (Chinese)		
Mongolian gerbil	46	0.02%
Other Rodents	635	0.26%
Rabbits	2133	0.88%

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Animal Species	Number of animals	Percentage
Cats	132	0.05%
Dogs	637	0.26%
Ferrets	1	0%
Other carnivores	1	0%
Horses, donkeys and cross-breeds	105	0.04%
Pigs	2447	1.01%
Goats	97	0.04%
Sheep	918	0.38%
Cattle	2734	1.13%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	21217	8.78%
Other birds	4260	1.76%
Reptiles	558	0.23%
Rana		
Xenopus	50	0.02%
Other Amphibians	531	0.22%
Zebra fish	19765	8.18%
Other Fish	74861	30.97%
Cephalopods		
Total	**241712**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	213502	95.63%
Animals born in the EU but not at a registered breeder	9222	4.13%
Animals born in rest of Europe		
Animals born in rest of world	539	0.24%
Total	**223263**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	100107	41.42%
Translational and applied research	27657	11.44%
Regulatory use and Routine production	54133	22.4%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	47646	19.71%
Preservation of species	6437	2.66%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5732	2.37%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**241712**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	8918	8.91%
Cardiovascular Blood and Lymphatic System	22979	22.95%
Nervous System	9106	9.1%
Respiratory System	503	0.5%
Gastrointestinal System including Liver	1727	1.73%
Musculoskeletal System	484	0.48%
Immune System	13127	13.11%
Urogenital/Reproductive System	12105	12.09%
Sensory Organs (skin, eyes and ears)	525	0.52%
Endocrine System/Metabolism	3777	3.77%
Multisystemic	6311	6.3%
Ethology / Animal Behaviour /Animal Biology	7542	7.53%
Other basic research	13003	12.99%
Total	**100107**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3761	13.6%
Human Infectious Disorders	1309	4.73%
Human Cardiovascular Disorders	1308	4.73%
Human Nervous and Mental Disorders	2009	7.26%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	861	3.11%
Human Musculoskeletal Disorders	114	0.41%
Human Immune Disorders	303	1.1%
Human Urogenital/Reproductive Disorders	496	1.79%
Human Sensory Organ Disorders (skin, eyes and ears)	112	0.4%
Human Endocrine/Metabolism Disorders	2066	7.47%

Translational and applied research	Number of uses	Percentage
Other Human Disorders	379	1.37%
Animal Diseases and Disorders	3643	13.17%
Animal Welfare	3914	14.15%
Diagnosis of diseases	7373	26.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	9	0.03%
Total	**27657**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	12209	22.55%
Other efficacy and tolerance testing	326	0.6%
Toxicity and other safety testing including pharmacology	25293	46.72%
Routine production	16305	30.12%
Total	**54133**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	523	4.28%
Pyrogenicity testing	81	0.66%
Batch potency testing	11397	93.35%
Other quality controls	208	1.7%
Total	**12209**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	4646	18.37%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation	637	2.52%
Eye irritation/corrosion	18	0.07%
Repeated dose toxicity	1440	5.69%
Reproductive toxicity	3136	12.4%
Developmental toxicity	274	1.08%
Kinetics	144	0.57%
Pharmaco-dynamics (incl safety pharmacology)	24	0.09%
Ecotoxicity	14374	56.83%
Safety testing in food and feed area	438	1.73%
Target animal safety	50	0.2%
Other toxicity/safety testing	112	0.44%
Total	**25293**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	994	21.39%
Other lethal methods	3652	78.61%
Non lethal methods		
Total	**4646**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	482	33.47%
29 - 90 days	552	38.33%
> 90 days	406	28.19%
Total	**1440**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	12714	88.45%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	1660	11.55%
Total	**14374**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	777	4.77%
Monoclonal antibody by mouse ascites method	230	1.41%
Other product types	15298	93.82%
Total	**16305**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2682	4.95%
Legislation on medicinal products for veterinary use and their residues	27478	50.76%
Medical devices legislation	1411	2.61%
Industrial chemicals legislation	4345	8.03%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	170	0.31%
Feed legislation including legislation for the safety of target animals, workers and environment	525	0.97%
Cosmetics legislation		
Other legislation	17522	32.37%
Total	**54133**	**100.00%**

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Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	44484	82.18%
Legislation satisfying national requirements only [within EU]	9649	17.82%
Legislation satisfying Non-EU requirements only		
Total	**54133**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	223263	92.37%
Yes	18449	7.63%
Total	**241712**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	19114	7.91%
Mild [up to and including]	110130	45.56%
Moderate	96317	39.85%
Severe	16151	6.68%
Total	**241712**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	216026	89.37%
Yes	25686	10.63%
Total	**241712**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	199255	82.43%
Genetically altered without a harmful phenotype	39574	16.37%
Genetically altered with a harmful phenotype	2883	1.19%
Total	**241712**	**100.00%**

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Denmark

Denmark: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period

Although the number of animals reported in Denmark has been declining for many years, and the total number for 2014 , reported only about 200.000 animals, the number reported for 2015 has increased to about 242.000 animals. This number is almost identical to the number of animals reported for 2013. However, the number for 2014 cannot be compared to previous years, as the reporting format has been changed. These data for 2015 suggest that the number of animals used for research has stabilized around 240.000 animals.

The number of pigs has increased significantly in 2015. The increase is primarily caused by an increase in research using pigs as animal models for human diseases. Also the number of cats has increased significantly in 2015. This is caused by clinical studies in treatment of type-2 diabetes in cats. The number of fish has also increased significantly in 2015. This is primarily caused by an increase in research in aqua cultures. Furthermore in a small country with a small scientific community, the change of focus in one or a few research groups can have a significant impact on the statistics for the whole country.

2. Information on significant increase or decrease in used animals in any of the specific areas and analysis of the reasons thereof

No major significant changes are visible in the statistics from 2015

3. Information on any changes in trends in actual severities and analysis of the reasons thereof

In general only few experiments with severe strain are licensed. This is reflected in that the actual reported severity is 0.89%. This is a decrease compared to 1.5% reported for 2014.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Denmark has established a 3R-center operating from 2014. The centre is funding 3R-research, collection and dissemination information on the 3R´s and establishing initiatives to analyze and implement 3R-strategies. Read more here: http://en.3rcenter.dk/

Furthermore the Danish National Committee strongly supports and collaborates with the animal welfare bodies, i.e. yearly meeting for all bodies, hands on exchange of best practice between institutions and companies and best practice guideline. Visit the website: Danish National Committee

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category

As Denmark has a relatively large production of trout, the species is commonly used in research. Hence it would be a good idea with a specific category for trout. Furthermore Denmark also has a large mink

industry, and this species too is often used in research. A specific category for mink will also be appreciated.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The classification “severe” has not been exceeded in 2015 in Denmark.

Denmark: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	155141	63.64%
Rats	48614	19.94%
Guinea-Pigs	2643	1.08%
Hamsters (Syrian)	172	0.07%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	86	0.04%
Rabbits	1665	0.68%
Cats	59	0.02%
Dogs	157	0.06%
Ferrets		
Other carnivores	886	0.36%
Horses, donkeys and cross-breeds	115	0.05%
Pigs	10576	4.34%
Goats	11	0%
Sheep	47	0.02%
Cattle	534	0.22%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	38	0.02%
Domestic fowl	2407	0.99%
Other birds	438	0.18%
Reptiles	265	0.11%
Rana		
Xenopus	64	0.03%
Other Amphibians	26	0.01%
Zebra fish	2530	1.04%
Other Fish	17318	7.1%
Cephalopods		
Total	**243792**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	205674	85.32%
Animals born in the EU but not at a registered breeder	27687	11.49%
Animals born in rest of Europe	1311	0.54%
Animals born in rest of world	6397	2.65%
Total	**241069**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	88453	36.28%
Translational and applied research	123439	50.63%
Regulatory use and Routine production	22956	9.42%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2660	1.09%
Preservation of species	258	0.11%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6023	2.47%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	3	0%
Total	**243792**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	5382	6.08%
Cardiovascular Blood and Lymphatic System	4860	5.49%
Nervous System	15725	17.78%
Respiratory System	1262	1.43%
Gastrointestinal System including Liver	2539	2.87%
Musculoskeletal System	2682	3.03%
Immune System	29246	33.06%
Urogenital/Reproductive System	2623	2.97%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	1503	1.7%
Endocrine System/Metabolism	12561	14.2%
Multisystemic	883	1%
Ethology / Animal Behaviour /Animal Biology	4924	5.57%
Other basic research	4263	4.82%
Total	**88453**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	9115	7.38%
Human Infectious Disorders	4683	3.79%
Human Cardiovascular Disorders	1404	1.14%
Human Nervous and Mental Disorders	35568	28.81%
Human Respiratory Disorders	75	0.06%
Human Gastrointestinal Disorders including Liver	258	0.21%
Human Musculoskeletal Disorders	400	0.32%
Human Immune Disorders	10037	8.13%
Human Urogenital/Reproductive Disorders	66	0.05%
Human Sensory Organ Disorders (skin, eyes and ears)	852	0.69%
Human Endocrine/Metabolism Disorders	39839	32.27%
Other Human Disorders	9137	7.4%
Animal Diseases and Disorders	7934	6.43%
Animal Welfare	3248	2.63%
Diagnosis of diseases	682	0.55%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	141	0.11%
Total	**123439**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	14819	64.55%
Other efficacy and tolerance testing	95	0.41%
Toxicity and other safety testing including pharmacology	8021	34.94%
Routine production	21	0.09%
Total	**22956**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3687	24.88%
Pyrogenicity testing		
Batch potency testing	11105	74.94%
Other quality controls	27	0.18%
Total	**14819**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	786	9.8%
Skin irritation/corrosion	12	0.15%
Skin sensitisation	138	1.72%
Eye irritation/corrosion	6	0.07%
Repeated dose toxicity	1755	21.88%
Carcinogenicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Developmental toxicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Kinetics	2095	26.12%
Pharmaco-dynamics (incl safety pharmacology)	9	0.11%
Ecotoxicity	3080	38.4%
Target animal safety	120	1.5%
Other toxicity/safety testing	20	0.25%
Total	**8021**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	80	10.18%
Other lethal methods		
Non lethal methods	706	89.82%
Total	**786**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1136	64.73%
29 - 90 days	488	27.81%
> 90 days	131	7.46%
Total	**1755**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	3080	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**3080**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	21	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**21**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19630	85.51%
Legislation on medicinal products for veterinary use and their residues	142	0.62%
Medical devices legislation	24	0.1%
Industrial chemicals legislation	1360	5.92%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1800	7.84%
Total	**22956**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	21134	92.06%
Legislation satisfying national requirements only [within EU]	1822	7.94%
Legislation satisfying Non-EU requirements only		
Total	**22956**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	241069	98.88%
Yes	2723	1.12%
Total	**243792**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21199	8.7%
Mild [up to and including]	136701	56.07%
Moderate	83727	34.34%
Severe	2165	0.89%
Total	**243792**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	238948	98.01%
Yes	4844	1.99%
Total	**243792**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	204237	83.78%
Genetically altered without a harmful phenotype	26191	10.74%
Genetically altered with a harmful phenotype	13364	5.48%
Total	**243792**	**100.00%**

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Denmark: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period

The overall number at animals used for scientific purposes in Denmark in 2016 is 253.546. In 2015 the same number was 244.411animals. This strengthens a trend, that the number of animals used in Denmark has been relatively stable over the last years.

As usually, mice, rats and fish covers more than 90 % of the animals, but the number of fish has increased a lot, going from 19.848 to 51.659. See 2. for further specification. At the same time, the number of mice and rats has decreased by 10 %.

The percentage of animals used for basic research has increased from 36 % to 41 %. This is due to the fact, that increased number of fish primarily has been used in basic research.

Animals used for regulatory purposes and for routine production have decreased from 9 % to less than 6 %.

Finally the number of animals experiencing severe suffering has doubled in 2016, still being on a relative low level of 1.78 %.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof

The clearest trend in 2016 was the large increase in the use of fish for research. But almost the whole increase was due to introduction of a new species and a new field of research in the statistics. There is a very strong research community in Denmark concerning breeding eel for human consumption.

Until now it has not been possible to breed eel, which could survive beyond the larvae stadium. However due to scientific breakthroughs, it has recently changed, and the bread eel larvae now develop into fish covered by the directive. This covers a number of 23.935 animals, accounting for almost the whole increase in the use of fish. Procedures also covered by the directive are then performed on the animals, making them part of the statistic.

As this is a very important and economical interesting area, the numbers of eel in research are suspected to rise in the coming years. As this area is considered to be basic research, the increase in eel will affect the ratio.

In regard to the decrease in the numbers of rats and mice, the overall assessment is, that a stronger competition on research grands and stronger financially focus on the universities have made an impact on the number of research project using animals.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

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The number of animals experiencing severe severity has doubled in 2016 from 0,89 % to 1,75 %. The main reason is that two large research groups have had specific new focus on models with the highest severity. As Denmark generally has few animals experiencing severe severity, a new focus from just one or two research groups will affect the numbers dramatically. However the level of severe severity in Denmark is still relatively low.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Also in 2016, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on www.3rcenter.dk.

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2016. Further information can be found on: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposium for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

It is difficult to investigate whether these efforts has a directly impact on the use of animals for research. However the decrease in the numbers of traditional animals as mice and rats will be followed to see, if some of this decrease has been influenced by the 3R initiatives.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The use of “other” categories has been used on an acceptable level in 2016.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No cases of animal experiencing the severe clarification exceeded was recorded in 2016 in Denmark.

Denmark: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	169970	58.77%
Rats	47575	16.45%
Guinea-Pigs	3362	1.16%
Hamsters (Syrian)	152	0.05%
Hamsters (Chinese)		
Mongolian gerbil		

Animal Species	Number of animals	Percentage
Other Rodents	4	0%
Rabbits	2370	0.82%
Cats	18	0.01%
Dogs	266	0.09%
Ferrets	2	0%
Other carnivores	627	0.22%
Horses, donkeys and cross-breeds	328	0.11%
Pigs	8066	2.79%
Goats	6	0%
Sheep	37	0.01%
Cattle	2077	0.72%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	55	0.02%
Domestic fowl	1732	0.6%
Other birds	373	0.13%
Reptiles	220	0.08%
Rana		
Xenopus	56	0.02%
Other Amphibians	30	0.01%
Zebra fish	3308	1.14%
Other Fish	48591	16.8%
Cephalopods		
Total	**289225**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	236103	83.01%
Animals born in the EU but not at a registered breeder	40201	14.13%
Animals born in rest of Europe	684	0.24%
Animals born in rest of world	7456	2.62%
Total	**284444**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	104787	36.23%
Translational and applied research	153016	52.91%
Regulatory use and Routine production	21532	7.44%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2792	0.97%
Preservation of species	1491	0.52%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5547	1.92%
Forensic enquiries	60	0.02%
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**289225**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6312	6.02%
Cardiovascular Blood and Lymphatic System	4789	4.57%
Nervous System	17706	16.9%
Respiratory System	1601	1.53%
Gastrointestinal System including Liver	4618	4.41%
Musculoskeletal System	2723	2.6%
Immune System	19079	18.21%
Urogenital/Reproductive System	1538	1.47%
Sensory Organs (skin, eyes and ears)	876	0.84%
Endocrine System/Metabolism	13964	13.33%
Multisystemic	949	0.91%
Ethology / Animal Behaviour /Animal Biology	25748	24.57%
Other basic research	4884	4.66%
Total	**104787**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	27113	17.72%
Human Infectious Disorders	6632	4.33%
Human Cardiovascular Disorders	1786	1.17%
Human Nervous and Mental Disorders	34826	22.76%
Human Respiratory Disorders	137	0.09%
Human Gastrointestinal Disorders including Liver	139	0.09%
Human Musculoskeletal Disorders	401	0.26%
Human Immune Disorders	7015	4.58%
Human Urogenital/Reproductive Disorders	641	0.42%
Human Sensory Organ Disorders (skin, eyes and ears)	455	0.3%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	40930	26.75%
Other Human Disorders	9135	5.97%
Animal Diseases and Disorders	19732	12.9%
Animal Welfare	2524	1.65%
Diagnosis of diseases	884	0.58%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	666	0.44%
Total	**153016**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	8833	41.02%
Other efficacy and tolerance testing	113	0.52%
Toxicity and other safety testing including pharmacology	12586	58.45%
Routine production		
Total	**21532**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3295	37.3%
Pyrogenicity testing		
Batch potency testing	5486	62.11%
Other quality controls	52	0.59%
Total	**8833**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	5366	42.63%
Skin irritation/corrosion	35	0.28%
Skin sensitisation	80	0.64%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	1701	13.52%
Kinetics	267	2.12%
Pharmaco-dynamics (incl safety pharmacology)	609	4.84%
Ecotoxicity	4528	35.98%
Total	**12586**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	5366	100%

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Other lethal methods		
Non lethal methods		
Total	5366	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	862	50.68%
29 - 90 days	229	13.46%
> 90 days	610	35.86%
Total	1701	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	3030	66.92%
Reproductive ecotoxicity		
Endocrine activity	1440	31.8%
Bioaccumulation	58	1.28%
Other ecotoxicity		
Total	4528	100.00%

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	17000	78.95%
Legislation on medicinal products for veterinary use and their residues	4	0.02%
Medical devices legislation		
Industrial chemicals legislation	2458	11.42%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	2070	9.61%
Total	21532	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19398	90.09%
Legislation satisfying national requirements only [within EU]	2134	9.91%
Legislation satisfying Non-EU requirements only		
Total	**21532**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	284444	98.35%
Yes	4781	1.65%
Total	**289225**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	22852	7.9%
Mild [up to and including]	181393	62.72%
Moderate	80451	27.82%
Severe	4529	1.57%
Total	**289225**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	287229	99.31%
Yes	1996	0.69%
Total	**289225**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	247082	85.43%
Genetically altered without a harmful phenotype	28548	9.87%
Genetically altered with a harmful phenotype	13595	4.7%
Total	**289225**	**100.00%**

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Denmark: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

The overall number of animals used for scientific purposes in Denmark in 2017 is 236,100. This is a significant decrease since 2016, where the number was 273,224 animals. But the total decrease is covered by the large drop in the number of fish – from 51,899 in 2016 to 17,125 in 2017. Taking this in account, the number of animals used in Denmark has been relatively stable over the last years

As usually, mice, rats and fish covers more than 90 % of the animals. The number of mice and rats has remained stable for several years (202,035 in 2015, 201,973 in 2016 and 201,621 in 2017).

The percentage of animals used for basic research is fallen from 38 % to 35 % reflecting the drop in fish (eel) used for this purpose.

Animals used for regulatory purposes and for routine production continues to be 8 %, confirming the relatively low number of animals used for that purpose in Denmark.

Finally the number of animals experiencing severe suffering has fallen in 2017 to a level of 0.74 %. This is confirming the trend that the percentage of severe suffering is varying around 1 %.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof

The clearest trend in 2017 was the large decrease in the use of fish for research. But as the large increase in 2016 was due to introduction of a new field of research in eel in the statistics, the large decrease is due to a change in research focus concerning the same animals.

Even though the total number of mice and rats is relatively stable, the number of mice has increased from 153,748 to 163,666 and the number of rats has decreased from 45,951 to 37,955. Some establishments traditionally using rats have been restructuring their laboratories in 2017, probably explaining the decrease in numbers. There is no obvious reason for the rice in the use of mice, but in a small country a strengthened focuses from a few research groups can have a large impact on the statistics. A rising use of GA animals could affect the number of mice, but the use of GA animals has not changed significantly from 2016 to 2017.

Finally the use of 3,680 cattle in 2017 is remarkable, as the number in 2016 was as low as 419 animals. However this is due to a few large “on farm” studies on cattle. The number probably will return to a much lower level in 2018.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The number of animals experiencing severe severity has fallen from 1,68 % in 2016 to 0,74 % in 2017. As Denmark generally has few animals experiencing severe severity, a changed focus from just one or two research groups will affect the numbers dramatically. The level of severe severity in Denmark is consistently relatively low.

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There has been an increase in the percentage of moderate severity from 29 % to 36 % and a corresponding drop in the percentage of mild severity from 61 % to 53 %. There is no apparent explanation for this change, but the numbers will be followed closely to identify any lasting change.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Also in 2017, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on www.3rcenter.dk.

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2017. Further information can be found on: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposiums for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In two cases the use of “other” is relatively high in Denmark – in other carnivores and other fish. The carnivores represent a strong focus on research in mink for farming and concerning fish, Denmark has a large focus on research on rainbow trout for farming, as well as a continuing focus on eel research.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No cases of animal experiencing the severe clarification exceeded were recorded in 2017 in Denmark.

Denmark: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	164137	68.98%
Rats	38498	16.18%
Guinea-Pigs	2947	1.24%
Hamsters (Syrian)	282	0.12%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	3	0%
Rabbits	2443	1.03%
Cats		
Dogs	214	0.09%

Animal Species	Number of animals	Percentage
Ferrets	4	0%
Other carnivores	1035	0.43%
Horses, donkeys and cross-breeds	119	0.05%
Pigs	5803	2.44%
Goats	1	0%
Sheep	66	0.03%
Cattle	3677	1.55%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	28	0.01%
Domestic fowl	466	0.2%
Other birds	408	0.17%
Reptiles	289	0.12%
Rana	4	0%
Xenopus	285	0.12%
Other Amphibians	47	0.02%
Zebra fish	1587	0.67%
Other Fish	15606	6.56%
Cephalopods		
Total	**237949**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	205163	87.11%
Animals born in the EU but not at a registered breeder	24582	10.44%
Animals born in rest of Europe	552	0.23%
Animals born in rest of world	5215	2.21%
Total	**235512**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		

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NHP Generation	Number of animals	Percentage
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	82918	34.85%
Translational and applied research	122146	51.33%
Regulatory use and Routine production	19865	8.35%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2875	1.21%
Preservation of species	5637	2.37%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4463	1.88%
Forensic enquiries	16	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	29	0.01%
Total	**237949**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6727	8.11%
Cardiovascular Blood and Lymphatic System	4270	5.15%
Nervous System	18241	22%
Respiratory System	2444	2.95%
Gastrointestinal System including Liver	2478	2.99%
Musculoskeletal System	3280	3.96%
Immune System	22727	27.41%
Urogenital/Reproductive System	2220	2.68%
Sensory Organs (skin, eyes and ears)	77	0.09%
Endocrine System/Metabolism	12632	15.23%
Multisystemic	485	0.58%
Ethology / Animal Behaviour /Animal Biology	2454	2.96%
Other basic research	4883	5.89%
Total	**82918**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	18429	15.09%
Human Infectious Disorders	7665	6.28%
Human Cardiovascular Disorders	2016	1.65%
Human Nervous and Mental Disorders	31509	25.8%
Human Respiratory Disorders	176	0.14%
Human Gastrointestinal Disorders including Liver	762	0.62%
Human Musculoskeletal Disorders	378	0.31%
Human Immune Disorders	4959	4.06%
Human Urogenital/Reproductive Disorders	647	0.53%
Human Sensory Organ Disorders (skin, eyes and ears)	336	0.28%
Human Endocrine/Metabolism Disorders	37015	30.3%
Other Human Disorders	9168	7.51%
Animal Diseases and Disorders	5708	4.67%

Translational and applied research	Number of uses	Percentage
Animal Welfare	1568	1.28%
Diagnosis of diseases	1023	0.84%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	787	0.64%
Total	**122146**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	8139	40.97%
Other efficacy and tolerance testing	725	3.65%
Toxicity and other safety testing including pharmacology	10257	51.63%
Routine production	744	3.75%
Total	**19865**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2504	30.77%
Pyrogenicity testing		
Batch potency testing	5601	68.82%
Other quality controls	34	0.42%
Total	**8139**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3968	38.69%
Skin irritation/corrosion	28	0.27%
Skin sensitisation	177	1.73%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	2205	21.5%
Reproductive toxicity	935	9.12%
Kinetics	818	7.98%
Pharmaco-dynamics (incl safety pharmacology)	26	0.25%
Ecotoxicity	2100	20.47%
Total	**10257**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	3968	100%
Other lethal methods		
Non lethal methods		
Total	**3968**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1382	62.68%
29 - 90 days	586	26.58%
> 90 days	237	10.75%
Total	**2205**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	120	5.71%
Chronic toxicity	1800	85.71%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	180	8.57%
Other ecotoxicity		
Total	**2100**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	288	38.71%
Monoclonal antibody by mouse ascites method		
Other product types	456	61.29%
Total	**744**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16634	83.74%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation	2987	15.04%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	244	1.23%
Total	**19865**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19765	99.5%
Legislation satisfying national requirements only [within EU]	100	0.5%
Legislation satisfying Non-EU requirements only		
Total	**19865**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235512	98.98%
Yes	2437	1.02%
Total	**237949**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	22871	9.61%
Mild [up to and including]	127013	53.38%
Moderate	86303	36.27%
Severe	1762	0.74%
Total	**237949**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	234261	98.45%
Yes	3688	1.55%
Total	**237949**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	198043	83.23%
Genetically altered without a harmful phenotype	27907	11.73%
Genetically altered with a harmful phenotype	11999	5.04%
Total	**237949**	**100.00%**

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Estonia

Estonia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

No significant trends are observed in 2015 compared to 2014. The number of companies dealing with experimental animals is the same. No new authorisations were given to small companies which do not have separate AWB at the place. Experiments done in such small companies are with small number of animals. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2014 Estonia reported that 50.55% of the animals used were used for basic research purpose. In 2015 the percentage for basic research was 83.53. In 2014 47.70% of animals were used for translational and applied research, in 2015 this percentage was 14.28. In 2014 8.28% of animals were used for legislation satisfying EU requirements, in 2015 this percentage was 38.53. In 2014 24.05% of animals were used for human cancer research, in 2015 this percentage was 85.38. These were the biggest changes in the number of animals used in certain categories. Main reason for such changes is finance. Human cancer, legislation satisfying EU requirements and translational and applied research projects got grants in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2014 13.16% of animals were classified as non-recovery, in 2015 this percentage was 7.01. In 2014 1.87% of animals were classified as severe, in 2015 this percentage was 8.02. As Estonia only gave 26 licences in 2015 these changes are not significant. The usage of animals mostly depends on finance (what grants are received). All projects are evaluated by PAC members.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

All fish classified as other fish were roaches. All birds classified as other birds were common gulls.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2965	76.99%
Rats	123	3.19%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	6	0.16%
Goats		
Sheep		
Cattle	283	7.35%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	294	7.63%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	180	4.67%
Cephalopods		
Total	**3851**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2920	78.2%
Animals born in the EU but not at a registered breeder	736	19.71%
Animals born in rest of Europe	78	2.09%
Animals born in rest of world		
Total	**3734**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3190	82.84%
Translational and applied research	570	14.8%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	83	2.16%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	8	0.21%
Total	**3851**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1338	41.94%
Cardiovascular Blood and Lymphatic System	12	0.38%
Nervous System	274	8.59%
Respiratory System		
Gastrointestinal System including Liver	78	2.45%
Musculoskeletal System		
Immune System	435	13.64%
Urogenital/Reproductive System	60	1.88%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	213	6.68%
Multisystemic	50	1.57%
Ethology / Animal Behaviour /Animal Biology	215	6.74%
Other basic research	515	16.14%
Total	**3190**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	483	84.74%
Human Infectious Disorders		
Human Cardiovascular Disorders	87	15.26%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**570**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3734	96.96%
Yes	117	3.04%
Total	3851	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	284	7.37%
Mild [up to and including]	1552	40.3%
Moderate	1681	43.65%
Severe	334	8.67%
Total	3851	100.00%

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3851	100%
Yes		
Total	3851	100.00%

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	3397	88.21%
Genetically altered without a harmful phenotype	454	11.79%
Genetically altered with a harmful phenotype		
Total	3851	100.00%

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Estonia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

No significant trends are observed in 2016 compared to 2015. One new authorisation was given to a company dealing with experimental animals, however they did not apply for a licence in 2016. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 2376 mice, 51 rats, 6 pigs, 566 cattle, 294 other birds, 180 other fish were used for basic research. In 2016 3079 mice, 90 rats, 252 other birds and 32 other fish were used for basic research. In 2015 550 mice and 45 rats were used for translational and applied research, in 2016 31 mice and no rats were used for that purpose. In 2015 56 mice and 27 rats were used for higher education purposes, however no animals were used for that purpose in 2016. In 2015 16 mice were used for the purpose of maintaining colonies, in 2016 the number of mice used for that purpose was 242. It can be said that the main difference between the years was that the number of animal used for maintaining colonies significantly increased and compared to 2015, in 2016 no animals were used for higher education purpose. Also, no cattle or other animal species were used in 2016 compared to 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 44.04% of animals used were classified as mild, in 2016 this percentage was 37.44. In 2015, 40.94% of animals used were classified as moderate, in 2016 this percentage was 48.85. In 2015, 8.02% of animals were severely used, in 2016 this percentage was 10.82. In 2015, 7.01% of animals were classified as non- recovery. In 2016 this percentage was 2.90. There are no major changes in actual severities when comparing the two years.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

All birds classified as other birds were great tits (*Parus major*). All fish classified as other fish were round gobies (*Neogobius melanostomus*).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

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PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3193	89.51%
Rats	90	2.52%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	252	7.06%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	32	0.9%
Cephalopods		
Total	**3567**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	3176	91.79%
Animals born in the EU but not at a registered breeder	284	8.21%
Animals born in rest of Europe		
Animals born in rest of world		
Total	3460	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3294	92.35%
Translational and applied research	31	0.87%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	242	6.78%
Total	3567	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1638	49.73%
Cardiovascular Blood and Lymphatic System	12	0.36%
Nervous System	546	16.58%
Respiratory System		
Gastrointestinal System including Liver	140	4.25%
Musculoskeletal System	75	2.28%
Immune System	20	0.61%
Urogenital/Reproductive System	30	0.91%

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Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	549	16.67%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology	284	8.62%
Other basic research		
Total	**3294**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	31	100%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**31**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3460	97%
Yes	107	3%
Total	**3567**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	108	3.03%
Mild [up to and including]	1395	39.11%
Moderate	1724	48.33%
Severe	340	9.53%
Total	**3567**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3351	93.94%
Yes	216	6.06%
Total	**3567**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2668	74.8%
Genetically altered without a harmful phenotype	899	25.2%
Genetically altered with a harmful phenotype		
Total	**3567**	**100.00%**

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Estonia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2016 some changes in trends were observed. Number of animals used dropped another 12% (decrease in 2015 vs 2016 was 10%). This year there we none in re-use (in 2016 3% from all uses). Creation of new GL dropped again, from 6,06% to 2,8% (none in 2015). Like in 2015 and 2016 no harmful GA lines were used in 2017. The GA animals used are thoroughly researched and known to have no harmful qualities. About 2/3 of the animals used are not genetically altered. This number has dropped from last year where about ¾ were not altered since more projects use GA animals. Insignificant changes in severities - non-recovery and mild have mildly increased, moderate and severe decreased. Changes in species – less mice, more rats were used; quantity of birds decreased as well; no fish were used but in 2017 again 16 cattle and 4 pigs were used (no projects in 2016). More animals came from an EU registered breeder (94,28% vs 91,79%).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Number of uses in translational and applied research rose from 0,87% to 6,68%. Human respiratory disorders were investigated with 210 uses. There were no projects of higher education or training for the acquisition, maintenance or improvement of vocational skills in 2016 but now in 2017 it took 1,21% of all uses. There were no competence courses in laboratory animal science in Estonia that year. Maintenance of colonies rose from 6,78% to 12,52% since laboratories are using more GA lines. No regulatory use in 2016 but 112 in 2017 – legislation on medicinal products for human use (from that 38 uses for carcinogenicity and 74 for genotoxicity). Oncology still is the most important research area, where 41% of the work is done. More uses than last year had cardiovascular, sensory, multisystemic, immune and nervous system.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016 39% of animals used were classified as mild, in 2017 this percentage was 44. In 2016, 48% of animals used were classified as moderate, in 2017 this percentage was 43. In 2016, 9,5% of animals were severely used, in 2017 this percentage was 8,7. In 2016, 3% of animals were classified as non-recovery. In 2017 this percentage was 4. There are no major changes in actual severities when comparing the two years. The proportion of moderate is higher than the average EU and might come from the facts that the committee is strict and that more harsh projects are done.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

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5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

From the birds that were classified as other birds 115 were common gulls and 65 were great tits. Proportion of birds 5,72% of all animals.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2578	81.95%
Rats	368	11.7%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	4	0.13%
Goats		
Sheep		
Cattle	16	0.51%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	180	5.72%
Reptiles		
Rana		
Xenopus		
Other Amphibians		

Animal Species	Number of animals	Percentage
Zebra fish		
Other Fish		
Cephalopods		
Total	3146	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2966	94.28%
Animals born in the EU but not at a registered breeder	180	5.72%
Animals born in rest of Europe		
Animals born in rest of world		
Total	3146	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2392	76.03%
Translational and applied research	210	6.68%
Regulatory use and Routine production	112	3.56%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	38	1.21%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	394	12.52%
Total	3146	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	985	41.18%
Cardiovascular Blood and Lymphatic System	93	3.89%
Nervous System	495	20.69%

Basic Research	Number of uses	Percentage
Respiratory System		
Gastrointestinal System including Liver	32	1.34%
Musculoskeletal System	88	3.68%
Immune System	99	4.14%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	32	1.34%
Endocrine System/Metabolism	219	9.16%
Multisystemic	153	6.4%
Ethology / Animal Behaviour /Animal Biology	180	7.53%
Other basic research	16	0.67%
Total	**2392**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders	210	100%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**210**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	112	100%
Total	**112**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	38	33.93%
Carcinogenicity	74	66.07%
Total	**112**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	38	100%
29 - 90 days		
> 90 days		
Total	**38**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		

Routine production	Number of uses	Percentage
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	112	100%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**112**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	112	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**112**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	3146	100%
Yes		
Total	**3146**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	132	4.2%
Mild [up to and including]	1385	44.02%
Moderate	1354	43.04%
Severe	275	8.74%
Total	**3146**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3058	97.2%
Yes	88	2.8%
Total	**3146**	**100.00%**

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Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1956	62.17%
Genetically altered without a harmful phenotype	1190	37.83%
Genetically altered with a harmful phenotype		
Total	**3146**	**100.00%**

Finland

Finland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, a total of 96 817 procedures in animals were done in Finland, which was 33 % less than 2014 (145 542 procedures in 2014). The greatest reductions were in the procedures with fish (other than zebra fish 38 483). The change was due to the ending of one project with large fish use. The use of mice in procedures decreased also (10 941). This may however be explained with the more precise reporting. The reductions in use of both species were mainly in basic research. The use of rats increased by 1679 rats in translational and applied research.

28 % of animals used were genetically altered (mice, rats and zebra fish). 7 % of them had a harmful phenotype.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 62 223 procedures - main areas being nervous system, immune system, multisystemic and ethology/animal behavior/animal biology. For the translational and applied research (25 634 procedures) the main category of purposes were human nervous and mental disorders (15 878 procedures).

Dogs reported as used in procedures (2619) included 2326 pet dogs which gave a blood sample for a study of disease genes and 196 pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 97 procedures including 71 re-use. Cats reported as used in procedures (100) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Actual severities of procedures: 60 % of the procedures were classified as non-recovery or mild, 34 % moderate and 6 % severe. By species, the severe procedures involved 2934 mice (5199 mice in 2014) and 2679 rats (1960 rats in 2014). Most of the severe procedures (4008) were done in category of human nervous and mental disorders.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	50047	51.69%
Rats	15976	16.5%
Guinea-Pigs	50	0.05%
Hamsters (Syrian)	197	0.2%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	213	0.22%
Cats	100	0.1%
Dogs	2619	2.71%
Ferrets		
Other carnivores	270	0.28%
Horses, donkeys and cross-breeds	48	0.05%
Pigs	479	0.49%
Goats		
Sheep	1128	1.17%
Cattle	87	0.09%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	2880	2.97%
Domestic fowl	3646	3.77%
Other birds	717	0.74%
Reptiles		
Rana	10	0.01%
Xenopus		
Other Amphibians		
Zebra fish	10821	11.18%
Other Fish	7529	7.78%
Cephalopods		
Total	**96817**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	76799	79.95%
Animals born in the EU but not at a registered breeder	18207	18.95%
Animals born in rest of Europe	7	0.01%
Animals born in rest of world	1042	1.08%
Total	**96055**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	62223	64.27%
Translational and applied research	25634	26.48%
Regulatory use and Routine production	5364	5.54%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1455	1.5%
Preservation of species	41	0.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1170	1.21%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	930	0.96%
Total	**96817**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	7529	12.1%
Cardiovascular Blood and Lymphatic System	5253	8.44%
Nervous System	14531	23.35%
Respiratory System		
Gastrointestinal System including Liver	558	0.9%
Musculoskeletal System	701	1.13%
Immune System	10115	16.26%
Urogenital/Reproductive System	500	0.8%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	1223	1.97%
Endocrine System/Metabolism	4000	6.43%
Multisystemic	8112	13.04%
Ethology / Animal Behaviour /Animal Biology	9425	15.15%
Other basic research	276	0.44%
Total	**62223**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2375	9.27%
Human Infectious Disorders		
Human Cardiovascular Disorders	604	2.36%
Human Nervous and Mental Disorders	15878	61.94%
Human Respiratory Disorders	62	0.24%
Human Gastrointestinal Disorders including Liver	24	0.09%
Human Musculoskeletal Disorders	16	0.06%
Human Immune Disorders	24	0.09%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1237	4.83%
Human Endocrine/Metabolism Disorders	85	0.33%
Other Human Disorders	23	0.09%
Animal Diseases and Disorders	4593	17.92%
Animal Welfare	444	1.73%
Diagnosis of diseases	127	0.5%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	142	0.55%
Total	**25634**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1576	29.38%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	2538	47.32%
Routine production	1250	23.3%
Total	**5364**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	1576	100%
Total	**1576**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	1.97%
Skin irritation/corrosion	10	0.39%
Skin sensitisation	40	1.58%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	94	3.7%
Kinetics	590	23.25%
Pharmaco-dynamics (incl safety pharmacology)	1754	69.11%
Total	**2538**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	50	100%
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	94	100%
29 - 90 days		
> 90 days		
Total	**94**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	1250	100%
Total	**1250**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3708	69.13%
Legislation on medicinal products for veterinary use and their residues	1656	30.87%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**5364**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	5364	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**5364**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	96055	99.21%
Yes	762	0.79%
Total	**96817**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	4977	5.14%
Mild [up to and including]	53408	55.16%
Moderate	32819	33.9%
Severe	5613	5.8%
Total	**96817**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	87608	90.49%
Yes	9209	9.51%
Total	**96817**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	69334	71.61%
Genetically altered without a harmful phenotype	22004	22.73%
Genetically altered with a harmful phenotype	5479	5.66%
Total	**96817**	**100.00%**

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Finland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, a total of 105 615 procedures in animals were done in Finland, which was 9 % more than in 2015 (96 817 procedures). The greatest increases were in the procedures with mice (7 792 animals more), other rodents (1364 more) and domestic fowls (4 765 more).

45 % of mice used were genetically altered and 13 % (7328 mice) had a harmful phenotype. With rats, 3 % were genetically altered, one rat with harmful phenotype. With zebrafish, the numbers were 58 % and 16 % (1206 zebra fish), respectively.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 55 744 procedures, main areas being Nervous system (14 320 procedures), Immune system, Multisystemic and Ethology/Animal behavior/Animal biology (8 795, 10 539 and 7 376, respectively). For the translational and applied research (40 591 procedures) the main categories of purposes were Human nervous and mental disorders (20 831 procedures) and Animal diseases and disorders (9 869 procedures). In regulatory use and routine production, 2 645 domestic fowls were used for quality control, 1 457 animals (sheep, pigs, domestic fowls and horses) for routine products and 2 916 animals (mice, rats, dogs, pigs) in toxicity and other safety testing.

The increased use of mice in procedures (16 %) took place in the translational and applied research in studies for Human nervous and mental disorders. Other rodents (bank voles: 1314 animals) were used in the basic research (Ethology/Animal behavior/Animal biology). The procedures in domestic fowls increased in the translational and applied research (Animal diseases and disorders) and in the regulatory use and routine production (Quality control).

Procedures reported as done in dogs (3961) included 3582 procedures in pet dogs which gave a blood sample for a study of disease genes. 244 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 135 procedures including 116 re-use. Cats reported as used in procedures (259) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

61,5 % of the procedures were classified as non-recovery or mild, 30 % moderate and 8,5 % severe. By species, the severe procedures involved 6 862 mice (2934 in 2015) and 2161 rats (2 679 in 2015). The severe procedures in mice and rats were done mainly in the purpose of Human nervous and mental disorders both in basic and translational research. The significant increase or severe procedures with mice was due to single projects with high animal numbers.

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4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	57839	54.76%
Rats	15297	14.48%
Guinea-Pigs	10	0.01%
Hamsters (Syrian)	273	0.26%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	1364	1.29%
Rabbits	237	0.22%
Cats	259	0.25%
Dogs	3961	3.75%
Ferrets		
Other carnivores	18	0.02%
Horses, donkeys and cross-breeds	76	0.07%
Pigs	611	0.58%
Goats		
Sheep	1350	1.28%
Cattle	541	0.51%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	103	0.1%
Domestic fowl	8411	7.96%

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Animal Species	Number of animals	Percentage
Other birds	501	0.47%
Reptiles		
Rana	2	0%
Xenopus		
Other Amphibians		
Zebra fish	7483	7.09%
Other Fish	7279	6.89%
Cephalopods		
Total	**105615**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	84134	80.23%
Animals born in the EU but not at a registered breeder	15053	14.35%
Animals born in rest of Europe	981	0.94%
Animals born in rest of world	4702	4.48%
Total	**104870**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	55744	52.78%
Translational and applied research	40591	38.43%
Regulatory use and Routine production	7026	6.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	35	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1753	1.66%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	466	0.44%
Total	**105615**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4212	7.56%
Cardiovascular Blood and Lymphatic System	5187	9.31%
Nervous System	14320	25.69%
Respiratory System	258	0.46%
Gastrointestinal System including Liver	501	0.9%
Musculoskeletal System	562	1.01%
Immune System	8795	15.78%
Urogenital/Reproductive System	524	0.94%
Sensory Organs (skin, eyes and ears)	310	0.56%
Endocrine System/Metabolism	2614	4.69%
Multisystemic	10539	18.91%
Ethology / Animal Behaviour /Animal Biology	7376	13.23%
Other basic research	546	0.98%
Total	**55744**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3325	8.19%
Human Infectious Disorders	995	2.45%
Human Cardiovascular Disorders	676	1.67%
Human Nervous and Mental Disorders	20831	51.32%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	74	0.18%
Human Musculoskeletal Disorders	1204	2.97%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	2169	5.34%
Human Endocrine/Metabolism Disorders	386	0.95%
Other Human Disorders	586	1.44%
Animal Diseases and Disorders	9869	24.31%
Animal Welfare	199	0.49%
Diagnosis of diseases	89	0.22%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	188	0.46%
Total	**40591**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2645	37.65%
Other efficacy and tolerance testing	8	0.11%
Toxicity and other safety testing including pharmacology	2916	41.5%
Routine production	1457	20.74%
Total	**7026**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	2645	100%

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total	**2645**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	49	1.68%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	196	6.72%
Kinetics	850	29.15%
Pharmaco-dynamics (incl safety pharmacology)	1821	62.45%
Total	**2916**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	9	18.37%
Other lethal methods		
Non lethal methods	40	81.63%
Total	**49**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	100	51.02%
29 - 90 days		
> 90 days	96	48.98%
Total	**196**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	317	21.76%
Monoclonal antibody by mouse ascites method		
Other product types	1140	78.24%
Total	**1457**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4332	61.66%
Legislation on medicinal products for veterinary use and their residues	2694	38.34%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**7026**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6709	95.49%
Legislation satisfying national requirements only [within EU]	317	4.51%
Legislation satisfying Non-EU requirements only		
Total	**7026**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	104870	99.29%
Yes	745	0.71%
Total	**105615**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9198	8.71%
Mild [up to and including]	55602	52.65%
Moderate	31797	30.11%
Severe	9018	8.54%
Total	**105615**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	101359	95.97%
Yes	4256	4.03%
Total	**105615**	**100.00%**

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Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	74960	70.97%
Genetically altered without a harmful phenotype	22120	20.94%
Genetically altered with a harmful phenotype	8535	8.08%
Total	**105615**	**100.00%**

Finland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, a total of 102 575 procedures in animals were done in Finland, which was 3 % less than in 2016 (105 615 procedures). The greatest decreases were in the procedures with mice (4 838 animals less) mainly in basic research and rats (1 825 less) in translational and applied research. The number of procedures with other fish increased (4 450 more).

48 % of mice used were genetically altered and 17 % (8817 mice) had a harmful phenotype. With rats, 4 % were genetically altered, all without a harmful phenotype. With zebrafish, 51 % of the used fish were genetically altered, all without a harmful phenotype.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 59 278 procedures, main areas being Nervous system (11 905 procedures, decreased) and Immune system (11 024 procedures, increased). Other areas of basic research were Multisystemic (7 587, decreased), Ethology/Animal Behavior/Animal Biology (7 546, no change), Oncology (6 791, increased) and Cardiovascular Blood and Lymphatic Systems (5 145, no change).

For the translational and applied research (33 521 procedures) the main categories of purposes were Human nervous and mental disorders (19 703 procedures, decreased), Human Cancer (5 016, increased) and Animal diseases and disorders (4 384 procedures, decreased).

In Regulatory use and Routine production, 3 395 domestic fowls were used for Quality control and 1 476 animals (sheep, pigs, domestic fowls and horses) for Routine products. For Toxicity and other safety testing, 2 868 animals (mice, rats, dogs, pigs, rabbits) were used mainly for Kinetics and Pharmaco-dynamics.

Procedures reported as done in dogs (3 061) included 2 840 procedures in pet dogs which gave a blood sample for a study of disease genes. 195 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 26 procedures including 26 re-use. Cats reported as used in procedures (311) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Actual severities of procedures: 8,9 % of the procedures were classified as non-recovery, 48,5 % mild, 34,1 % moderate and 8,5 % severe. By species, the severe procedures involved 7 125 mice (6 862 in 2016) and 1 568 rats (2 161 in 2016). There were changes in the numbers of procedures with mild or moderate severity without clear reasons for them. As in previous years, the severe procedures were done mainly in the purpose of Human nervous and mental disorders in translational research (6 722 procedures).

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4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

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6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	53001	51.67%
Rats	13472	13.13%
Guinea-Pigs	9	0.01%
Hamsters (Syrian)	149	0.15%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	690	0.67%
Rabbits	227	0.22%
Cats	311	0.3%
Dogs	3061	2.98%
Ferrets		
Other carnivores	107	0.1%
Horses, donkeys and cross-breeds	77	0.08%
Pigs	632	0.62%
Goats		
Sheep	1319	1.29%
Cattle	216	0.21%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1533	1.49%
Domestic fowl	8485	8.27%

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Animal Species	Number of animals	Percentage
Other birds	404	0.39%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	7153	6.97%
Other Fish	11729	11.43%
Cephalopods		
Total	**102575**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	76287	74.48%
Animals born in the EU but not at a registered breeder	23562	23%
Animals born in rest of Europe	5	0%
Animals born in rest of world	2572	2.51%
Total	**102426**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	59278	57.79%
Translational and applied research	33521	32.68%
Regulatory use and Routine production	7895	7.7%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	60	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1606	1.57%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	215	0.21%
Total	**102575**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6791	11.46%
Cardiovascular Blood and Lymphatic System	5145	8.68%
Nervous System	11905	20.08%
Respiratory System	80	0.13%
Gastrointestinal System including Liver	545	0.92%
Musculoskeletal System	337	0.57%
Immune System	11024	18.6%
Urogenital/Reproductive System	181	0.31%
Sensory Organs (skin, eyes and ears)	268	0.45%
Endocrine System/Metabolism	1387	2.34%
Multisystemic	7587	12.8%
Ethology / Animal Behaviour /Animal Biology	7546	12.73%
Other basic research	6482	10.93%
Total	**59278**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	5016	14.96%
Human Infectious Disorders	860	2.57%
Human Cardiovascular Disorders	662	1.97%
Human Nervous and Mental Disorders	19703	58.78%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	117	0.35%
Human Musculoskeletal Disorders	605	1.8%
Human Immune Disorders	71	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	477	1.42%
Human Endocrine/Metabolism Disorders	442	1.32%
Other Human Disorders	759	2.26%
Animal Diseases and Disorders	4384	13.08%
Animal Welfare	226	0.67%
Diagnosis of diseases	123	0.37%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	68	0.2%
Total	**33521**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	3395	43%
Other efficacy and tolerance testing	156	1.98%
Toxicity and other safety testing including pharmacology	2868	36.33%
Routine production	1476	18.7%
Total	**7895**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	3395	100%

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total	**3395**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	134	4.67%
Kinetics	1171	40.83%
Pharmaco-dynamics (incl safety pharmacology)	1556	54.25%
Other toxicity/safety testing	7	0.24%
Total	**2868**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	134	100%
29 - 90 days		
> 90 days		
Total	**134**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	296	20.05%
Monoclonal antibody by mouse ascites method		
Other product types	1180	79.95%
Total	**1476**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4468	56.59%
Legislation on medicinal products for veterinary use and their residues	3395	43%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	32	0.41%
Cosmetics legislation		
Other legislation		
Total	**7895**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7599	96.25%
Legislation satisfying national requirements only [within EU]	296	3.75%
Legislation satisfying Non-EU requirements only		
Total	**7895**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	102426	99.85%
Yes	149	0.15%
Total	**102575**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9082	8.85%
Mild [up to and including]	49770	48.52%
Moderate	34984	34.11%
Severe	8739	8.52%
Total	**102575**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	97716	95.26%
Yes	4859	4.74%
Total	**102575**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	73080	71.25%
Genetically altered without a harmful phenotype	20678	20.16%
Genetically altered with a harmful phenotype	8817	8.6%
Total	**102575**	**100.00%**

France

France: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period (2014).

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2015 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2014 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

- only animals for which the experimental procedures ended in 2015 are recorded;
- captive-bred animals present in user establishments are excluded;
- animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
- animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection

Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Grouping species of the same taxon in the 'other' category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.6% of animals used (11,665 animals), 'other fish' account for 29.6% (524,024 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as 'other' (44,248 animals), while 'domestic fowl' account for 48,528.

Finally, with respect to the distribution of animals involved in procedures laid down in the rules, almost half are entered in the 'other' category, which suggests that the proposed headings are not the most appropriate, or have been misunderstood by users. Particular attention will be given to how this section is completed in the next survey.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the 'severe' classification being exceeded have been identified.

France: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1007245	52.97%
Rats	157183	8.27%
Guinea-Pigs	44414	2.34%
Hamsters (Syrian)	10986	0.58%
Hamsters (Chinese)		
Mongolian gerbil	1417	0.07%
Other Rodents	755	0.04%
Rabbits	108110	5.69%
Cats	336	0.02%

Animal Species	Number of animals	Percentage
Dogs	3143	0.17%
Ferrets	155	0.01%
Other carnivores	30	0%
Horses, donkeys and cross-breeds	629	0.03%
Pigs	12203	0.64%
Goats	436	0.02%
Sheep	3446	0.18%
Cattle	2203	0.12%
Prosimians	157	0.01%
Marmoset and tamarins	97	0.01%
Cynomolgus monkey	2756	0.14%
Rhesus monkey	64	0%
Vervets (Chlorocebus spp.)	56	0%
Baboons	18	0%
Squirrel monkey	13	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1772	0.09%
Domestic fowl	66734	3.51%
Other birds	46433	2.44%
Reptiles	1051	0.06%
Rana	306	0.02%
Xenopus	1644	0.09%
Other Amphibians	3167	0.17%
Zebra fish	11399	0.6%
Other Fish	413183	21.73%
Cephalopods	1	0%
Total	**1901542**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1550643	82.26%
Animals born in the EU but not at a registered breeder	258592	13.72%
Animals born in rest of Europe	66947	3.55%
Animals born in rest of world	8893	0.47%
Total	**1885075**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	128	6.92%
Animals born in rest of Europe	14	0.76%
Animals born in Asia	42	2.27%
Animals born in America	55	2.97%
Animals born in Africa	1521	82.17%
Animals born elsewhere	91	4.92%
Total	**1851**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0	1	0.05%
F1	1202	64.94%
F2 or greater	433	23.39%
Self-sustaining colony	215	11.62%
Total	**1851**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	792453	41.67%
Translational and applied research	432557	22.75%
Regulatory use and Routine production	572144	30.09%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1122	0.06%
Preservation of species	3380	0.18%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	28062	1.48%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	71824	3.78%
Total	**1901542**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	63910	8.06%
Cardiovascular Blood and Lymphatic System	40007	5.05%
Nervous System	92332	11.65%
Respiratory System	11520	1.45%
Gastrointestinal System including Liver	63028	7.95%
Musculoskeletal System	9931	1.25%
Immune System	68167	8.6%
Urogenital/Reproductive System	26770	3.38%
Sensory Organs (skin, eyes and ears)	12399	1.56%
Endocrine System/Metabolism	26196	3.31%
Multisystemic	29703	3.75%
Ethology / Animal Behaviour /Animal Biology	345624	43.61%
Other basic research	2866	0.36%
Total	**792453**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	126277	29.19%
Human Infectious Disorders	65335	15.1%
Human Cardiovascular Disorders	9735	2.25%
Human Nervous and Mental Disorders	61259	14.16%
Human Respiratory Disorders	3043	0.7%
Human Gastrointestinal Disorders including Liver	7405	1.71%
Human Musculoskeletal Disorders	12075	2.79%
Human Immune Disorders	11943	2.76%
Human Urogenital/Reproductive Disorders	2756	0.64%
Human Sensory Organ Disorders (skin, eyes and ears)	9717	2.25%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	22966	5.31%
Other Human Disorders	1387	0.32%
Animal Diseases and Disorders	45194	10.45%
Animal Welfare	2656	0.61%
Diagnosis of diseases	31652	7.32%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	19157	4.43%
Total	**432557**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	276166	48.27%
Other efficacy and tolerance testing	39738	6.95%
Toxicity and other safety testing including pharmacology	102867	17.98%
Routine production	153373	26.81%
Total	**572144**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	62846	22.76%
Pyrogenicity testing	5981	2.17%
Batch potency testing	207339	75.08%
Other quality controls		
Total	**276166**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	7869	7.65%
Skin irritation/corrosion	1750	1.7%
Skin sensitisation	11491	11.17%
Eye irritation/corrosion	548	0.53%
Repeated dose toxicity	22904	22.27%
Carcinogenicity	1054	1.02%
Genotoxicity	854	0.83%
Reproductive toxicity	13109	12.74%
Developmental toxicity	8293	8.06%
Neurotoxicity	202	0.2%
Kinetics	8841	8.59%
Pharmaco-dynamics (incl safety pharmacology)	9119	8.86%
Phototoxicity	420	0.41%
Ecotoxicity	13360	12.99%
Safety testing in food and feed area	733	0.71%
Target animal safety	273	0.27%
Other toxicity/safety testing	2047	1.99%
Total	**102867**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	2713	34.48%
Other lethal methods	1373	17.45%
Non lethal methods	3783	48.07%
Total	**7869**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13008	56.79%
29 - 90 days	4542	19.83%
> 90 days	5354	23.38%
Total	**22904**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	9383	70.23%
Chronic toxicity	3977	29.77%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**13360**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	91483	59.65%
Monoclonal antibody by mouse ascites method	24200	15.78%
Other product types	37690	24.57%
Total	**153373**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	368792	64.46%
Legislation on medicinal products for veterinary use and their residues	115003	20.1%
Medical devices legislation	40847	7.14%
Industrial chemicals legislation	7479	1.31%
Plant protection product legislation	7026	1.23%
Biocides legislation	394	0.07%
Food legislation including food contact material	1033	0.18%
Feed legislation including legislation for the safety of target animals, workers and environment	27971	4.89%
Cosmetics legislation		
Other legislation	3599	0.63%
Total	**572144**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	565901	98.91%
Legislation satisfying national requirements only [within EU]	1871	0.33%
Legislation satisfying Non-EU requirements only	4372	0.76%
Total	**572144**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1886926	99.23%
Yes	14616	0.77%
Total	**1901542**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	81482	4.29%
Mild [up to and including]	845322	44.45%
Moderate	782033	41.13%
Severe	192705	10.13%
Total	**1901542**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1873951	98.55%
Yes	27591	1.45%
Total	**1901542**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1487378	78.22%
Genetically altered without a harmful phenotype	324456	17.06%
Genetically altered with a harmful phenotype	89708	4.72%
Total	**1901542**	**100.00%**

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France: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period (2015).

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2016 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2015 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

- only animals for which the experimental procedures ended in 2016 are recorded;
- captive-bred animals present in user establishments are excluded;
- animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
- animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals

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for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Grouping species of the same taxon in the 'other' category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.5 % of animals used (11,399 animals), 'other fish' account for 21.7 % (413,183 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as 'other' (46,433 animals), while 'domestic fowl' account for 66,734.

Finally, with respect to the distribution of animals involved in procedures imposed by the rules, particular attention was given to completing this section, which had been misunderstood by users in the previous survey. Only 1% of animals were entered in the 'other' category in this survey.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the 'severe' classification being exceeded have been identified.

France: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1144745	59.67%
Rats	172209	8.98%
Guinea-Pigs	44705	2.33%
Hamsters (Syrian)	10481	0.55%
Hamsters (Chinese)	287	0.01%
Mongolian gerbil	817	0.04%
Other Rodents	651	0.03%
Rabbits	117531	6.13%
Cats	1067	0.06%
Dogs	4204	0.22%
Ferrets	160	0.01%
Other carnivores	23	0%
Horses, donkeys and cross-breeds	540	0.03%

Animal Species	Number of animals	Percentage
Pigs	11707	0.61%
Goats	1025	0.05%
Sheep	5763	0.3%
Cattle	2492	0.13%
Prosimians	1	0%
Marmoset and tamarins	41	0%
Cynomolgus monkey	3170	0.17%
Rhesus monkey	173	0.01%
Vervets (Chlorocebus spp.)	23	0%
Baboons	92	0%
Squirrel monkey	8	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	20	0%
Domestic fowl	56759	2.96%
Other birds	14633	0.76%
Reptiles	4958	0.26%
Rana	36	0%
Xenopus	10078	0.53%
Other Amphibians	2081	0.11%
Zebra fish	13893	0.72%
Other Fish	293589	15.3%
Cephalopods	440	0.02%
Total	**1918402**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1611211	85.67%
Animals born in the EU but not at a registered breeder	185781	9.88%
Animals born in rest of Europe	59305	3.15%
Animals born in rest of world	24313	1.29%
Total	**1880610**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	126	5.44%
Animals born in rest of Europe		
Animals born in Asia	182	7.85%
Animals born in America	12	0.52%
Animals born in Africa	1979	85.38%
Animals born elsewhere	19	0.82%
Total	**2318**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0	5	0.22%
F1	1030	44.43%
F2 or greater	1272	54.87%
Self-sustaining colony	11	0.47%
Total	**2318**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	809504	42.2%
Translational and applied research	482233	25.14%
Regulatory use and Routine production	517479	26.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	635	0.03%
Preservation of species	16750	0.87%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	34195	1.78%
Forensic enquiries	28	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	57578	3%
Total	**1918402**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	81024	10.01%
Cardiovascular Blood and Lymphatic System	30831	3.81%
Nervous System	133609	16.51%
Respiratory System	7721	0.95%
Gastrointestinal System including Liver	33673	4.16%
Musculoskeletal System	14431	1.78%
Immune System	81497	10.07%
Urogenital/Reproductive System	14140	1.75%
Sensory Organs (skin, eyes and ears)	12221	1.51%
Endocrine System/Metabolism	63208	7.81%
Multisystemic	36302	4.48%
Ethology / Animal Behaviour /Animal Biology	226122	27.93%
Other basic research	74725	9.23%
Total	**809504**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	95944	19.9%
Human Infectious Disorders	39380	8.17%
Human Cardiovascular Disorders	10632	2.2%
Human Nervous and Mental Disorders	51007	10.58%
Human Respiratory Disorders	1530	0.32%
Human Gastrointestinal Disorders including Liver	11753	2.44%
Human Musculoskeletal Disorders	12804	2.66%
Human Immune Disorders	19730	4.09%
Human Urogenital/Reproductive Disorders	727	0.15%
Human Sensory Organ Disorders (skin, eyes and ears)	10749	2.23%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	17398	3.61%
Other Human Disorders	5443	1.13%
Animal Diseases and Disorders	70126	14.54%
Animal Welfare	749	0.16%
Diagnosis of diseases	115230	23.9%
Plant diseases	56	0.01%
Non-regulatory toxicology and ecotoxicology	18975	3.93%
Total	**482233**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	236097	45.62%
Other efficacy and tolerance testing	27122	5.24%
Toxicity and other safety testing including pharmacology	104065	20.11%
Routine production	150195	29.02%
Total	**517479**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	25789	10.92%
Pyrogenicity testing	7689	3.26%
Batch potency testing	164164	69.53%
Other quality controls	38455	16.29%
Total	**236097**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	4796	4.61%
Skin irritation/corrosion	823	0.79%
Skin sensitisation	13287	12.77%
Eye irritation/corrosion	283	0.27%
Repeated dose toxicity	24301	23.35%
Carcinogenicity	412	0.4%
Genotoxicity	736	0.71%
Reproductive toxicity	16635	15.99%
Developmental toxicity	6451	6.2%
Neurotoxicity	18	0.02%
Kinetics	12205	11.73%
Pharmaco-dynamics (incl safety pharmacology)	10704	10.29%
Phototoxicity	403	0.39%
Ecotoxicity	11352	10.91%
Safety testing in food and feed area	294	0.28%
Target animal safety	58	0.06%
Other toxicity/safety testing	1307	1.26%
Total	**104065**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	706	14.72%
Other lethal methods	1256	26.19%
Non lethal methods	2834	59.09%
Total	**4796**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13624	56.06%
29 - 90 days	5861	24.12%
> 90 days	4816	19.82%
Total	**24301**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10156	89.46%
Chronic toxicity	1078	9.5%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	42	0.37%
Other ecotoxicity	76	0.67%
Total	**11352**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	73841	49.16%
Monoclonal antibody by mouse ascites method	46128	30.71%
Other product types	30226	20.12%
Total	**150195**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	340076	65.72%
Legislation on medicinal products for veterinary use and their residues	79098	15.29%
Medical devices legislation	66507	12.85%
Industrial chemicals legislation	12412	2.4%
Plant protection product legislation	3970	0.77%
Biocides legislation	439	0.08%
Food legislation including food contact material	715	0.14%
Feed legislation including legislation for the safety of target animals, workers and environment	13556	2.62%
Cosmetics legislation		
Other legislation	706	0.14%
Total	**517479**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	497155	96.07%
Legislation satisfying national requirements only [within EU]	1318	0.25%
Legislation satisfying Non-EU requirements only	19006	3.67%
Total	**517479**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1882928	98.15%
Yes	35474	1.85%
Total	**1918402**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	105941	5.52%
Mild [up to and including]	766947	39.98%
Moderate	726836	37.89%
Severe	318678	16.61%
Total	**1918402**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1874323	97.7%
Yes	44079	2.3%
Total	**1918402**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1501546	78.27%
Genetically altered without a harmful phenotype	372200	19.4%
Genetically altered with a harmful phenotype	44656	2.33%
Total	**1918402**	**100.00%**

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France: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period (2016).

The 2017 survey comprises the responses of 552 establishments authorised to use animals for scientific purposes, representing an increase of 8.2% compared to 2016, which reflects an improved response rate to the survey.

The number of animals is decreasing (1,914,174 in 2017 compared to 1,918,481 in 2016, amounting to a decrease of 4,307 animals or 0.22%). This decrease is all the more significant since the number of respondents to the 2017 survey is considerably higher than it was in 2016. This trend will be reviewed once the 2018 figures are available at the end of 2019.

The decrease observed is significant and supported by the fact the survey response rate has increased by around 8%.

Apart from the number of animals, the type of species used in experimental procedures, the degree of severity and the proportion of genetically modified animals remain extremely close to the previous year's figures.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The statistics are not yet fully comparable from one year to the next, because France is still in a transitional period in order to implement the Directive. Subject to that reservation, we can nevertheless detect the following trends:

- stable use of non-human primates and a decrease in the number of domestic carnivores (dogs and cats) compared to 2016, which can be linked with concerted efforts made for several years to reduce the use of these sensitive species;

- an increase in the proportion of F2 generation non-human primates, reflecting a gradual shift towards achieving the 100% target set for 2022;

- stable use of genetically modified animals and a large reduction in the proportion of harmful genotypes (2.8% of animals in 2017).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severity is very stable from one year to the next. There has been a slight increase in the number of animals used in moderate procedures compared to mild procedures (see graph below). However, this change does not appear to be significant: it could be the result of establishments applying the severity assessment criteria better, thanks to the educational work carried out by the ethics committees and the Ministry responsible for research.

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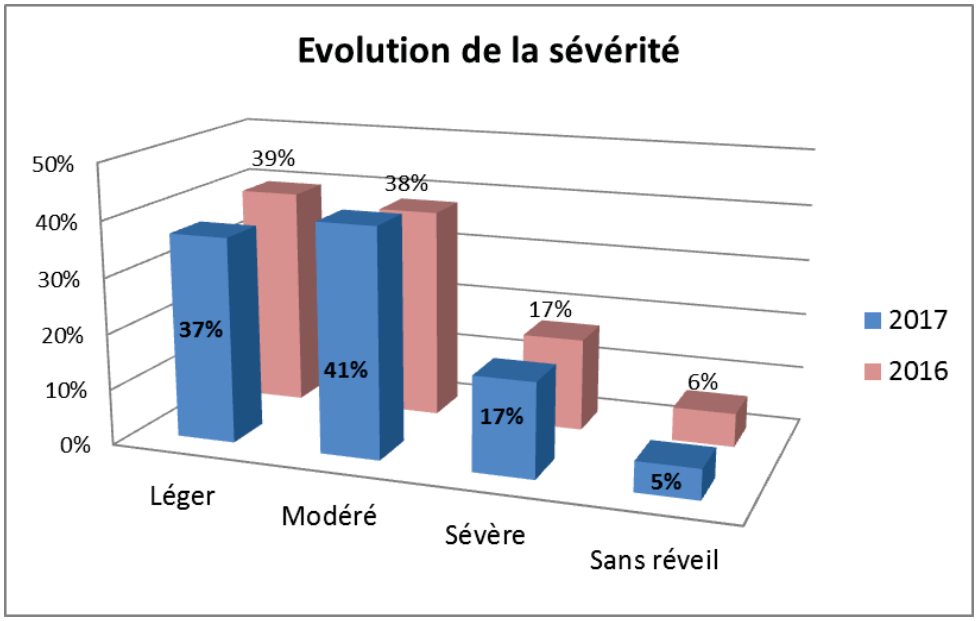

Key to graph:

Changes in severity			
Mild	Moderate	Severe	Non-recovery

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

France continues to promote the principles of replacement, refinement and reduction very actively, in particular through an ambitious training programme for staff in charge of both caring for animals and designing and carrying out scientific projects. The work of the National Commission for Animal Testing (CNEA) and the National Ethical Reflection Committee on Animal Testing (CNREEA), each of which meets several times a year, is also crucial.

The national platform for the development of alternative methods (FRANCOPA), which is a member of the European ECOPA network and brings together all stakeholders, also works to promote the three Rs.

The French authorities can also draw on the expertise of almost 130 ethical committees spread throughout France, which, on a local level, all help researchers think more about ethical issues, raise awareness of these three principles and encourage the sharing of best practice.

We believe that the decrease in the average number of animals used per establishment, referred to above (question 1), is partly the result of these efforts.

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5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As in previous years, the 'other fish' category remains very large, corresponding to 13.8% of the animals used (267,800 animals). This category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

The 'other birds' category still covers 1.4% of animals (27,200 animals), compared to 43,100 'domestic fowl'.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

No authorisations were granted in 2017 for requests exceeding the 'severe' classification.

France: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1134517	59.27%
Rats	183714	9.6%
Guinea-Pigs	45034	2.35%
Hamsters (Syrian)	6529	0.34%
Hamsters (Chinese)	167	0.01%
Mongolian gerbil	429	0.02%
Other Rodents	957	0.05%
Rabbits	127204	6.65%
Cats	867	0.05%
Dogs	4106	0.21%
Ferrets	148	0.01%
Other carnivores	27	0%
Horses, donkeys and cross-breeds	305	0.02%
Pigs	10346	0.54%
Goats	838	0.04%
Sheep	5396	0.28%
Cattle	1777	0.09%
Prosimians	86	0%
Marmoset and tamarins	224	0.01%
Cynomolgus monkey	3279	0.17%
Rhesus monkey	71	0%
Vervets (Chlorocebus spp.)	38	0%
Baboons	32	0%
Squirrel monkey	7	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	9	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	18525	0.97%

Animal Species	Number of animals	Percentage
Domestic fowl	43144	2.25%
Other birds	27225	1.42%
Reptiles	3462	0.18%
Rana	118	0.01%
Xenopus	4897	0.26%
Other Amphibians	742	0.04%
Zebra fish	21879	1.14%
Other Fish	268074	14%
Cephalopods	1	0%
Total	**1914174**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1564017	83.58%
Animals born in the EU but not at a registered breeder	204920	10.95%
Animals born in rest of Europe	48681	2.6%
Animals born in rest of world	53666	2.87%
Total	**1871284**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	236	10.24%
Animals born in rest of Europe	5	0.22%
Animals born in Asia	130	5.64%
Animals born in America	35	1.52%
Animals born in Africa	1729	75.04%
Animals born elsewhere	169	7.34%
Total	**2304**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	885	38.41%
F2 or greater	1285	55.77%
Self-sustaining colony	134	5.82%
Total	**2304**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	731041	38.19%
Translational and applied research	479372	25.04%
Regulatory use and Routine production	574030	29.99%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4918	0.26%
Preservation of species	18786	0.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	35512	1.86%
Forensic enquiries	8	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	70507	3.68%
Total	**1914174**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	94213	12.89%
Cardiovascular Blood and Lymphatic System	32577	4.46%
Nervous System	141408	19.34%
Respiratory System	12314	1.68%
Gastrointestinal System including Liver	28076	3.84%
Musculoskeletal System	17501	2.39%
Immune System	92193	12.61%
Urogenital/Reproductive System	19906	2.72%
Sensory Organs (skin, eyes and ears)	5435	0.74%
Endocrine System/Metabolism	40708	5.57%
Multisystemic	20896	2.86%
Ethology / Animal Behaviour /Animal Biology	164456	22.5%
Other basic research	61358	8.39%
Total	**731041**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	120343	25.1%
Human Infectious Disorders	52555	10.96%
Human Cardiovascular Disorders	15203	3.17%
Human Nervous and Mental Disorders	46348	9.67%
Human Respiratory Disorders	6669	1.39%
Human Gastrointestinal Disorders including Liver	12373	2.58%
Human Musculoskeletal Disorders	14481	3.02%
Human Immune Disorders	19048	3.97%
Human Urogenital/Reproductive Disorders	2240	0.47%
Human Sensory Organ Disorders (skin, eyes and ears)	7760	1.62%
Human Endocrine/Metabolism Disorders	12502	2.61%
Other Human Disorders	9742	2.03%
Animal Diseases and Disorders	37943	7.92%
Animal Welfare	216	0.05%
Diagnosis of diseases	97413	20.32%
Plant diseases	89	0.02%
Non-regulatory toxicology and ecotoxicology	24447	5.1%
Total	**479372**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	201610	35.12%
Other efficacy and tolerance testing	83928	14.62%
Toxicity and other safety testing including pharmacology	113238	19.73%
Routine production	175254	30.53%
Total	**574030**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	20294	10.07%
Pyrogenicity testing	6191	3.07%
Batch potency testing	138017	68.46%
Other quality controls	37108	18.41%
Total	**201610**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3294	2.91%
Skin irritation/corrosion	1754	1.55%
Skin sensitisation	14019	12.38%
Eye irritation/corrosion	253	0.22%
Repeated dose toxicity	24250	21.42%
Carcinogenicity	2295	2.03%
Genotoxicity	486	0.43%
Reproductive toxicity	14165	12.51%
Developmental toxicity	7483	6.61%
Neurotoxicity		
Kinetics	18338	16.19%
Pharmaco-dynamics (incl safety pharmacology)	9821	8.67%
Phototoxicity	521	0.46%
Ecotoxicity	13533	11.95%
Safety testing in food and feed area	1570	1.39%
Target animal safety	171	0.15%
Other toxicity/safety testing	1285	1.13%
Total	**113238**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	702	21.31%
Other lethal methods	561	17.03%
Non lethal methods	2031	61.66%
Total	**3294**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	12892	53.16%
29 - 90 days	6543	26.98%
> 90 days	4815	19.86%
Total	**24250**	**100.00%**

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10955	80.95%
Chronic toxicity	1107	8.18%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	846	6.25%
Other ecotoxicity	625	4.62%
Total	**13533**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	74243	42.36%
Monoclonal antibody by mouse ascites method	44198	25.22%
Other product types	56813	32.42%
Total	**175254**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	334865	58.34%
Legislation on medicinal products for veterinary use and their residues	82088	14.3%
Medical devices legislation	64309	11.2%
Industrial chemicals legislation	12737	2.22%
Plant protection product legislation	4541	0.79%
Biocides legislation	757	0.13%
Food legislation including food contact material	698	0.12%
Feed legislation including legislation for the safety of target animals, workers and environment	73260	12.76%
Cosmetics legislation		
Other legislation	775	0.14%
Total	**574030**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	552522	96.25%
Legislation satisfying national requirements only [within EU]	2643	0.46%
Legislation satisfying Non-EU requirements only	18865	3.29%
Total	**574030**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1873588	97.88%
Yes	40586	2.12%
Total	**1914174**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	103094	5.39%
Mild [up to and including]	703783	36.77%
Moderate	780853	40.79%
Severe	326444	17.05%
Total	**1914174**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1868750	97.63%
Yes	45424	2.37%
Total	**1914174**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1485568	77.61%
Genetically altered without a harmful phenotype	375530	19.62%
Genetically altered with a harmful phenotype	53076	2.77%
Total	**1914174**	**100.00%**

Germany

Germany: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 82% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 68% of the animals used. Approximately 8% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 755,000 animals were used to this end in 2015, which means that overall approximately 34,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,115,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 40% (in 2014 this was approximately 34%). In particular mice (91%) and fish (7%) were used.

Primates

The number of primates used also rose slightly. In 2015 a total of 3,141 primates were used, 293 more than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 4,491 and 1,112 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. There are no relevant differences compared to the previous year.

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 48% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal

diseases. Approximately 31% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 6% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2014 there was an increase in the areas of basic research (approximately 5%) and the manufacture and quality control of medical products or toxicological safety tests (approximately 6%), while in the area of other purposes there was a decrease of approximately 10%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 14%) and the immune system (approximately 27%) was particularly important in 2015. As such, research into the immune system showed an increase of approximately 10% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. Here, too, there was an increase of approximately 10% as compared to 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 63%). Here a slight increase as compared to the previous year (approximately 60%) can be seen. The share of animal experiments classified as 'medium' or 'severe' was approximately 24% and 5% respectively. A slight decrease can be seen as compared to the previous year (21% and 6% respectively). The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 8%. Here as well, a decrease can be seen as compared to 2014 (13%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. This prize consists of a monetary award of €15,000. In addition, the German government's involvement in reducing the number of animals used in experiments is part of the BMEL's initiative 'Minding animals – new ways to improve animal welfare'. In the context of this initiative, the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch, ZEBET) within the German Federal Institute for Risk

Assessment (Bundesinstitut für Risikobewertung) was expanded into the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R).

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Category 'other animal species'

In this category, particularly in the areas 'other rodent species' and 'other fish species', there are a greater number of additional animal species.

Under rodents, the common vole was used in particular. This primarily concerns animals caught in the wild which were re-released after the experiment was finished. These animals were mainly used in the context of research into common vole populations and their development on agricultural land. As a rule the severity classification for the animals involved was 'low'.

For fish, primarily local wild fish (e.g. common bream, brown trout, common roach, stickleback) were used in the context of basic ethological research. Here, too, this primarily concerns animals caught in the wild which were re-released after the experiment was finished. And here too the severity classification was 'low' as a rule.

Category 'other uses'

The emphasis in this category is in the areas 'basic research' and 'regulatory purposes'.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- studies of evolutionary changes in humans and animals;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research into the structure and function of G-protein-coupled receptors;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was 'low'.

In addition, in the area of **regulatory experiments** the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
- propagation of pathogens for developing in vitro diagnostics;

- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was 'low'.

Category 'other legal provisions'

In the context of this category, predominantly experiments were carried out to test substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz). The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2015 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1400822	68.49%
Rats	263318	12.87%
Guinea-Pigs	18237	0.89%
Hamsters (Syrian)	1390	0.07%
Hamsters (Chinese)	30	0%
Mongolian gerbil	4568	0.22%
Other Rodents	12793	0.63%
Rabbits	110988	5.43%
Cats	1112	0.05%
Dogs	4491	0.22%
Ferrets	230	0.01%
Other carnivores	686	0.03%
Horses, donkeys and cross-breeds	1507	0.07%
Pigs	12305	0.6%
Goats	904	0.04%
Sheep	2290	0.11%
Cattle	4029	0.2%
Prosimians	102	0%
Marmoset and tamarins	292	0.01%
Cynomolgus monkey	2678	0.13%
Rhesus monkey	39	0%
Vervets (Chlorocebus spp.)		
Baboons	6	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	1	0%
Other species of New World Monkeys (Ceboidea)		

Animal Species	Number of animals	Percentage
Apes		
Other Mammals	1383	0.07%
Domestic fowl	25658	1.25%
Other birds	13663	0.67%
Reptiles	501	0.02%
Rana	132	0.01%
Xenopus	4038	0.2%
Other Amphibians	2190	0.11%
Zebra fish	88147	4.31%
Other Fish	66731	3.26%
Cephalopods		
Total	**2045261**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1888405	94.58%
Animals born in the EU but not at a registered breeder	82266	4.12%
Animals born in rest of Europe	11491	0.58%
Animals born in rest of world	14466	0.72%
Total	**1996628**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	414	17.31%
Animals born in rest of Europe		
Animals born in Asia	1237	51.71%
Animals born in America	9	0.38%
Animals born in Africa	732	30.6%
Animals born elsewhere		
Total	**2392**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	505	21.11%
F2 or greater	1204	50.33%
Self-sustaining colony	683	28.55%
Total	**2392**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	975689	47.7%
Translational and applied research	312138	15.26%
Regulatory use and Routine production	629182	30.76%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5991	0.29%
Preservation of species	29297	1.43%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	49389	2.41%
Forensic enquiries	15	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	43560	2.13%
Total	**2045261**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	81162	8.32%
Cardiovascular Blood and Lymphatic System	81552	8.36%
Nervous System	140795	14.43%
Respiratory System	33612	3.44%
Gastrointestinal System including Liver	26877	2.75%
Musculoskeletal System	18068	1.85%
Immune System	263000	26.96%
Urogenital/Reproductive System	20090	2.06%
Sensory Organs (skin, eyes and ears)	27615	2.83%
Endocrine System/Metabolism	43757	4.48%
Multisystemic	49023	5.02%
Ethology / Animal Behaviour /Animal Biology	31730	3.25%
Other basic research	158408	16.24%
Total	**975689**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	115200	36.91%
Human Infectious Disorders	21784	6.98%
Human Cardiovascular Disorders	16246	5.2%
Human Nervous and Mental Disorders	47429	15.19%
Human Respiratory Disorders	15252	4.89%
Human Gastrointestinal Disorders including Liver	8736	2.8%
Human Musculoskeletal Disorders	3253	1.04%
Human Immune Disorders	14081	4.51%
Human Urogenital/Reproductive Disorders	5321	1.7%
Human Sensory Organ Disorders (skin, eyes and ears)	3123	1%
Human Endocrine/Metabolism Disorders	20409	6.54%
Other Human Disorders	2224	0.71%
Animal Diseases and Disorders	20203	6.47%
Animal Welfare	4743	1.52%
Diagnosis of diseases	4539	1.45%
Plant diseases	21	0.01%
Non-regulatory toxicology and ecotoxicology	9574	3.07%
Total	**312138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	235332	37.4%
Other efficacy and tolerance testing	45385	7.21%
Toxicity and other safety testing including pharmacology	256282	40.73%
Routine production	92183	14.65%
Total	**629182**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	43768	18.6%
Pyrogenicity testing	6992	2.97%
Batch potency testing	184434	78.37%
Other quality controls	138	0.06%
Total	**235332**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	8608	3.36%
Skin irritation/corrosion	894	0.35%
Skin sensitisation	11170	4.36%
Eye irritation/corrosion	225	0.09%
Repeated dose toxicity	22769	8.88%
Carcinogenicity	5053	1.97%
Genotoxicity	4167	1.63%
Reproductive toxicity	22388	8.74%
Developmental toxicity	15019	5.86%
Neurotoxicity	90	0.04%
Kinetics	37692	14.71%
Pharmaco-dynamics (incl safety pharmacology)	88650	34.59%
Phototoxicity	12	0%
Ecotoxicity	31374	12.24%
Safety testing in food and feed area		
Target animal safety	1601	0.62%
Other toxicity/safety testing	6570	2.56%
Total	**256282**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	3559	41.35%
Other lethal methods	117	1.36%
Non lethal methods	4932	57.3%
Total	**8608**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	17256	75.79%
29 - 90 days	3132	13.76%
> 90 days	2381	10.46%
Total	**22769**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	8021	25.57%
Chronic toxicity	6288	20.04%
Reproductive ecotoxicity	1643	5.24%
Endocrine activity	8258	26.32%
Bioaccumulation	1858	5.92%
Other ecotoxicity	5306	16.91%
Total	**31374**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	86209	93.52%
Monoclonal antibody by mouse ascites method	894	0.97%
Other product types	5080	5.51%
Total	**92183**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	441537	70.18%
Legislation on medicinal products for veterinary use and their residues	38179	6.07%
Medical devices legislation	61866	9.83%
Industrial chemicals legislation	50563	8.04%
Plant protection product legislation	31544	5.01%
Biocides legislation	1200	0.19%
Food legislation including food contact material	38	0.01%
Feed legislation including legislation for the safety of target animals, workers and environment	1638	0.26%
Cosmetics legislation		
Other legislation	2617	0.42%
Total	**629182**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	593854	94.39%
Legislation satisfying national requirements only [within EU]	19377	3.08%
Legislation satisfying Non-EU requirements only	15951	2.54%
Total	**629182**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1999020	97.74%
Yes	46241	2.26%
Total	**2045261**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	159720	7.81%
Mild [up to and including]	1282093	62.69%
Moderate	489855	23.95%
Severe	113593	5.55%
Total	**2045261**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1889941	92.41%
Yes	155320	7.59%
Total	**2045261**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1304619	63.79%
Genetically altered without a harmful phenotype	626034	30.61%
Genetically altered with a harmful phenotype	114608	5.6%
Total	**2045261**	**100.00%**

Germany: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 79% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 726,000 animals were used to this end in 2016, which means that overall approximately 29,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,200,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 42% (in 2015 this was approximately 40%). In particular mice (86%) and fish (12%) were used.

Primates

The number of primates used also showed a definite decrease. In 2015 a total of 2,462 primates were used, 679 fewer than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 3,977 and 766 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. As compared to the previous year, there was a decrease in the number of dogs (4,491 in 2015) and cats (1,112 in 2015).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 53% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 14% were used for researching human and animal diseases. Approximately 26% of the animals were used in the manufacture and quality control of

medical products or for toxicological safety tests. Approximately 7% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2015 there was an increase in the area of basic research (approximately 5%), while in the area of the manufacture and quality control of medical products or toxicological safety tests there was a decrease of approximately 6%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 15%) and the immune system (approximately 20%) was particularly important in 2016. As such, research into the immune system showed a decrease of approximately 7% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. No change can be seen here as compared to 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 63%). The share of animal experiments classified as 'medium' or 'severe' was approximately 23% and 7% respectively. Compared to the previous year, the number of experiments classified as 'severe' showed a slight increase of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 7% and thereby at the level of the previous year (approximately 8%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. In 2016 the amount of the prize was increased from €15,000 to €25,000. In addition, the German government's involvement in reducing the number of animals used in experiments is part of the BMEL's initiative 'Minding animals - new ways to improve animal welfare'.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Category 'other animal species'

In this category, particularly in the areas 'other fish species' and 'other bird species', there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, common nase) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was 'low'.

Among birds, primarily turkeys and local wild bird species (e.g. tit, pheasant, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was 'low'.

Category 'other uses'

The emphasis in this category is in the areas 'basic research' and 'regulatory purposes'.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was 'low'.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
- propagation of pathogens for developing in vitro diagnostics;
- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was 'low'.

Category 'other legal provisions'

In the context of this category the following other legal provisions are particularly referred to:

- test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
- test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);

- test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
- test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2016 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1400971	65.83%
Rats	244274	11.48%
Guinea-Pigs	14184	0.67%
Hamsters (Syrian)	1101	0.05%
Hamsters (Chinese)	2	0%
Mongolian gerbil	4769	0.22%
Other Rodents	6639	0.31%
Rabbits	98331	4.62%
Cats	766	0.04%
Dogs	3964	0.19%
Ferrets	130	0.01%
Other carnivores	474	0.02%
Horses, donkeys and cross-breeds	1270	0.06%
Pigs	16727	0.79%
Goats	223	0.01%
Sheep	3750	0.18%
Cattle	5432	0.26%
Prosimians	117	0.01%
Marmoset and tamarins	113	0.01%
Cynomolgus monkey	2058	0.1%
Rhesus monkey	86	0%
Vervets (Chlorocebus spp.)	18	0%
Baboons	8	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	18	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1143	0.05%
Domestic fowl	29853	1.4%
Other birds	16554	0.78%
Reptiles	454	0.02%

Animal Species	Number of animals	Percentage
Rana	930	0.04%
Xenopus	5237	0.25%
Other Amphibians	2675	0.13%
Zebra fish	178224	8.37%
Other Fish	87759	4.12%
Cephalopods		
Total	**2128254**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1951771	94.31%
Animals born in the EU but not at a registered breeder	94479	4.57%
Animals born in rest of Europe	9258	0.45%
Animals born in rest of world	14101	0.68%
Total	**2069609**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	192	10.89%
Animals born in rest of Europe	2	0.11%
Animals born in Asia	1039	58.93%
Animals born in America		
Animals born in Africa	530	30.06%
Animals born elsewhere		
Total	**1763**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	403	22.86%
F2 or greater	895	50.77%
Self-sustaining colony	465	26.38%
Total	**1763**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1117731	52.52%
Translational and applied research	307138	14.43%
Regulatory use and Routine production	554982	26.08%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8101	0.38%
Preservation of species	40387	1.9%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	48931	2.3%
Forensic enquiries	28	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	50956	2.39%
Total	**2128254**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage

Basic Research	Number of uses	Percentage
Oncology	84836	7.59%
Cardiovascular Blood and Lymphatic System	101807	9.11%
Nervous System	168180	15.05%
Respiratory System	24355	2.18%
Gastrointestinal System including Liver	31097	2.78%
Musculoskeletal System	19328	1.73%
Immune System	220107	19.69%
Urogenital/Reproductive System	25928	2.32%
Sensory Organs (skin, eyes and ears)	28599	2.56%
Endocrine System/Metabolism	117143	10.48%
Multisystemic	137863	12.33%
Ethology / Animal Behaviour /Animal Biology	35228	3.15%
Other basic research	123260	11.03%
Total	**1117731**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	115230	37.52%
Human Infectious Disorders	22052	7.18%
Human Cardiovascular Disorders	14597	4.75%
Human Nervous and Mental Disorders	41343	13.46%
Human Respiratory Disorders	16124	5.25%
Human Gastrointestinal Disorders including Liver	10359	3.37%
Human Musculoskeletal Disorders	3572	1.16%
Human Immune Disorders	14685	4.78%
Human Urogenital/Reproductive Disorders	3773	1.23%
Human Sensory Organ Disorders (skin, eyes and ears)	5713	1.86%
Human Endocrine/Metabolism Disorders	14638	4.77%
Other Human Disorders	4223	1.37%
Animal Diseases and Disorders	23117	7.53%
Animal Welfare	7202	2.34%
Diagnosis of diseases	3412	1.11%
Plant diseases	17	0.01%
Non-regulatory toxicology and ecotoxicology	7081	2.31%
Total	**307138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	186497	33.6%
Other efficacy and tolerance testing	45456	8.19%
Toxicity and other safety testing including pharmacology	228227	41.12%
Routine production	94802	17.08%
Total	**554982**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	27627	14.81%
Pyrogenicity testing	347	0.19%
Batch potency testing	155904	83.6%
Other quality controls	2619	1.4%
Total	**186497**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	7255	3.18%
Skin irritation/corrosion	758	0.33%
Skin sensitisation	8604	3.77%
Eye irritation/corrosion	200	0.09%
Repeated dose toxicity	18970	8.31%
Carcinogenicity	799	0.35%
Genotoxicity	2743	1.2%
Reproductive toxicity	14000	6.13%
Developmental toxicity	17916	7.85%
Neurotoxicity	166	0.07%
Kinetics	30657	13.43%
Pharmaco-dynamics (incl safety pharmacology)	92116	40.36%
Phototoxicity		
Ecotoxicity	27424	12.02%
Safety testing in food and feed area	86	0.04%
Target animal safety	3905	1.71%
Other toxicity/safety testing	2628	1.15%
Total	**228227**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4278	58.97%
Other lethal methods	301	4.15%
Non lethal methods	2676	36.88%
Total	**7255**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	12698	66.94%
29 - 90 days	4491	23.67%
> 90 days	1781	9.39%
Total	**18970**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	6189	22.57%
Chronic toxicity	10807	39.41%
Reproductive ecotoxicity	1465	5.34%
Endocrine activity	5940	21.66%
Bioaccumulation	2831	10.32%
Other ecotoxicity	192	0.7%
Total	**27424**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	88584	93.44%
Monoclonal antibody by mouse ascites method	2147	2.26%
Other product types	4071	4.29%
Total	**94802**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	389067	70.1%
Legislation on medicinal products for veterinary use and their residues	29785	5.37%
Medical devices legislation	56928	10.26%
Industrial chemicals legislation	36967	6.66%
Plant protection product legislation	33617	6.06%
Biocides legislation	2077	0.37%
Food legislation including food contact material	3	0%
Feed legislation including legislation for the safety of target animals, workers and environment	3068	0.55%
Cosmetics legislation		
Other legislation	3470	0.63%
Total	**554982**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	501983	90.45%
Legislation satisfying national requirements only [within EU]	51318	9.25%
Legislation satisfying Non-EU requirements only	1681	0.3%
Total	**554982**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2071372	97.33%
Yes	56882	2.67%
Total	**2128254**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	146265	6.87%
Mild [up to and including]	1324548	62.24%
Moderate	500009	23.49%
Severe	157432	7.4%
Total	**2128254**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2027088	95.25%
Yes	101166	4.75%
Total	**2128254**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1273498	59.84%
Genetically altered without a harmful phenotype	723600	34%
Genetically altered with a harmful phenotype	131156	6.16%
Total	**2128254**	**100.00%**

Germany: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 80% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds. Here, too, the figures are virtually unchanged compared to the previous year.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 736,000 animals were used to this end in 2017, which means that overall approximately 11,000 more animals were used than in the previous year. Correspondingly, these animals are not included in the numbers of experimental animals submitted to the European Commission.

Genetically modified animals

The number of genetically modified animals has remained largely stable in comparison to the previous year. Approximately 1,150,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 41% (in 2016 this was approximately 42%). In particular mice (89%) and fish (10%) were used.

Primates

However, the number of primates used showed a definite increase. In 2017 a total of 3,525 primates were used, 1,063 more than in the previous year.

Simians have a genome that is comparable to that of humans, and their total bodily function is also more similar to that of humans. Therefore it is likely that some diseases that cannot be imitated well in the mouse by means of genetic modification can present well in simians in this way. These genetically modified simians could result in a major step towards better understanding very significant, hitherto incurable and terminal diseases and therefore put new therapies within our grasp.

Dogs and cats

The number of dogs and cats used amounted to 3,334 and 718 respectively, used in particular for statutory testing and for applied research. As compared to the previous year, there was an overall decrease in the number of dogs (3,977 in 2016) and cats (766 in 2016).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 50% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal diseases. Approximately 27% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 8% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2016 there was a slight decrease in the area of basic research (approximately 3%), while the other areas each saw a minimal increase of approximately 1%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 21%) and the immune system (approximately 20%) was particularly important in 2017. As such, research into the nervous system showed an increase of approximately 6% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 41% of test animals used in this field of research were utilised. This is a slight increase as compared to 2016 (approximately 37%).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 59%). The share of animal experiments classified as 'medium' or 'severe' was approximately 27% and 5% respectively. Compared to the previous year, the number of experiments classified as 'medium' showed a slight increase of 4%, while the number of experiments classified as 'severe' showed a slight decrease of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 9% and thereby at a slightly higher level than the previous year (approximately 7%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The German Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) is endeavouring to reduce the number of animals used in experiments. For this reason various projects are initiated and supported with the goal of replacing animal experiments with alternative methods as soon as possible. These projects include establishing and operating the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R), promoting research by the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR), supporting the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur

Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments) and annually awarding the BMEL's Animal Welfare Research Prize. In 2016 the amount of the prize was increased from €15,000 to €25,000.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Category 'other animal species'
In this category, particularly in the areas 'other fish species' and 'other bird species', there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, brown trout) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was 'low'.

Among birds, primarily turkeys and local wild bird species (e.g. tit, duck, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was 'low'.

Moreover, in the areas 'other carnivores' and 'other amphibians' there were a smaller number of additional species. For instance, among carnivores minks were particularly used in the context of vaccine tolerability testing, while in the area of amphibians primarily the common toad, fire salamander, axolotl and common frog were used with the aim of protecting the natural environment in the interest of human and animal health or welfare.

Category 'other uses'
The emphasis in this category is in the areas 'basic research' and 'regulatory purposes'.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was between 'low' and 'medium'.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- testing the effectiveness and mechanism of feed additives;
- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was between 'low' and 'medium'.

Category 'other legal provisions'

In the context of this category the following other legal provisions are particularly referred to:

- test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
- test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);
- test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
- test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1368447	66.15%
Rats	255449	12.35%
Guinea-Pigs	14851	0.72%
Hamsters (Syrian)	1222	0.06%
Hamsters (Chinese)	8	0%
Mongolian gerbil	4255	0.21%
Other Rodents	9950	0.48%
Rabbits	92661	4.48%
Cats	718	0.03%
Dogs	3330	0.16%
Ferrets	196	0.01%
Other carnivores	535	0.03%
Horses, donkeys and cross-breeds	1209	0.06%
Pigs	17347	0.84%
Goats	212	0.01%
Sheep	3053	0.15%
Cattle	6332	0.31%

Animal Species	Number of animals	Percentage
Prosimians	87	0%
Marmoset and tamarins	224	0.01%
Cynomolgus monkey	3002	0.15%
Rhesus monkey	117	0.01%
Vervets (Chlorocebus spp.)	15	0%
Baboons	14	0%
Squirrel monkey	1	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	12	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1352	0.07%
Domestic fowl	24920	1.2%
Other birds	12000	0.58%
Reptiles	369	0.02%
Rana	377	0.02%
Xenopus	4546	0.22%
Other Amphibians	2652	0.13%
Zebra fish	141676	6.85%
Other Fish	97674	4.72%
Cephalopods		
Total	**2068813**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1900118	93.64%
Animals born in the EU but not at a registered breeder	100821	4.97%
Animals born in rest of Europe	15127	0.75%
Animals born in rest of world	13056	0.64%
Total	**2029122**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	360	13.39%
Animals born in rest of Europe		
Animals born in Asia	1699	63.21%
Animals born in America		
Animals born in Africa	628	23.36%
Animals born elsewhere	1	0.04%
Total	**2688**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	338	12.57%
F2 or greater	1786	66.44%
Self-sustaining colony	564	20.98%
Total	**2688**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1039225	50.23%
Translational and applied research	304599	14.72%
Regulatory use and Routine production	556946	26.92%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8491	0.41%
Preservation of species	41156	1.99%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	53121	2.57%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	65275	3.16%
Total	**2068813**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	91387	8.79%
Cardiovascular Blood and Lymphatic System	109053	10.49%
Nervous System	216128	20.8%
Respiratory System	23579	2.27%
Gastrointestinal System including Liver	33087	3.18%
Musculoskeletal System	25657	2.47%
Immune System	202581	19.49%
Urogenital/Reproductive System	23426	2.25%
Sensory Organs (skin, eyes and ears)	27801	2.68%
Endocrine System/Metabolism	57885	5.57%
Multisystemic	57475	5.53%
Ethology / Animal Behaviour /Animal Biology	46306	4.46%
Other basic research	124860	12.01%
Total	**1039225**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	125614	41.24%
Human Infectious Disorders	18388	6.04%
Human Cardiovascular Disorders	16923	5.56%
Human Nervous and Mental Disorders	38573	12.66%
Human Respiratory Disorders	13371	4.39%
Human Gastrointestinal Disorders including Liver	15898	5.22%
Human Musculoskeletal Disorders	3939	1.29%
Human Immune Disorders	11659	3.83%
Human Urogenital/Reproductive Disorders	4784	1.57%
Human Sensory Organ Disorders (skin, eyes and ears)	6500	2.13%
Human Endocrine/Metabolism Disorders	12138	3.98%
Other Human Disorders	1227	0.4%
Animal Diseases and Disorders	17368	5.7%
Animal Welfare	6271	2.06%
Diagnosis of diseases	2488	0.82%
Plant diseases	69	0.02%
Non-regulatory toxicology and ecotoxicology	9389	3.08%
Total	**304599**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	188089	33.77%
Other efficacy and tolerance testing	32991	5.92%
Toxicity and other safety testing including pharmacology	260473	46.77%
Routine production	75393	13.54%
Total	**556946**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	19382	10.3%
Pyrogenicity testing	5591	2.97%
Batch potency testing	161272	85.74%
Other quality controls	1844	0.98%
Total	**188089**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10357	3.98%
Skin irritation/corrosion	884	0.34%
Skin sensitisation	8711	3.34%
Eye irritation/corrosion	171	0.07%
Repeated dose toxicity	19136	7.35%
Carcinogenicity	1961	0.75%
Genotoxicity	3522	1.35%
Reproductive toxicity	21926	8.42%
Developmental toxicity	35887	13.78%
Neurotoxicity	86	0.03%
Kinetics	31782	12.2%
Pharmaco-dynamics (incl safety pharmacology)	79250	30.43%
Phototoxicity		
Ecotoxicity	38843	14.91%
Safety testing in food and feed area	1721	0.66%
Target animal safety	3423	1.31%
Other toxicity/safety testing	2813	1.08%
Total	**260473**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4136	39.93%
Other lethal methods	182	1.76%
Non lethal methods	6039	58.31%
Total	**10357**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13183	68.89%
29 - 90 days	4136	21.61%
> 90 days	1817	9.5%
Total	**19136**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	6957	17.91%
Chronic toxicity	16704	43%
Reproductive ecotoxicity	904	2.33%
Endocrine activity	5840	15.03%
Bioaccumulation	1807	4.65%
Other ecotoxicity	6631	17.07%
Total	**38843**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	73520	97.52%
Monoclonal antibody by mouse ascites method	384	0.51%
Other product types	1489	1.97%
Total	**75393**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	372333	66.85%
Legislation on medicinal products for veterinary use and their residues	23641	4.24%
Medical devices legislation	54817	9.84%
Industrial chemicals legislation	50724	9.11%
Plant protection product legislation	46229	8.3%
Biocides legislation	2366	0.42%
Food legislation including food contact material	14	0%
Feed legislation including legislation for the safety of target animals, workers and environment	3554	0.64%
Cosmetics legislation		
Other legislation	3268	0.59%
Total	**556946**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	543850	97.65%
Legislation satisfying national requirements only [within EU]	4078	0.73%
Legislation satisfying Non-EU requirements only	9018	1.62%
Total	**556946**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2031810	98.21%
Yes	37003	1.79%
Total	**2068813**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	178095	8.61%
Mild [up to and including]	1226990	59.31%
Moderate	548621	26.52%
Severe	115107	5.56%
Total	**2068813**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1891562	91.43%
Yes	177251	8.57%
Total	**2068813**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1241283	60%
Genetically altered without a harmful phenotype	658801	31.84%
Genetically altered with a harmful phenotype	168729	8.16%
Total	**2068813**	**100.00%**

Greece

Greece: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

An increasing trend in the use of animals used for scientific purposes may be observed in 2015 compared to 2014. This is justified due to the fact that a lot of European research projects, which were funded by the European Union (ERC) were performed. 2015 has been a period where applications to receive funding from HORIZON 2020 were pending or were in the process to be approved.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

A) A significant use of fish is depicted in Greek statistical data in 2015 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 4-fold increase of use of domestic fowls is being recorded for 2015 and can be attributed the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2014, which can be attributed to the research projects performed

D) There is an increasing trend regarding the reuse of animals in the context of an attempt to reduce the number of animals used for scientific purposes.

E) A significant increase in the use of genetically altered animals without a harmful genotype by approximately 20% can be attributed to the HORIZON 2020 related projects.

F) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

G) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

An increase of “severe” use of animals is reported for 2015 compared to 2014 and is attributed to projects which included complicated surgical techniques, oncology and toxicology tests for regulatory use and routine production.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A significant proportion of other fish is reported in Greece for 2015. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

In one case legislation on medicinal products for veterinary use and their residues is recorded.

Rodents have been used for various ‘other” purposes in 2015, but not in an exceptional trend.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2015.

Greece: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	28849	53.67%
Rats	2205	4.1%
Guinea-Pigs	11	0.02%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	611	1.14%
Cats	47	0.09%
Dogs	4	0.01%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	430	0.8%
Goats		
Sheep	8	0.01%

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Animal Species	Number of animals	Percentage
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	1606	2.99%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians	200	0.37%
Zebra fish	4675	8.7%
Other Fish	15099	28.09%
Cephalopods		
Total	**53748**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	53337	99.96%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world	20	0.04%
Total	**53357**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	1	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**1**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	1	100%
Self-sustaining colony		
Total	**1**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38599	71.81%
Translational and applied research	6463	12.02%
Regulatory use and Routine production	7589	14.12%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1097	2.04%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**53748**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4102	10.63%
Cardiovascular Blood and Lymphatic System	6710	17.38%
Nervous System	1541	3.99%
Respiratory System	124	0.32%
Gastrointestinal System including Liver	896	2.32%
Musculoskeletal System	908	2.35%
Immune System	3325	8.61%
Urogenital/Reproductive System	179	0.46%
Sensory Organs (skin, eyes and ears)	745	1.93%
Endocrine System/Metabolism	1110	2.88%
Multisystemic	1098	2.84%
Ethology / Animal Behaviour /Animal Biology	14299	37.05%
Other basic research	3562	9.23%
Total	**38599**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	915	14.16%
Human Infectious Disorders	470	7.27%
Human Cardiovascular Disorders	1	0.02%
Human Nervous and Mental Disorders	967	14.96%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	160	2.48%
Human Musculoskeletal Disorders	1825	28.24%
Human Immune Disorders	205	3.17%
Human Urogenital/Reproductive Disorders	12	0.19%
Human Sensory Organ Disorders (skin, eyes and ears)	90	1.39%
Human Endocrine/Metabolism Disorders	83	1.28%
Other Human Disorders	404	6.25%
Animal Diseases and Disorders		
Animal Welfare	165	2.55%
Diagnosis of diseases	788	12.19%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	378	5.85%
Total	**6463**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Toxicity and other safety testing including pharmacology	7580	99.88%
Routine production	9	0.12%
Total	**7589**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	800	10.55%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	6780	89.45%
Total	**7580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	800	100%
Other lethal methods		
Non lethal methods		
Total	**800**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	9	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	9	100.00%

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	9	0.12%
Legislation on medicinal products for veterinary use and their residues	800	10.54%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	6780	89.34%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	7589	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7589	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	7589	100.00%

First uses and re-uses

Re-use	Number of uses	Percentage
No	53358	99.27%
Yes	390	0.73%
Total	**53748**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	949	1.77%
Mild [up to and including]	37804	70.34%
Moderate	11905	22.15%
Severe	3090	5.75%
Total	**53748**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	51409	95.65%
Yes	2339	4.35%
Total	**53748**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	40705	75.73%
Genetically altered without a harmful phenotype	11085	20.62%
Genetically altered with a harmful phenotype	1958	3.64%
Total	**53748**	**100.00%**

Greece: Narrative 2016

1. **General information on any changes in trends observed since the previous reporting period.**

Any significant changes of trends observed in 2016 compared to 2015 regarding the purpose of authorised projects can be attributed to their nature and number. This is directly related to funding resources and the choice of research purpose by user establishments.

A significant decrease in the use of animals for the creation of new genetic lines is reported and can be attributed to the lack of relevant funding by European research projects or absence of relevant application forms by researchers.

2**. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 2-fold increase of use of domestic fowls is being recorded for 2016 and can be attributed to the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2015, which can be attributed to the research projects performed during 2016.

D) A significant decrease in the use of genetically altered animals without a harmful phenotype by approximately 5% and an increase of genetically altered animals with a harmful phenotype can be attributed to relevant authorised projects.

E) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

F) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

No particular change in trends in actual severities are reported.

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4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A significant proportion of other fish is reported in Greece for 2016. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

Rodents have been used for mouse development from epiblast derived cells in 2016, but not in an exceptional trend.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2016.

Greece: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	23946	52.65%
Rats	2222	4.89%
Guinea-Pigs	13	0.03%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	491	1.08%
Cats	13	0.03%
Dogs	3	0.01%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	333	0.73%
Goats		
Sheep	12	0.03%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0.01%

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Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	3200	7.04%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	130	0.29%
Other Fish	15117	33.24%
Cephalopods		
Total	**45483**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	45127	99.83%
Animals born in the EU but not at a registered breeder	30	0.07%
Animals born in rest of Europe		
Animals born in rest of world	48	0.11%
Total	**45205**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**1**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	1	100%
Self-sustaining colony		
Total	**1**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	33690	74.07%
Translational and applied research	4514	9.92%
Regulatory use and Routine production	6630	14.58%
Protection of the natural environment in the interests of the health or welfare of human		

Purpose Category	Number of uses	Percentage
beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	649	1.43%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**45483**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	2377	7.06%
Cardiovascular Blood and Lymphatic System	2855	8.47%
Nervous System	1753	5.2%
Respiratory System	335	0.99%
Gastrointestinal System including Liver	915	2.72%
Musculoskeletal System	502	1.49%
Immune System	1300	3.86%
Urogenital/Reproductive System	97	0.29%
Sensory Organs (skin, eyes and ears)	1284	3.81%
Endocrine System/Metabolism	742	2.2%
Multisystemic	3075	9.13%
Ethology / Animal Behaviour /Animal Biology	14957	44.4%
Other basic research	3498	10.38%
Total	**33690**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1319	29.22%
Human Infectious Disorders	224	4.96%
Human Cardiovascular Disorders	385	8.53%
Human Nervous and Mental Disorders	526	11.65%
Human Respiratory Disorders	422	9.35%
Human Gastrointestinal Disorders including Liver	204	4.52%
Human Musculoskeletal Disorders	841	18.63%
Human Immune Disorders	135	2.99%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	67	1.48%
Human Endocrine/Metabolism Disorders	136	3.01%
Other Human Disorders	207	4.59%
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	48	1.06%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**4514**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		

Regulatory use and Routine production	Number of uses	Percentage
Routine production		
Toxicity and other safety testing including pharmacology	6630	100%
Total	6630	100.00%

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	6630	100%
Total	6630	100.00%

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	6630	100%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**6630**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6630	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6630**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	45206	99.39%
Yes	277	0.61%
Total	**45483**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1873	4.12%
Mild [up to and including]	32156	70.7%
Moderate	8903	19.57%
Severe	2551	5.61%
Total	**45483**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	45053	99.05%
Yes	430	0.95%
Total	**45483**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	34912	76.76%
Genetically altered without a harmful phenotype	7683	16.89%
Genetically altered with a harmful phenotype	2888	6.35%
Total	**45483**	**100.00%**

Greece: Narrative 2017

1. **General information on any changes in trends observed since the previous reporting period.**

A significant increase in the use of animals for the creation of new genetic lines is reported and can be attributed to the increase of funding by European research projects.

A significant increase in the number of animals undergone “non-recovery” procedures has been reported. This is proportional to the number of animals used for higher education of training for the acquisition, training of improvement of vocational skills.

A new user establishment was authorised in 2017, which performs research projects on the protection of natural environment in the interests of the health of welfare of humans and animals. This is a new category of purposes in Greece.

2**. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A significant decrease in the use of domestic fowl is reported due to lack of relevant projects performed in 2017 by a user establishment.

C) Regarding the use of cephalopods (first time for Greece in 2017):

The application of the protocol had the objective to assess the sensitivity and immune response of *O. vulgaris* against common fish pathogens under different physicochemical water parameters (i.e. different temperatures). Animals are infected either intramuscularly or intravenously, hemolymph is collected for the assessment of immune stimulation and at the end of the experiment, organ samples are collected to assess immune responses and bacteria presence internally. All procedures are carried out under anesthesia, while organ sampling is performed after euthanasia with an overdose of anesthetic. In 2017, the protocol was applied once in 33 animals. From these, 9 individuals either died or used for the collection of samples and for 24 individuals, the protocol was characterized as mild. *O. vulgaris* were used by a newly authorised user establishment.

D) Regarding the use of animals for the protection of natural environment in the interests of the health or welfare of human beings or animals, that is recorded for the first time in 2017, these were used by a newly authorised user establishment.

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E) It has to be noted that the use of various species differs among each year according to the protocols authorised and funding received by user establishments. Minor changing trends can be recorded.

F) It has to be noted that the use of animals for translational and applied research has increased by approximately 40% in total. This percentage in general differs among each year according to the protocols authorised and funding received by user establishments.

G) It has to be noted that the use of animals for various systems either for basic or translational and applied research varies among each year according to the nature of protocols chosen by researchers.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

A) Animals with “Non recovery” severity seem to have diminished due to a decrease in higher education trainings programs that are performed with the use of live animals in Greece.

B) The application of experimental protocols on teleosts by a newly authorised user establishment had the objective to assess either resistance of fish to fish pathogens or the efficacy of vaccines. These protocols were classified as severe because mortality is caused near to or more than > 70%. For 2017, gilthead sea bream and European sea bass were used.

C) A significant increase in the use of animals in translational/applied research for human cancer has been noted in 2017 compared to 2016 which has resulted in the relevant increase of the severe use of those animals. This can attributed to the increase of funding research programmes in this sector.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory animal science training courses are organised annually in Greece.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A) A significant proportion of other fish is reported in Greece for 2017. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

B) A number of rodents have been reported under ‘Translational/ Applied research”: Other human disorders, as having been used in multisystemic protocols including arthritis and enteropathy.

C) A number of rodents have been reported for aging studies using “mild” procedures.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2017.

Greece: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	25479	54.52%
Rats	2438	5.22%
Guinea-Pigs	6	0.01%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	213	0.46%
Cats	8	0.02%
Dogs	41	0.09%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	289	0.62%
Goats		
Sheep	8	0.02%
Cattle	3	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	1	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	6	0.01%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	1859	3.98%
Other Fish	16346	34.98%
Cephalopods	33	0.07%
Total	**46730**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	45596	98.55%
Animals born in the EU but not at a registered breeder	33	0.07%
Animals born in rest of Europe		
Animals born in rest of world	640	1.38%
Total	**46269**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	27573	59%
Translational and applied research	8058	17.24%
Regulatory use and Routine production	6887	14.74%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3093	6.62%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1119	2.39%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**46730**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	923	3.35%
Cardiovascular Blood and Lymphatic System	1315	4.77%
Nervous System	1204	4.37%
Respiratory System		
Gastrointestinal System including Liver	428	1.55%
Musculoskeletal System	520	1.89%
Immune System	2225	8.07%
Urogenital/Reproductive System	242	0.88%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	988	3.58%
Endocrine System/Metabolism	843	3.06%
Multisystemic	99	0.36%
Ethology / Animal Behaviour /Animal Biology	14686	53.26%
Other basic research	4100	14.87%
Total	**27573**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2487	30.86%
Human Infectious Disorders	271	3.36%
Human Cardiovascular Disorders	967	12%
Human Nervous and Mental Disorders	1372	17.03%
Human Respiratory Disorders	291	3.61%
Human Gastrointestinal Disorders including Liver	363	4.5%
Human Musculoskeletal Disorders	710	8.81%
Human Immune Disorders	200	2.48%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	381	4.73%
Human Endocrine/Metabolism Disorders	34	0.42%
Other Human Disorders	648	8.04%
Animal Diseases and Disorders		
Animal Welfare	40	0.5%
Diagnosis of diseases	230	2.85%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	64	0.79%
Total	**8058**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	6887	100%
Total	**6887**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Pharmaco-dynamics (incl safety pharmacology)	10	0.15%
Safety testing in food and feed area	6877	99.85%
Total	**6887**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	10	0.15%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	6877	99.85%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**6887**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6887	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6887**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	46269	99.01%
Yes	461	0.99%
Total	**46730**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3646	7.8%
Mild [up to and including]	29392	62.9%
Moderate	9198	19.68%
Severe	4494	9.62%
Total	**46730**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	42770	91.53%
Yes	3960	8.47%
Total	**46730**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	31622	67.67%
Genetically altered without a harmful phenotype	12982	27.78%
Genetically altered with a harmful phenotype	2126	4.55%
Total	**46730**	**100.00%**

Hungary

Hungary: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2015 was 195 603 which represents 2.7 % decrease compared to the same figure of 2014. The number of re-uses has been decreased by 56% (from 6584 to 2924).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The increase was 10.8% in the number of mice, 3.65% in case of rats, 23.22% for guinea-pigs and 29.08% in the case of rabbits. Both the number and the proportion of rodents increased since 2014 (hamsters and other rodents represents only a small percentage of rodents), the proportion of them is about 63% (it was 57% in 2014 and 61% in 2013).

The number of used birds is still very high (50 117), and the proportion of domestic fowls grew among them from 89.39% to 96.23% (mainly because of the decrease in the number of other poultry species).

The number of used cats was more than 4 times higher than in 2014 (60 compared to 14), in contrast the number of dogs decreased by 42% (from 859 to 495).

There was a 10% decrease in the number of pigs (in opposition to the growing tendency during the last few years). Notable changes can be observed also in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

The number of zebra fish and other fishes decreased by 83% and more than 25%. The number of amphibians also decreased by about 25% (form 8373 to 6286), but it is still high compared to the period between 2007 and 2012 (it was ranged between 340 and 1807). The number of reptiles is only 12 compared to 62 in 2014.

When analysed by the purposes of the use of animals a large decrease can be observed in the fundamental biological research segment (more than 47%), and the number of animals used in education has also decreased (by nearly 62%). On the other hand remarkable increase can be observed in applied and translational research (almost 28%) – which was a key reason for the increase in the number of used rodents –, in regulatory and routine production (16.59%), and also in the number of animals used for the preservation of species (more than 70%) and used for the protection of the natural environment (which is 133 times more than in 2014).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of non-recoveries was dropped from 21.61% to 12.78%, the proportion of severe uses from 6.90% to 6.01%, and the moderate uses from 16.55% to 14.12%. On the other hand mild uses increased from 54.95% to 67.10%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Xenopus spp., *Rana temporaria* or *Rana pipiens* were not used in 2015; therefore the ratio of other amphibians is 100%. High number of *Bufo bufo* (5400 individuals, 85.91% of all amphibians), and also *Lissotriton vulgaris* (526 individuals) and *Rana dalmatina* (360 individuals) used for the preservation of species and for the protection of the natural environment in the interest of the health or welfare of human beings or animals.

The ratio of other fish is 69.23% mainly due to the high number of *Poecilia reticulata* used in regulatory ecotoxicology tests (2250 individuals, 49.82% of other fish) and farm fish species (e.g. *Cyprinus carpio*).

The ratio of other category in routine production is 100% (it is worth to note that the total number of animals used for routine production is quite low, only 603 individuals, so a single project can greatly influence the ratio).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	84650	43.28%
Rats	35037	17.91%
Guinea-Pigs	4113	2.1%
Hamsters (Syrian)	1	0%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	36	0.02%
Rabbits	5256	2.69%
Cats	60	0.03%
Dogs	495	0.25%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	2884	1.47%
Goats		

Animal Species	Number of animals	Percentage
Sheep	110	0.06%
Cattle	20	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	48230	24.66%
Other birds	1887	0.96%
Reptiles	12	0.01%
Rana		
Xenopus		
Other Amphibians	6286	3.21%
Zebra fish	2007	1.03%
Other Fish	4516	2.31%
Cephalopods		
Total	**195603**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	174024	90.32%
Animals born in the EU but not at a registered breeder	15917	8.26%
Animals born in rest of Europe	2236	1.16%
Animals born in rest of world	499	0.26%
Total	**192676**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	3	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**3**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	3	100%
Self-sustaining colony		
Total	**3**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38544	19.71%
Translational and applied research	63815	32.62%
Regulatory use and Routine production	84310	43.1%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6006	3.07%
Preservation of species	960	0.49%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1968	1.01%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**195603**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	5013	13.01%
Cardiovascular Blood and Lymphatic System	2813	7.3%
Nervous System	12887	33.43%
Respiratory System	299	0.78%
Gastrointestinal System including Liver	2069	5.37%
Musculoskeletal System	382	0.99%
Immune System	3075	7.98%
Urogenital/Reproductive System	2459	6.38%
Sensory Organs (skin, eyes and ears)	239	0.62%
Endocrine System/Metabolism	2249	5.83%
Multisystemic	2259	5.86%
Ethology / Animal Behaviour /Animal Biology	2443	6.34%
Other basic research	2357	6.12%
Total	**38544**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2223	3.48%
Human Infectious Disorders	228	0.36%
Human Cardiovascular Disorders	499	0.78%
Human Nervous and Mental Disorders	43979	68.92%
Human Respiratory Disorders	81	0.13%
Human Gastrointestinal Disorders including Liver	278	0.44%
Human Musculoskeletal Disorders		
Human Immune Disorders	580	0.91%
Human Urogenital/Reproductive Disorders	179	0.28%
Human Sensory Organ Disorders (skin, eyes and ears)	74	0.12%
Human Endocrine/Metabolism Disorders	116	0.18%
Other Human Disorders	294	0.46%
Animal Diseases and Disorders	11335	17.76%
Animal Welfare	492	0.77%
Diagnosis of diseases	1981	3.1%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1476	2.31%
Total	**63815**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	49504	58.72%
Other efficacy and tolerance testing	192	0.23%
Toxicity and other safety testing including pharmacology	34011	40.34%
Routine production	603	0.72%
Total	**84310**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	17400	35.15%
Pyrogenicity testing	952	1.92%
Batch potency testing	30891	62.4%
Other quality controls	261	0.53%
Total	**49504**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16836	49.5%
Skin irritation/corrosion	336	0.99%
Skin sensitisation	4800	14.11%
Eye irritation/corrosion	329	0.97%
Repeated dose toxicity	3705	10.89%
Carcinogenicity		
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Genotoxicity	643	1.89%
Reproductive toxicity	1048	3.08%
Developmental toxicity	667	1.96%
Kinetics	486	1.43%
Pharmaco-dynamics (incl safety pharmacology)	392	1.15%
Ecotoxicity	3936	11.57%
Target animal safety	694	2.04%
Other toxicity/safety testing	139	0.41%
Total	**34011**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	15320	91%
Other lethal methods		
Non lethal methods	1516	9%
Total	**16836**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2226	60.08%
29 - 90 days	615	16.6%
> 90 days	864	23.32%
Total	**3705**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3936	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**3936**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	603	100%
Total	**603**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25232	29.93%
Legislation on medicinal products for veterinary use and their residues	51951	61.62%
Medical devices legislation	30	0.04%
Industrial chemicals legislation		
Plant protection product legislation	4664	5.53%
Biocides legislation	3	0%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	180	0.21%
Cosmetics legislation		
Other legislation	2250	2.67%
Total	**84310**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	83159	98.63%
Legislation satisfying national requirements only [within EU]	310	0.37%
Legislation satisfying Non-EU requirements only	841	1%
Total	**84310**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	192679	98.51%
Yes	2924	1.49%
Total	**195603**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	24993	12.78%
Mild [up to and including]	131240	67.1%
Moderate	27617	14.12%
Severe	11753	6.01%
Total	**195603**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	194120	99.24%
Yes	1483	0.76%
Total	**195603**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	188601	96.42%
Genetically altered without a harmful phenotype	6574	3.36%
Genetically altered with a harmful phenotype	428	0.22%
Total	**195603**	**100.00%**

Hungary: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2016 was 170 075 which represents about 13% decrease compared to the same figure of 2015 (there was also a downward trend in the last few years). The number of re-uses has also been decreased by 15% (from 2924 to 2493).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The vast majority (92.39%) of used animals – as in previous years – were warm-blooded vertebrates. There was increase in the proportion of mammals (form 67.82% to 75.14%) and amphibians (from 3.21% to 4.79%), while the proportion of birds and fish decreased (the birds from 25.62% to 17.25% and the fish from 3.30% to 2.82%).

The proportion of rodents among mammals is about the same as last year. The increase was 10.63% in the number of rats and 23.85% in case of guinea-pigs. On the other hand there was an about 11% decrease in the number of mice. Hamsters and other rodents represent only a small percentage of rodents. The number of rabbits decreased by 35.65%.

The number of used cats was more than 4 times lower than in 2015 (14 compared to 60), in contrast the number of dogs increased by 27.27% (from 495 to 630). No non-human primate was used in 2016 (compared to the 3 Rhesus monkeys in 2015).

There was a 25.83% increase in the number of pigs. Notable decrease can be observed in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

There was an about 41% decrease in the number of used birds. The number of domestic fowl decreased by 43.39%, while the number of other birds increased by 8 %.

The number of other fishes decreased by 35%. The proportion of zebra fish is almost the same as in 2015. The number of other amphibians increased by 29.45% (form 6286 to 8137). The number of reptiles is only 2 compared to 12 in 2015.

When analysed by the purposes of the use of animals a large decrease can be observed in regulatory and routine production (about 25%) and in the number of animals used for the protection of the natural environment (nearly 85%). On the other hand remarkable increase can be observed in the number of animals used for the preservation of species (which is more than 5 times more than in 2015), used in education (more than 36%) and in the fundamental biological research segment (5.53%). The proportion of animals in applied and translational research is almost the same as in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

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The proportion of mild uses was dropped from 67.10% to 48.80%. On the other hand moderate uses increased from 14.12% to 23.98%, severe uses from 6.01% to 8.19% and non-recoveries from 12.78% to 19.03%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Only 6 *Rana temporaria* or *Rana pipiens* were used in 2016; therefore the ratio of other amphibians is 99.93%. High number of *Bufo bufo* (4830 individuals, 59.31% of all amphibians) and *Rana dalmatina* (3270 individuals, 40.16% of all amphibians) were used.

The ratio of other fish is 61.11% mainly due to the high number of farm fish species (e.g. *Cyprinus carpio, Oncorhynchus mykiss*) and *Poecilia reticulata* used in regulatory ecotoxicology tests.

The ratio of other category in routine production is 45.15% (it is worth to note that the total number of animals used for routine production is quite low, only 846 individuals, so a single project can greatly influence the ratio).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	76079	44.73%
Rats	38762	22.79%
Guinea-Pigs	5094	3%
Hamsters (Syrian)	63	0.04%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	40	0.02%
Rabbits	3363	1.98%
Cats	14	0.01%
Dogs	630	0.37%
Ferrets	8	0%
Other carnivores		
Horses, donkeys and cross-breeds		

Animal Species	Number of animals	Percentage
Pigs	3629	2.13%
Goats		
Sheep	91	0.05%
Cattle	16	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	27304	16.05%
Other birds	2039	1.2%
Reptiles	2	0%
Rana	6	0%
Xenopus		
Other Amphibians	8137	4.78%
Zebra fish	1866	1.1%
Other Fish	2932	1.72%
Cephalopods		
Total	**170075**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	147713	88.14%
Animals born in the EU but not at a registered breeder	19479	11.62%
Animals born in rest of Europe	40	0.02%
Animals born in rest of world	350	0.21%
Total	**167582**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

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Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	40678	23.92%
Translational and applied research	57752	33.96%
Regulatory use and Routine production	62895	36.98%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	950	0.56%
Preservation of species	5112	3.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2688	1.58%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**170075**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3669	9.02%
Cardiovascular Blood and Lymphatic System	2451	6.03%
Nervous System	15998	39.33%
Respiratory System	993	2.44%
Gastrointestinal System including Liver	3428	8.43%
Musculoskeletal System	663	1.63%
Immune System	3088	7.59%
Urogenital/Reproductive System	1759	4.32%
Sensory Organs (skin, eyes and ears)	721	1.77%
Endocrine System/Metabolism	2204	5.42%
Multisystemic	2112	5.19%
Ethology / Animal Behaviour /Animal Biology	1634	4.02%
Other basic research	1958	4.81%
Total	**40678**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3290	5.7%
Human Infectious Disorders	1367	2.37%
Human Cardiovascular Disorders	508	0.88%
Human Nervous and Mental Disorders	26418	45.74%
Human Respiratory Disorders	239	0.41%
Human Gastrointestinal Disorders including Liver	758	1.31%
Human Musculoskeletal Disorders	29	0.05%
Human Immune Disorders	354	0.61%
Human Urogenital/Reproductive Disorders	3	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	50	0.09%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	36	0.06%
Animal Diseases and Disorders	15687	27.16%
Animal Welfare	478	0.83%
Diagnosis of diseases	4509	7.81%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	4026	6.97%
Total	**57752**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25445	40.46%
Other efficacy and tolerance testing	70	0.11%
Toxicity and other safety testing including pharmacology	36534	58.09%
Routine production	846	1.35%
Total	**62895**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	11247	44.2%
Pyrogenicity testing	646	2.54%
Batch potency testing	13252	52.08%
Other quality controls	300	1.18%
Total	**25445**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	19234	52.65%
Skin irritation/corrosion	184	0.5%
Skin sensitisation	5438	14.88%
Eye irritation/corrosion	131	0.36%
Repeated dose toxicity	3804	10.41%
Carcinogenicity		
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Genotoxicity	1272	3.48%
Reproductive toxicity	340	0.93%
Developmental toxicity	1656	4.53%
Kinetics	875	2.4%
Pharmaco-dynamics (incl safety pharmacology)	204	0.56%
Ecotoxicity	2555	6.99%
Target animal safety	130	0.36%
Other toxicity/safety testing	711	1.95%
Total	**36534**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	16581	86.21%
Other lethal methods		
Non lethal methods	2653	13.79%
Total	**19234**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	466	12.25%
29 - 90 days	126	3.31%
> 90 days	3212	84.44%
Total	**3804**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2555	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**2555**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	114	13.48%
Monoclonal antibody by mouse ascites method	350	41.37%
Other product types	382	45.15%
Total	**846**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	27171	43.2%
Legislation on medicinal products for veterinary use and their residues	31160	49.54%
Medical devices legislation	21	0.03%
Industrial chemicals legislation	2966	4.72%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	526	0.84%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1051	1.67%
Total	**62895**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	61739	98.16%
Legislation satisfying national requirements only [within EU]	723	1.15%
Legislation satisfying Non-EU requirements only	433	0.69%
Total	**62895**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	167582	98.53%
Yes	2493	1.47%
Total	**170075**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	32367	19.03%
Mild [up to and including]	82993	48.8%
Moderate	40784	23.98%
Severe	13931	8.19%
Total	**170075**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	168864	99.29%
Yes	1211	0.71%
Total	**170075**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	162097	95.31%
Genetically altered without a harmful phenotype	7170	4.22%
Genetically altered with a harmful phenotype	808	0.48%
Total	**170075**	**100.00%**

Hungary: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2017 was 141 183 which represents about 17% decrease compared to the same figure of 2016 (there was also a downward trend in the last few years). The number of re-uses has been increased by 300% (from 2493 to 7520).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The vast majority (97.58%) of used animals were warm-blooded vertebrates. There was increase in the proportion of mammals (form 75.14% to 78.28%) and birds (from 17.25% to 19.30%), while the proportion of amphibians and fish decreased (amphibians from 4.79% to 0.0% and the fish from 2.82% to 2.42%).

The proportion of rodents among mammals increased from 93.93% to 95.92%. There was 19% decrease in the number of mice and 30% in the number of rats. In case of guinea-pigs was 11% increase. On the other hand there was a dramatically increase at other rodents. Hamsters decreased to 0%. The number of rabbits decreased by 53%.

The number of used cats was a small increase (14 compared to 16). The number of dogs decreased by 36% (from 630 to 463). Two non-human primate was used in 2017 (compared to the 0 Rhesus monkeys in 2016).

There was 33.72% decrease in the number of pigs. Notable decrease can be observed in the proportion of other sheep, but increase in case of cattle, but their number is relatively low which could cause fluctuation.

The number of domestic fowl decreased by 7.82%, while the number of other birds increased by 2.2 %.

The proportion of zebra fish increased by 16.8% and other fish decreased by 59.95%. The number of other amphibians dramatically decreased to 0% (form 8137). The number of reptiles is 0 compared to 2 in 2016.

When analysed by the purposes of the use of animals a small increase can be observed in regulatory and routine production (about 6.3%) and in the number of animals used for the protection of the natural environment and preservation of species decreased to 0%. The proportion of basic research, animals in applied and translational research shows decrease than in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of mild uses was increased from 48.80% to 49.85%. and moderate uses also from 23.98% to 28.60%, severe uses from 8.19% to 12.76%. It means there was 30% increase in number of severe procedures. This increase was highly influented by two projects with animal diseases and disorders purpose. It contains 5071 Gallus gallus domesticus and 1224 Sus scrofa domesticus.

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On the other hand non-recoveries decreased from 19.03% to 8.79%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The number of other amphibians dramatically decreased from 8137 to 0 in 2017. The reason is there is an establishment, where in 2016 investigated *Rana dalmatina, Bufo bufo, Lissortion vulgaris*. There was mainly eggs collection at the natural habitat and after incubation investigated juvenils and natural predators. At the end of the project more than 3700 amphibians were released into their habitat. These projects were categorized into protection of the natural environment and preservation of species. It explains the dramatically decrease to 0 value in purpose category.

The number of used rabbits decreased by 53%. In 2016 there were projects a batch safety testing project with 1097 rabbits and a pyrogenicity testing with 606 rabbits. The reason for the 53% decrease is this 2 projects ended in 2016.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	65876	46.8%
Rats	33946	24.12%
Guinea-Pigs	5765	4.1%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	1583	1.12%
Cats	16	0.01%
Dogs	463	0.33%
Ferrets	4	0%
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	2405	1.71%
Goats		

Animal Species	Number of animals	Percentage
Sheep		
Cattle	33	0.02%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	2	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	25169	17.88%
Other birds	2084	1.48%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	2243	1.59%
Other Fish	1174	0.83%
Cephalopods		
Total	**140763**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	126683	95.08%
Animals born in the EU but not at a registered breeder	5062	3.8%
Animals born in rest of Europe	1187	0.89%
Animals born in rest of world	309	0.23%
Total	**133241**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	2	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**2**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	2	100%
Self-sustaining colony		
Total	**2**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38539	27.38%
Translational and applied research	41847	29.73%
Regulatory use and Routine production	58007	41.21%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2370	1.68%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**140763**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3346	8.68%
Cardiovascular Blood and Lymphatic System	3406	8.84%
Nervous System	16498	42.81%
Respiratory System	718	1.86%
Gastrointestinal System including Liver	1865	4.84%
Musculoskeletal System	189	0.49%
Immune System	4412	11.45%
Urogenital/Reproductive System	1678	4.35%
Sensory Organs (skin, eyes and ears)	488	1.27%
Endocrine System/Metabolism	1417	3.68%
Multisystemic	2369	6.15%
Ethology / Animal Behaviour /Animal Biology	526	1.36%
Other basic research	1627	4.22%
Total	**38539**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	4919	11.75%
Human Infectious Disorders	581	1.39%
Human Cardiovascular Disorders	293	0.7%
Human Nervous and Mental Disorders	20172	48.2%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	211	0.5%
Human Musculoskeletal Disorders	79	0.19%
Human Immune Disorders	89	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	40	0.1%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders		
Other Human Disorders	224	0.54%
Animal Diseases and Disorders	9410	22.49%
Animal Welfare	4573	10.93%
Diagnosis of diseases	788	1.88%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	460	1.1%
Total	**41847**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	27156	46.82%
Other efficacy and tolerance testing	329	0.57%
Toxicity and other safety testing including pharmacology	29813	51.4%
Routine production	709	1.22%
Total	**58007**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	10102	37.2%
Pyrogenicity testing	29	0.11%
Batch potency testing	16682	61.43%
Other quality controls	343	1.26%
Total	**27156**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	17639	59.17%
Skin irritation/corrosion	293	0.98%
Skin sensitisation	4629	15.53%
Eye irritation/corrosion	137	0.46%
Repeated dose toxicity	1125	3.77%
Carcinogenicity	40	0.13%
Genotoxicity	562	1.89%
Reproductive toxicity	833	2.79%
Developmental toxicity	1286	4.31%
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Kinetics	1207	4.05%
Pharmaco-dynamics (incl safety pharmacology)	569	1.91%
Ecotoxicity	1028	3.45%
Other toxicity/safety testing	465	1.56%
Total	**29813**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	14255	80.82%
Other lethal methods		
Non lethal methods	3384	19.18%
Total	**17639**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	438	38.93%
29 - 90 days	75	6.67%
> 90 days	612	54.4%
Total	**1125**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1028	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1028**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	40	5.64%
Monoclonal antibody by mouse ascites method	157	22.14%
Other product types	512	72.21%
Total	**709**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25062	43.21%
Legislation on medicinal products for veterinary use and their residues	28770	49.6%
Medical devices legislation	516	0.89%
Industrial chemicals legislation	834	1.44%
Plant protection product legislation	2167	3.74%
Biocides legislation		
Food legislation including food contact material	461	0.79%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	197	0.34%
Total	**58007**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	56731	97.8%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	1276	2.2%
Total	**58007**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	133243	94.66%
Yes	7520	5.34%
Total	**140763**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	12410	8.82%
Mild [up to and including]	70383	50%
Moderate	39954	28.38%
Severe	18016	12.8%
Total	**140763**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	139882	99.37%
Yes	881	0.63%
Total	**140763**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	132229	93.94%
Genetically altered without a harmful phenotype	7898	5.61%
Genetically altered with a harmful phenotype	636	0.45%
Total	**140763**	**100.00%**

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Ireland

Ireland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

- There was a 1% increase in animal uses from 2014 to 2015.
- There was a 31% drop in procedures reported as severe from 2014 to 2015.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

- Although the majority of animals are still used for regulatory purposes, basic research overtook translational research as the second most common project purpose. The increase in numbers used for basic research went from 34,512 in 2014 to 42,347 in 2015, an increase of 23%. The species that account for most of this increase in basic research were cattle, pigs and fish, in particular cattle of which there were 7,246 uses in 2015 compared to 2,712 uses in 2014. A significant amount of agricultural research is performed in Ireland, and much of this is reported (based on our advice) as 'Basic research – ethology/animal behaviour/animal biology' because it involves feeding trials and investigation into reproductive efficiency. For example, over 2000 cattle were used for a single epidemiological study of the key factors affecting reproductive efficiency of beef cattle herds. This could potentially also be considered as translational research but it doesn't quite fit into the categories 'animal diseases and disorders' nor 'animal welfare'.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

- Non-recovery: 1% (2014) to 2% (2015)
- Mild: 28% (2014) to 50% (2015)
- Moderate: 32% (2014) to 22% (2015)
- Severe: 40% (2014) to 27% (2015)
- Overall there was a drop in severe and moderate procedures and an increase in mild and non-recovery procedures. The reason for this is unknown; but we would be cautious about over-interpreting this as it may be due to people becoming more accustomed to recording actual severity properly, rather than recording what they were prospectively authorised for.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- In 2015 we made it mandatory for humane endpoints to be implemented for LD50 tests in Ireland; however progress is slow re-validating the different assays so this has not impacted on the statistics, and the eventual impact on the statistics will probably be minimal, as animals will

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have already reached a ‘severe’ severity when they are culled. We have also been in frequent contact with pharmaceutical companies producing botulinum toxin products in relation to the replacement of animal tests with non-animal assays so we would hope to see a drop in LD50 testing over the next few years when more of these cell-based assays become available for use.

- In 2015 we also contacted all pharmaceutical companies using rabbit pyrogen testing for their products in Ireland requesting they switch to an alternative or provide robust scientific justification for the use of an animal test. This communication has not had a major impact on the statistics for 2015 with 570 rabbits used for pyrogen testing in 2015 (versus 597 in 2014) but we would hope that the positive impact of this dialogue becomes evident in the 2016 statistics..

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

- We did not have many animals reported under the ‘other’ category because we combed through each submission and made sure that if there was an appropriate pre-existing category available, that it was chosen. However, it should be noted that as previously mentioned, a lot of the agricultural research in Ireland could be considered translational, yet there is no appropriate translational category. Animal diseases and disorders is not accurate because these are healthy animals and animal welfare is not appropriate either as most of the research is not to benefit the animal, but to improve yields (e.g. milk, meat) and efficiency and therefore benefit the farmer and the economy. Perhaps there could be a translational category appropriate for this type of work?

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

- The severe classification was not exceeded in 2015.

Ireland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	190585	83.47%
Rats	9876	4.33%
Guinea-Pigs	1929	0.84%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	2490	1.09%
Cats	164	0.07%
Dogs	587	0.26%
Ferrets	621	0.27%
Other carnivores		
Horses, donkeys and cross-breeds	127	0.06%

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Animal Species	Number of animals	Percentage
Pigs	2372	1.04%
Goats	71	0.03%
Sheep	1112	0.49%
Cattle	11119	4.87%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	20	0.01%
Domestic fowl	113	0.05%
Other birds	572	0.25%
Reptiles		
Rana		
Xenopus	420	0.18%
Other Amphibians		
Zebra fish	1489	0.65%
Other Fish	4672	2.05%
Cephalopods		
Total	**228339**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	209587	92.77%
Animals born in the EU but not at a registered breeder	15014	6.65%
Animals born in rest of Europe	129	0.06%
Animals born in rest of world	1195	0.53%
Total	**225925**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	42179	18.47%
Translational and applied research	22516	9.86%
Regulatory use and Routine production	157872	69.14%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	815	0.36%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	389	0.17%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	4568	2%
Total	**228339**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1061	2.52%
Cardiovascular Blood and Lymphatic System	429	1.02%
Nervous System	8542	20.25%
Respiratory System	473	1.12%
Gastrointestinal System including Liver	2943	6.98%
Musculoskeletal System	278	0.66%
Immune System	13168	31.22%
Urogenital/Reproductive System	2378	5.64%
Sensory Organs (skin, eyes and ears)	1543	3.66%
Endocrine System/Metabolism	578	1.37%
Multisystemic	1601	3.8%
Ethology / Animal Behaviour /Animal Biology	9185	21.78%
Other basic research		
Total	**42179**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1209	5.37%
Human Infectious Disorders	1413	6.28%
Human Cardiovascular Disorders	1002	4.45%
Human Nervous and Mental Disorders	4173	18.53%
Human Respiratory Disorders	562	2.5%
Human Gastrointestinal Disorders including Liver	300	1.33%
Human Musculoskeletal Disorders	1776	7.89%
Human Immune Disorders	540	2.4%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1133	5.03%
Human Endocrine/Metabolism Disorders	139	0.62%
Other Human Disorders		
Animal Diseases and Disorders	9656	42.89%
Animal Welfare	240	1.07%
Diagnosis of diseases	373	1.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**22516**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	156621	99.21%
Other efficacy and tolerance testing	640	0.41%
Toxicity and other safety testing including pharmacology	611	0.39%
Routine production		
Total	**157872**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	6021	3.84%
Pyrogenicity testing	570	0.36%
Batch potency testing	150030	95.79%
Other quality controls		
Total	**156621**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Ecotoxicity	559	91.49%
Target animal safety	52	8.51%
Total	**611**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	559	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**559**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	155248	98.34%
Legislation on medicinal products for veterinary use and their residues	2047	1.3%
Medical devices legislation	18	0.01%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	559	0.35%
Total	**157872**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	157872	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**157872**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225925	98.94%
Yes	2414	1.06%
Total	**228339**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3020	1.32%
Mild [up to and including]	113368	49.65%
Moderate	49705	21.77%
Severe	62246	27.26%
Total	**228339**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	226472	99.18%
Yes	1867	0.82%
Total	**228339**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	212262	92.96%
Genetically altered without a harmful phenotype	15476	6.78%
Genetically altered with a harmful phenotype	601	0.26%
Total	**228339**	**100.00%**

Ireland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

- There was a 1% decrease on number of uses reported from 2015.
- There was 21% drop in reported reuse.
- Basic research has reduced by 33% and Translational and applied has increased by 14%.
- The number of uses for Maintenance of colonies of established GA animals not used in other procedures has dropped by 80%.

  It is difficult to say with certainty what the reasons for these changes are.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As in previous years, in 2016 mice were still the most commonly used species representing 85% of overall animal use. Significant changes in species from 2015 to 2016 include the drop in the number of uses of cattle by 46% and the increased use of 'other fish' (e.g. salmon, eels and trout) by 125%. The decrease in cattle use relates to the completion of a particularly large country-wide cattle study in 2015. The increase in the use of 'other fish' relates to the increased tracking of eel and salmon stocks in Ireland (using tagging methods) due to concerns regarding their conservation status.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

- Majority of procedures are still mild (44%)
- Moderate procedures have increased from 22 to 26% of use
- Severe procedures have increased from 27 to 29%
- Non-recovery procedures have dropped from 2% to 1%

Clear trends in relation to severity may take a few more years to emerge as users are still becoming acquainted with the new reporting requirements.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The HPRA has made specific proactive efforts in communicating with contract research organisations and pharmaceutical companies in relation to the introduction of non-animal alternatives for regulatory tests, e.g. rabbit pyrogen and LD50 testing, as well as the introduction of earlier humane endpoints (for LD50 testing). However, due to the complex and protracted process involved in gaining regulatory acceptance and approval for such changes to regulatory testing protocols, an impact on the annual statistics is not expected until the 2018 report at the earliest.

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5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category ‘other fish’ represented 5% of animal use. This primarily represents wild fish being studied for conservation projects. For example, European eels are a critically endangered species and Irish salmon stocks are critically low, so monitoring projects are required to improve the survival of these species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This was not exceeded nor was exemption granted at all during 2016.

Ireland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	192121	84.66%
Rats	9892	4.36%
Guinea-Pigs	964	0.42%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	1228	0.54%
Cats	271	0.12%
Dogs	356	0.16%
Ferrets	404	0.18%
Other carnivores		
Horses, donkeys and cross-breeds	204	0.09%
Pigs	1209	0.53%
Goats	30	0.01%
Sheep	1323	0.58%
Cattle	6044	2.66%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	196	0.09%
Other birds	674	0.3%
Reptiles		
Rana		

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Animal Species	Number of animals	Percentage
Xenopus	60	0.03%
Other Amphibians		
Zebra fish	1439	0.63%
Other Fish	10519	4.64%
Cephalopods		
Total	**226934**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	209821	93.28%
Animals born in the EU but not at a registered breeder	14166	6.3%
Animals born in rest of Europe	455	0.2%
Animals born in rest of world	487	0.22%
Total	**224929**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	28340	12.49%
Translational and applied research	26230	11.56%
Regulatory use and Routine production	170976	75.34%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	235	0.1%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	250	0.11%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	903	0.4%
Total	**226934**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	213	0.75%

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Basic Research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	803	2.83%
Nervous System	3876	13.68%
Respiratory System	1081	3.81%
Gastrointestinal System including Liver	2388	8.43%
Musculoskeletal System	68	0.24%
Immune System	6667	23.53%
Urogenital/Reproductive System	4	0.01%
Sensory Organs (skin, eyes and ears)	553	1.95%
Endocrine System/Metabolism	101	0.36%
Multisystemic	717	2.53%
Ethology / Animal Behaviour /Animal Biology	11868	41.88%
Other basic research	1	0%
Total	**28340**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1566	5.97%
Human Infectious Disorders	947	3.61%
Human Cardiovascular Disorders	2086	7.95%
Human Nervous and Mental Disorders	9308	35.49%
Human Respiratory Disorders	80	0.3%
Human Gastrointestinal Disorders including Liver	369	1.41%
Human Musculoskeletal Disorders	538	2.05%
Human Immune Disorders	1130	4.31%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1553	5.92%
Human Endocrine/Metabolism Disorders	584	2.23%
Other Human Disorders		
Animal Diseases and Disorders	7691	29.32%
Animal Welfare	360	1.37%
Diagnosis of diseases	18	0.07%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**26230**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	169714	99.26%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	1262	0.74%
Total	**170976**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1630	0.96%
Pyrogenicity testing	506	0.3%
Batch potency testing	167549	98.72%
Other quality controls	29	0.02%
Total	**169714**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Kinetics	12	0.95%
Pharmaco-dynamics (incl safety pharmacology)	30	2.38%
Ecotoxicity	1180	93.5%
Target animal safety	40	3.17%
Total	**1262**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1180	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total	1180	100.00%

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	167227	97.81%
Legislation on medicinal products for veterinary use and their residues	2540	1.49%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1209	0.71%
Total	170976	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	139897	81.82%
Legislation satisfying national requirements only [within EU]	29	0.02%
Legislation satisfying Non-EU requirements only	31050	18.16%
Total	170976	100.00%

First uses and re-uses

Re-use	Number of uses	Percentage
No	224929	99.12%
Yes	2005	0.88%
Total	226934	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2357	1.04%
Mild [up to and including]	99442	43.82%
Moderate	58832	25.92%
Severe	66303	29.22%
Total	226934	100.00%

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	225555	99.39%
Yes	1379	0.61%
Total	**226934**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	216565	95.43%
Genetically altered without a harmful phenotype	8360	3.68%
Genetically altered with a harmful phenotype	2009	0.89%
Total	**226934**	**100.00%**

Ireland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

- There was a 7% increase in animal use from the previous year (2016)
- This increase is accounted for by an increase in regulatory testing which is 80% of all testing.
- The use of cattle has dropped by 46% from the previous year, cats have dropped by 100% and dogs by 75%.
- There was a 67% decrease on reuse from the previous year.
- Basic research has dropped by 70% and Translational and Applied research has increased by 14%.
- There is a 28% drop in number of uses reported for 'Maintenance of colonies of established GA animals not used in other procedures'.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

- The 7% increase in animal numbers is due to increased regulatory testing, largely due to increased batch potency testing. The main reason for this was a breakdown of a non-animal alternative test, resulting in increased animal testing. Another smaller proportion of this increase was due to the use of additional animals for the validation of humane endpoints for batch potency testing.
- The reduction in cattle was due to the completion of a very large country-wide agricultural project. The reduction in dogs and cats was due to the closure of a dog and cat facility.
- The drop in basic research and increase in translational is not likely due to a true change in the type of research being conducted, but likely more accurate reporting.
- The reason for the drop in uses reported for 'maintenance of colonies of established GA animals not used in other procedures' is not known, but could be due to more efficient GA breeding.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There was a very slight increase in mild procedures (44 to 47%) and a slight decrease in moderate procedures (26 to 23%) but otherwise the proportions remained the same.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- We focused a lot of efforts in ensuring that there is a move to non-animal alternatives for batch potency testing; however this is not reflected in the figures in 2017, but it is expected that it will

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be reflected in the 2018 figures on. For the animals that still must be used for this type of testing, we have also required the establishment to work on implementing humane endpoints for these tests. This should, over time, reduce the animals in the 'severe' actual severity category, but this is not yet reflected in the figures.

- We have also put efforts into ensuring that rabbit pyrogen testing is only carried out where justified, by contacting the pharmaceutical companies that employ this type of testing. Since 2014 there has been a 48% reduction in this type of testing.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

There was no significant use of the 'other' categories at all. With regards to species, 'other fish' account for 4% of animal use and 'other birds' less than 1%. These relates to studies of wild animals, such as tagging and conservation projects.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This was not exceeded during 2017.

Ireland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	206908	85.39%
Rats	16858	6.96%
Guinea-Pigs	518	0.21%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	400	0.17%
Cats		
Dogs	89	0.04%
Ferrets	442	0.18%
Other carnivores		
Horses, donkeys and cross-breeds	60	0.02%
Pigs	1547	0.64%
Goats	11	0%
Sheep	1321	0.55%
Cattle	3244	1.34%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		

Animal Species	Number of animals	Percentage
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	40	0.02%
Other birds	823	0.34%
Reptiles		
Rana		
Xenopus	18	0.01%
Other Amphibians		
Zebra fish	236	0.1%
Other Fish	9787	4.04%
Cephalopods		
Total	**242302**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	227994	94.36%
Animals born in the EU but not at a registered breeder	13065	5.41%
Animals born in rest of Europe	121	0.05%
Animals born in rest of world	447	0.18%
Total	**241627**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	8558	3.53%
Translational and applied research	29815	12.3%
Regulatory use and Routine production	194816	80.4%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8366	3.45%
Preservation of species		

Purpose Category	Number of uses	Percentage
Higher education or training for the acquisition, maintenance or improvement of vocational skills	274	0.11%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	473	0.2%
Total	**242302**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	391	4.57%
Cardiovascular Blood and Lymphatic System	5	0.06%
Nervous System	2068	24.16%
Respiratory System	724	8.46%
Gastrointestinal System including Liver	1111	12.98%
Musculoskeletal System	192	2.24%
Immune System	991	11.58%
Urogenital/Reproductive System	238	2.78%
Sensory Organs (skin, eyes and ears)	54	0.63%
Endocrine System/Metabolism	139	1.62%
Multisystemic	6	0.07%
Ethology / Animal Behaviour /Animal Biology	2635	30.79%
Other basic research	4	0.05%
Total	**8558**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	754	2.53%
Human Infectious Disorders	780	2.62%
Human Cardiovascular Disorders	1195	4.01%
Human Nervous and Mental Disorders	9381	31.46%
Human Respiratory Disorders	277	0.93%
Human Gastrointestinal Disorders including Liver	1114	3.74%
Human Musculoskeletal Disorders	747	2.51%
Human Immune Disorders	8230	27.6%
Human Urogenital/Reproductive Disorders	50	0.17%
Human Sensory Organ Disorders (skin, eyes and ears)	2057	6.9%
Human Endocrine/Metabolism Disorders	444	1.49%
Other Human Disorders		
Animal Diseases and Disorders	2115	7.09%
Animal Welfare	2553	8.56%
Diagnosis of diseases	118	0.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**29815**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	194247	99.71%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	540	0.28%
Routine production	29	0.01%
Total	**194816**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1920	0.99%
Pyrogenicity testing	312	0.16%
Batch potency testing	192015	98.85%
Other quality controls		
Total	**194247**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Ecotoxicity	500	92.59%
Target animal safety	40	7.41%
Total	**540**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

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Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	500	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**500**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	29	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**29**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	185727	95.33%
Legislation on medicinal products for veterinary use and their residues	8589	4.41%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	500	0.26%
Total	**194816**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	194784	99.98%
Legislation satisfying national requirements only [within EU]	32	0.02%
Legislation satisfying Non-EU requirements only		
Total	**194816**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	241627	99.72%
Yes	675	0.28%
Total	**242302**	**100.00%**

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Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2283	0.94%
Mild [up to and including]	114261	47.16%
Moderate	55162	22.77%
Severe	70596	29.14%
Total	**242302**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	241716	99.76%
Yes	586	0.24%
Total	**242302**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	234806	96.91%
Genetically altered without a harmful phenotype	5737	2.37%
Genetically altered with a harmful phenotype	1759	0.73%
Total	**242302**	**100.00%**

Italy

Italy: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, the total number of animals used in testing was 581,935, the first time this figure had fallen below 600,000. In general, the decrease in 2015 as compared to the previous year reflects the downward trend in the total number of animals used in testing, which has consistently remained below the one million mark since 1999.

In 2015, rodents and rabbits accounted for 91.19% of the animal species used. Within these species, there was an increase in the number of rats, rabbits and 'other rodents' used, while on the other hand there was a marked decrease from 485,820 to 373,483 in the number of mice used.

On the whole there has been a decrease in the use of other animal species, except for a slight increase as regards domestic fowl (from 28,215 in 2014 to 30,984 in 2015).

The total number of animals used went from 691,666 in 2014 to 581,935 in 2015, a percentage decrease of -15.86%. (See Table 1)

Table 1

Animal species	2014	% of the 2014 total	2015	% of the 2015 total	DIFFERENCE IN THE NUMBER OF ANIMALS	% DIFFERENCE 2014 / 2015
Rodents and rabbits	639,914	92.52	530,677	91.19	-109,237	-17.07
Other animal species	51,752	7.48	51,258	8.81	-494	-0.95
Total (all species)	**691,666**	**100.00**	**581,935**	**100.00**	**-109,737**	**-15.86**

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

37.26% of the animals were used in basic biological studies.

24.92% of the animals were used in translational or applied research.

36.07% of the animals were used for regulatory use and routine production.

1.75% of the animals were used for other purposes.

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No animals were used for forensic enquiries.

Table 2

Purpose of studies	2014 %	2015 %	% DIFFERENCE
Basic research	41.84	37.26	-4.58
Translational research	31.77	24.92	-6.85
Regulatory testing	25.45	36.07	10.62
Other	0.94	1.75	0.81

2015 saw an increase in the number of animals used for regulatory testing, while there was a decrease in the number of animals used for both basic research and translational research and a very slight increase for other purposes (see Table 2).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals was recorded for the second time in 2015. A comparison between 2014 and 2015 shows that more than 47% of the animals experienced a 'mild' level of suffering, followed by 39% of animals with 'moderate' suffering, with neither the 'non-recovery' nor 'severe' suffering levels exceeding 7% (see Table 3).

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2014	4.89	49.09	42.90	3.12
2015	6.16	47.58	39.44	6.82

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is €1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

Also worth noting is the work of the Animal Welfare Bodies (*Organismi Preposti al Benessere Animale* (OPBAs)) under Article 25 of Legislative Decree No 26/2014. OPBAs are required to issue a reasoned opinion on research projects that are to be submitted for ministerial authorisation, verifying the correct application of the Three Rs principle and assessing the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals used.

As far as staff training is concerned, various conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes. The Ministry of Health sends its own experts as lecturers to such training events.

The Ministry provided training at no fewer than ten training courses in 2015.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Nothing to report.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	373666	63.69%
Rats	130972	22.32%
Guinea-Pigs	16668	2.84%
Hamsters (Syrian)	488	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	494	0.08%
Rabbits	9775	1.67%
Cats		
Dogs	601	0.1%

Animal Species	Number of animals	Percentage
Ferrets	14	0%
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	1746	0.3%
Goats	4	0%
Sheep	235	0.04%
Cattle	733	0.12%
Prosimians		
Marmoset and tamarins	3	0%
Cynomolgus monkey	278	0.05%
Rhesus monkey	4	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	8	0%
Other species of New World Monkeys (Ceboidea)	24	0%
Apes		
Other Mammals	16	0%
Domestic fowl	33020	5.63%
Other birds	750	0.13%
Reptiles	100	0.02%
Rana		
Xenopus	422	0.07%
Other Amphibians	7	0%
Zebra fish	11331	1.93%
Other Fish	5328	0.91%
Cephalopods	12	0%
Total	**586699**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	544052	93.53%
Animals born in the EU but not at a registered breeder	35311	6.07%
Animals born in rest of Europe	1167	0.2%
Animals born in rest of world	1181	0.2%
Total	**581711**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	4	1.79%
Animals born in rest of Europe		
Animals born in Asia	112	50%
Animals born in America		
Animals born in Africa	108	48.21%
Animals born elsewhere		
Total	**224**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	54	24.11%
F2 or greater	169	75.45%
Self-sustaining colony	1	0.45%
Total	**224**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	218615	37.26%
Translational and applied research	146213	24.92%
Regulatory use and Routine production	211615	36.07%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	76	0.01%
Preservation of species	228	0.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1042	0.18%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	8910	1.52%
Total	**586699**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	61958	28.34%
Cardiovascular Blood and Lymphatic System	9112	4.17%
Nervous System	83400	38.15%
Respiratory System	4470	2.04%
Gastrointestinal System including Liver	7690	3.52%
Musculoskeletal System	5485	2.51%
Immune System	22940	10.49%
Urogenital/Reproductive System	2015	0.92%
Sensory Organs (skin, eyes and ears)	1556	0.71%
Endocrine System/Metabolism	4640	2.12%
Multisystemic	5293	2.42%
Ethology / Animal Behaviour /Animal Biology	7120	3.26%
Other basic research	2936	1.34%
Total	**218615**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	40751	27.87%
Human Infectious Disorders	17960	12.28%
Human Cardiovascular Disorders	2606	1.78%
Human Nervous and Mental Disorders	21148	14.46%
Human Respiratory Disorders	17944	12.27%
Human Gastrointestinal Disorders including Liver	2428	1.66%
Human Musculoskeletal Disorders	2809	1.92%
Human Immune Disorders	6644	4.54%
Human Urogenital/Reproductive Disorders	2842	1.94%
Human Sensory Organ Disorders (skin, eyes and ears)	1908	1.3%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	7589	5.19%
Other Human Disorders	3820	2.61%
Animal Diseases and Disorders	365	0.25%
Animal Welfare	466	0.32%
Diagnosis of diseases	16369	11.2%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	564	0.39%
Total	**146213**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	108737	51.38%
Other efficacy and tolerance testing	36979	17.47%
Toxicity and other safety testing including pharmacology	62965	29.75%
Routine production	2934	1.39%
Total	**211615**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	26087	23.99%
Pyrogenicity testing	4007	3.69%
Batch potency testing	75036	69.01%
Other quality controls	3607	3.32%
Total	**108737**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	15574	24.73%
Skin irritation/corrosion	583	0.93%
Skin sensitisation	10312	16.38%
Eye irritation/corrosion	54	0.09%
Repeated dose toxicity	8137	12.92%
Carcinogenicity	873	1.39%
Genotoxicity	378	0.6%
Reproductive toxicity	6583	10.46%
Developmental toxicity	4162	6.61%
Neurotoxicity	200	0.32%
Kinetics	5513	8.76%
Pharmaco-dynamics (incl safety pharmacology)	504	0.8%
Phototoxicity	164	0.26%
Ecotoxicity	3985	6.33%
Safety testing in food and feed area	4970	7.89%
Target animal safety	196	0.31%
Other toxicity/safety testing	777	1.23%
Total	**62965**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	6296	40.43%
Other lethal methods	120	0.77%
Non lethal methods	9158	58.8%
Total	**15574**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4350	53.46%
29 - 90 days	2841	34.91%
> 90 days	946	11.63%
Total	**8137**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3319	83.29%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	666	16.71%
Total	**3985**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1115	38%
Monoclonal antibody by mouse ascites method	1520	51.81%
Other product types	299	10.19%
Total	**2934**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	133861	63.26%
Legislation on medicinal products for veterinary use and their residues	31907	15.08%
Medical devices legislation	16980	8.02%
Industrial chemicals legislation	8704	4.11%
Plant protection product legislation	734	0.35%
Biocides legislation	1749	0.83%
Food legislation including food contact material	11973	5.66%
Feed legislation including legislation for the safety of target animals, workers and environment	706	0.33%
Cosmetics legislation		
Other legislation	5001	2.36%
Total	**211615**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	204055	96.43%
Legislation satisfying national requirements only [within EU]	2085	0.99%
Legislation satisfying Non-EU requirements only	5475	2.59%
Total	**211615**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	581935	99.19%
Yes	4764	0.81%
Total	**586699**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	36159	6.16%
Mild [up to and including]	279151	47.58%
Moderate	231395	39.44%
Severe	39994	6.82%
Total	**586699**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	582552	99.29%
Yes	4147	0.71%
Total	**586699**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	463538	79.01%
Genetically altered without a harmful phenotype	110917	18.91%
Genetically altered with a harmful phenotype	12244	2.09%
Total	**586699**	**100.00%**

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Italy: Narrative 2016

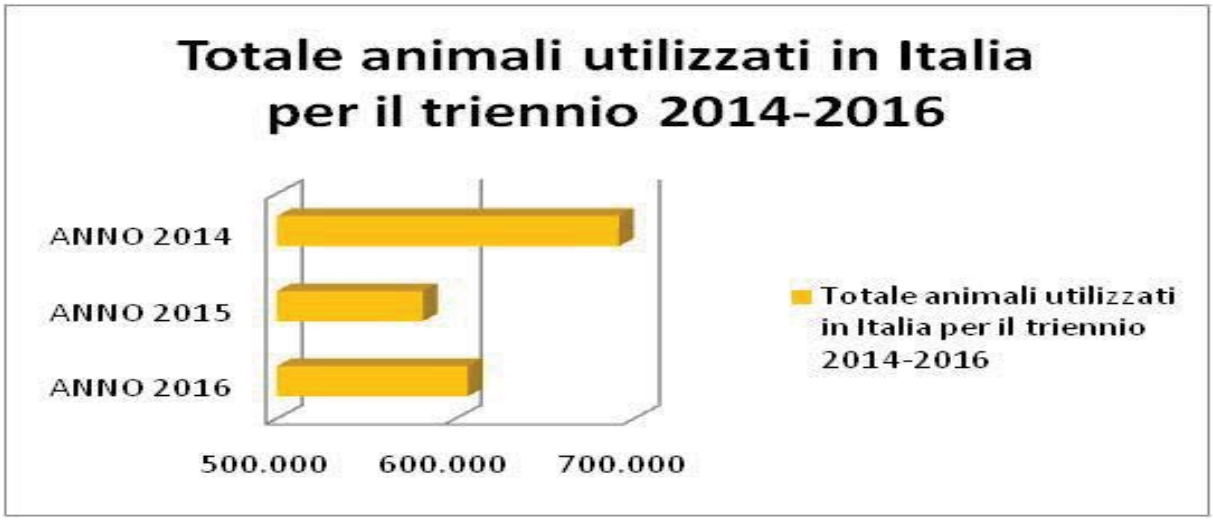
Introduction

The data for Italy for 2016 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

1. General information on any changes in trends observed since the previous reporting period.

In 2016, the total number of animals used in testing was 607,097, i.e. slightly more than 600,000. This was lower than in 2014 (691,666 animals; -12.23%) and slightly higher than in 2015 (581,935; +4.32%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

Figure 1



Translation of legend: Total number of animals used in Italy 2014-2016

In 2016, rodents and rabbits accounted for 90.36% of the animal species used. Within these species, there was an increase in the number of mice and rabbits as compared to 2015, while the use of rats decreased slightly.

For other animal species – which, in 2016, accounted for 9.64% of the total – there was an increase in the use of domestic fowl, fish (zebrafish) and amphibians (Xenopus). (See Table 1)

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Table 1

Animal species	2014	% of the 2014 total	2015	% of the 2015 total	2016	% of the 2016 total	DIFFERENCE IN THE NUMBER OF ANIMALS 2014 / 2016	% DIFFERENCE 2014 / 2016
Rodents and rabbits	639,914	92.52	530,677	91.19	548,578	90.36	-91,336	-14.27
Other animal species	51,752	7.48	51,258	8.81	58,519	9.64	6,767	13.07
Total (all species)	**691,666**	**100.00**	**581,935**	**100.00**	**607,097**	**100.00**	**-84,569**	**-12.23**

2. Information on significant increase or decreases in use animals in any of the specific areas and analysis of the reasons thereof.

35.42% of the animals were used in basic biological studies.

26.54% were used in translational or applied research.

37.11% were used for regulatory use and routine production.

0.93% for other purposes.

No animals were used for forensic enquiries.

Table 2

Purpose of studies	2014 %	2016 %	DIFFERENCE 2014 / 2016 %
Basic research	41.84	35.42	-6.42
Translational research	31.77	26.54	-5.23
Regulatory testing	25.45	37.11	11.66
Other	0.94	0.93	-0.01

The downward trend in the number of animals used in basic research and translational research was confirmed in 2016.

The use of animals in regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose. (See Table 2)

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals was recorded for the third time in 2016. Comparing 2014, 2015 and 2016 shows that there were no material variations in the 'non-recovery' and 'mild' suffering levels, while there has been an increase in the 'severe' category (see Table 3).

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2014	4.89%	49.09%	42.90%	3.12%
2015	6.16%	47.58%	39.44%	6.82%
2016	4.81%	50.42%	34.11%	10.66%

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is € 1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

Animal Welfare Bodies (OPBAs)

In 2016, greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions made it possible to verify, to the best extent possible, the correct application of the Three Rs principle, particularly in the basic research and translational research sectors. The OPBAs' work enabled an assessment of the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals to be used, thus giving rise to a general downward trend in animal use except in the regulatory sector.

As far as staff skills are concerned, conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes, with experts from the Ministry of Health participating as lecturers. The Ministry provided training at a total of 15 training courses in 2016.

Lastly, it is worth stressing the importance of the first National Animal Welfare Conference, which was devised and organised by the Directorate-General for Animal Health and Veterinary Medicines (DGSAF) at the Ministry of Health. The Conference had the positive effect of putting the spotlight on the issue of animal welfare in all sectors. More specifically, one session was devoted entirely to the topic of protecting the animals used for scientific purposes. The speakers stressed the innovations and developments brought about by Legislative Decree No 26/2014, which transposed the European Directive, but also highlighted the problem areas in which it is necessary to keep working so as to ensure that projects are assessed ever more carefully while keeping to the deadlines set in the Directive.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Nothing to report.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	388976	63.59%
Rats	128186	20.96%
Guinea-Pigs	16977	2.78%
Hamsters (Syrian)	553	0.09%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	143	0.02%
Rabbits	15245	2.49%
Cats		
Dogs	486	0.08%
Ferrets	7	0%
Other carnivores		
Horses, donkeys and cross-breeds	19	0%
Pigs	1534	0.25%
Goats	53	0.01%
Sheep	232	0.04%
Cattle	115	0.02%
Prosimians		

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Animal Species	Number of animals	Percentage
Marmoset and tamarins	9	0%
Cynomolgus monkey	488	0.08%
Rhesus monkey	6	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	8	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	36701	6%
Other birds	468	0.08%
Reptiles	57	0.01%
Rana		
Xenopus	771	0.13%
Other Amphibians	8	0%
Zebra fish	14664	2.4%
Other Fish	6001	0.98%
Cephalopods		
Total	**611707**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	557983	91.97%
Animals born in the EU but not at a registered breeder	46168	7.61%
Animals born in rest of Europe	835	0.14%
Animals born in rest of world	1690	0.28%
Total	**606676**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	139	33.02%
Animals born in America		
Animals born in Africa	282	66.98%
Animals born elsewhere		
Total	**421**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	94	22.33%
F2 or greater	327	77.67%
Self-sustaining colony		
Total	**421**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	216654	35.42%
Translational and applied research	162406	26.55%
Regulatory use and Routine production	226969	37.1%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1551	0.25%
Preservation of species	167	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1787	0.29%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2173	0.36%
Total	**611707**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	59961	27.68%
Cardiovascular Blood and Lymphatic System	9330	4.31%
Nervous System	82143	37.91%
Respiratory System	2755	1.27%
Gastrointestinal System including Liver	4929	2.28%
Musculoskeletal System	8391	3.87%
Immune System	20124	9.29%
Urogenital/Reproductive System	4933	2.28%
Sensory Organs (skin, eyes and ears)	1689	0.78%
Endocrine System/Metabolism	5655	2.61%
Multisystemic	7227	3.34%
Ethology / Animal Behaviour /Animal Biology	6098	2.81%
Other basic research	3419	1.58%
Total	**216654**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	45578	28.06%
Human Infectious Disorders	29058	17.89%
Human Cardiovascular Disorders	2074	1.28%
Human Nervous and Mental Disorders	19042	11.72%
Human Respiratory Disorders	17539	10.8%
Human Gastrointestinal Disorders including Liver	4221	2.6%
Human Musculoskeletal Disorders	6107	3.76%
Human Immune Disorders	5657	3.48%
Human Urogenital/Reproductive Disorders	1334	0.82%
Human Sensory Organ Disorders (skin, eyes and ears)	3540	2.18%
Human Endocrine/Metabolism Disorders	3441	2.12%
Other Human Disorders	6573	4.05%
Animal Diseases and Disorders	4309	2.65%
Animal Welfare	81	0.05%
Diagnosis of diseases	13214	8.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	638	0.39%
Total	**162406**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	111607	49.17%
Other efficacy and tolerance testing	48352	21.3%
Toxicity and other safety testing including pharmacology	65075	28.67%
Routine production	1935	0.85%
Total	**226969**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	24249	21.73%
Pyrogenicity testing	4352	3.9%
Batch potency testing	79363	71.11%
Other quality controls	3643	3.26%
Total	**111607**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	11131	17.1%
Skin irritation/corrosion	738	1.13%
Skin sensitisation	11885	18.26%
Eye irritation/corrosion	134	0.21%
Repeated dose toxicity	8838	13.58%
Carcinogenicity	229	0.35%
Genotoxicity	307	0.47%
Reproductive toxicity	955	1.47%
Developmental toxicity	8593	13.2%
Neurotoxicity	25	0.04%
Kinetics	6155	9.46%
Pharmaco-dynamics (incl safety pharmacology)	495	0.76%
Phototoxicity	66	0.1%
Ecotoxicity	3833	5.89%
Safety testing in food and feed area	11049	16.98%
Target animal safety	24	0.04%
Other toxicity/safety testing	618	0.95%
Total	**65075**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1003	9.01%
Other lethal methods	439	3.94%
Non lethal methods	9689	87.05%
Total	**11131**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2794	31.61%
29 - 90 days	4214	47.68%
> 90 days	1830	20.71%
Total	**8838**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3317	86.54%
Chronic toxicity	158	4.12%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	358	9.34%
Total	**3833**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1089	56.28%
Monoclonal antibody by mouse ascites method		
Other product types	846	43.72%
Total	**1935**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	147217	64.86%
Legislation on medicinal products for veterinary use and their residues	35207	15.51%
Medical devices legislation	18639	8.21%
Industrial chemicals legislation	9129	4.02%
Plant protection product legislation	401	0.18%
Biocides legislation	1119	0.49%
Food legislation including food contact material	11974	5.28%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	3283	1.45%
Total	**226969**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	215219	94.82%
Legislation satisfying national requirements only [within EU]	1884	0.83%
Legislation satisfying Non-EU requirements only	9866	4.35%
Total	**226969**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	607097	99.25%
Yes	4610	0.75%
Total	**611707**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	29421	4.81%
Mild [up to and including]	308396	50.42%
Moderate	208660	34.11%
Severe	65230	10.66%
Total	**611707**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	604369	98.8%
Yes	7338	1.2%
Total	**611707**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	488643	79.88%
Genetically altered without a harmful phenotype	108952	17.81%
Genetically altered with a harmful phenotype	14112	2.31%
Total	**611707**	**100.00%**

Italy: Narrative 2017

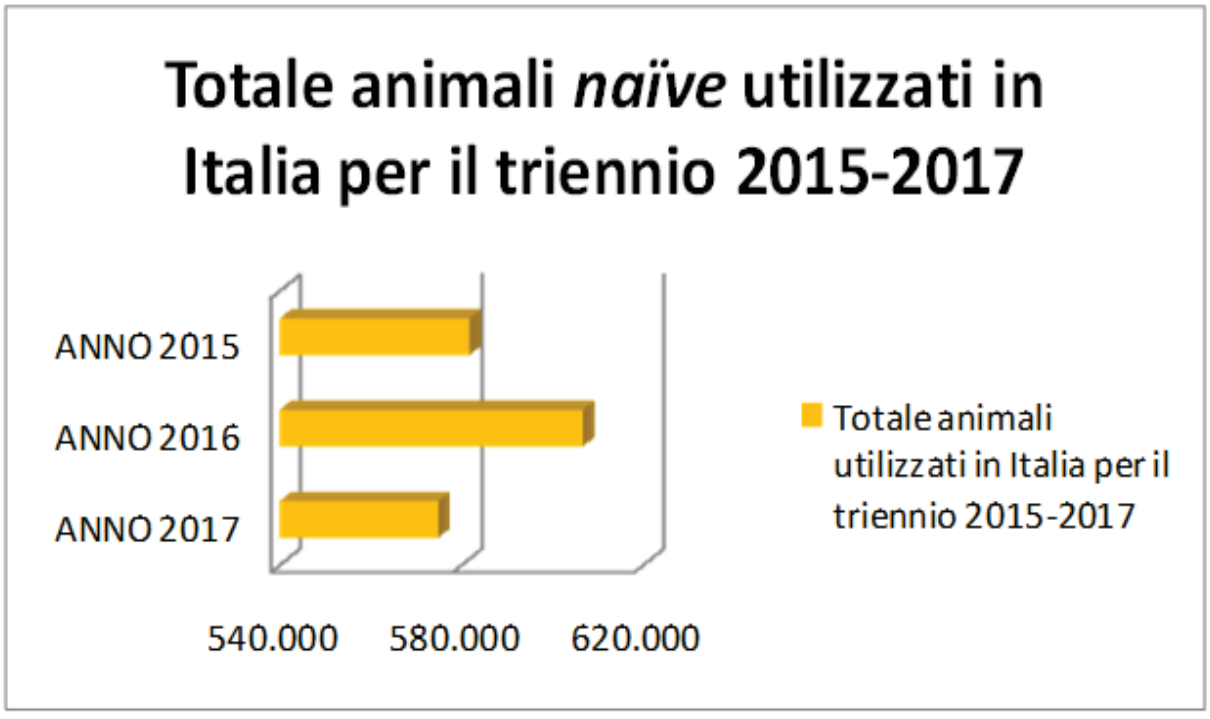
Introduction

The data for Italy for 2017 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the total number of animals used in testing for the first time ('naïve' animals) was 575,352, i.e. fewer than 600,000. This was lower than in 2015 (-1.20%) and 2016 (-5.54%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

Figure 1



Translation of legends:

- *Total number of naïve animals used in Italy 2015-2017*
- *Total number of animals used in Italy 2015-2017*

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2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015-2017 (see Table 1), rodents and animals accounted for 89.55% of the animal species used, including reused animals. Within these species, there was a decrease in the number of rodents and a significant increase in the number of rabbits. The increase in the number of rabbits is explained by the fact that around 95% of them are used in regulatory testing, i.e. tests that are compulsory under European or international law.

With regard to regulatory tests on rabbits, 78% of rabbits were used for quality controls on batches of medicines for human use, medical devices and veterinary medicines.

Another increase was in the use of non-human primates in regulatory tests (toxicity and other safety tests) required by European and international law (from 86.75% in 2015 to 97.27% in 2017). In consequence, there was a percentage decrease in non-human primates used in basic research in the three-year period concerned (from 11.67% in 2015 to 0.68% in 2017).

The most frequently used species was Macaca fascicularis; 2017 saw an increase in the use of generation F1 animals owing to reduced availability of generation F2 animals from breeding establishments and suppliers of non-human primates and the simultaneous increase in the number of regulatory tests.

For other animal species, there was a continuous increase in the 2015-2017 period in the use of:

- zebrafish in basic and translational research in the area of oncology and gastrointestinal diseases and in regulatory testing (ecotoxicity);
- other fish in translational research in the area of animal diseases.

Table 1

Animal species	% of the 2015 total	% of the 2016 total	% of the 2017 total	AVERAGE % - 2015-2017	% DIFFERENCE 2015 / 2017
Rodents	89.02%	87.43%	84.73%	87.06%	-4.82 %
Rabbits	1.66%	2.49%	3.33%	2.49%	+97.70%
Total rodents + rabbits	**90.68%**	**89.82%**	**88.06%**	**89.52%**	-2.89%
Other animal species	**9.32%**	**10.18%**	**11.94%**	**10.48%**	+28.11%
Total (all species)	**100.00%**	**100.00%**	**100.00%**	**100.00%**	

For 2017:
33.55% of the animals were used in basic biological studies.
26.48% were used in translational or applied research.
38.96% were used for regulatory use and routine production.
1.01% of the animals were used for other purposes.
No animals were used for forensic enquiries.

Table 2
Animal uses by purpose of studies

Purpose of studies	% 2015	% 2016	% 2017
Basic research	37.26%	35.42%	33.55%
Translational research	24.92%	26.54%	26.48%
Regulatory testing	36.07%	37.11%	38.96%
Other	1.75%	0.93%	1.01%

The downward trend in the number of animals used for basic research was confirmed in 2017.

The use of animals for regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose and is continually increasing (see Table 2).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals (see Table 3) was recorded for the fourth time in 2017.

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2015	6.16%	47.58%	39.44%	6.82%
2016	4.81%	50.42%	36.11%	10.66%
2017	5.49%	48.45%	30.55%	15.50%

Comparing the data for the 2015-2017 period shows that:
- there were no material variations in the 'non-recovery' and 'mild' suffering levels, which together represent 54%;
- there was a continuous decrease in the 'moderate' suffering level;
- there was an increase in the 'severe' category.

The animal species most concerned by the increase in the 'severe' suffering level is mice, at around 80%.

The correlation between the 'severe' suffering level and purpose is as follows:
- 46.62% for basic research (in particular for studies of central nervous system diseases and cancer);
- 37.14% for translational research (in particular for cancer);
- 15.89% for regulatory tests (in particular for toxicity);
- 0.35% for other purposes (maintenance of colonies of genetically altered animals).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal

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Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarked funding for the development and validation of alternative methods and for staff training. The funding was € 1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

National Committee for the Protection of Animals Used for Scientific Purposes

The National Committee for the Protection of Animals Used for Scientific Purposes was set up in February 2017. It is made up of members representing academia, public scientific research institutions, the Ministry of Health, the Italian National Institute of Health and the National Reference Centre for Alternative Methods and Welfare and Care of Laboratory Animals.

After drawing up its rules of procedure, its activities included providing the Ministry of Health with advice on preparing the draft ministerial decree on staff training.

Since October 2017 the National Committee has been working on organising the work of the Animal Welfare Bodies (OBPAs) with the aim of harmonising that work, particularly as regards preliminary assessment of research projects with a view to issuing the reasoned opinion needed for authorisation applications for such projects.

To that end, the National Committee has launched a major initiative to raise awareness among OPBAs so as to harmonise their activities in both logistical and technical terms, and in particular to encourage the sharing of project assessment criteria.

Animal Welfare Bodies (OPBAs)

In general terms, 2017 saw the consolidation of greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions. This made it possible to verify, to the best possible extent, the correct application of the Three Rs principle, particularly as regards the replacement or reduction of animal use, with clear results in the basic research and translational research sectors.

As far as staff skills are concerned, conferences, workshops and courses were organised by various public or private bodies, with experts from the Ministry of Health participating as lecturers/speakers in 14 events.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

The 'other' heading is used for the main sub-sectors, which mainly concern the regulatory field.

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More specifically:

Animals used in routine production:

Other efficacy and tolerance testing (immunogenicity for human vaccines)

Other efficacy and tolerance testing (production of inactivated antigens for animal vaccines)

Animals used in the quality control sector:

Other quality controls (efficacy testing on rodenticides; testing for contaminants in veterinary medicines)

Animals used in the toxicity testing sector:

Other toxicity/safety testing (for drugs of abuse; for anomalous toxicity; for local tolerance)

Animals used in the acute and sub-acute toxicity methods sector:

Other lethal methods (testing in accordance with OECD 402 and OECD 423)

Animals used in the toxicity/ecotoxicity testing sector:

Other tests: (Diagnostic ecotoxicity testing)

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	358128	61.74%
Rats	118104	20.36%
Guinea-Pigs	14357	2.48%
Hamsters (Syrian)	277	0.05%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	647	0.11%
Rabbits	19325	3.33%
Cats		
Dogs	639	0.11%
Ferrets	42	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	17	0%
Pigs	1657	0.29%
Goats	23	0%
Sheep	192	0.03%
Cattle	279	0.05%
Prosimians		
Marmoset and tamarins	1	0%
Cynomolgus monkey	569	0.1%
Rhesus monkey	4	0%

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Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	30	0.01%
Domestic fowl	34715	5.98%
Other birds	420	0.07%
Reptiles		
Rana		
Xenopus	401	0.07%
Other Amphibians		
Zebra fish	19508	3.36%
Other Fish	10715	1.85%
Cephalopods	10	0%
Total	**580060**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	507078	88.22%
Animals born in the EU but not at a registered breeder	65027	11.31%
Animals born in rest of Europe	874	0.15%
Animals born in rest of world	1825	0.32%
Total	**574804**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	0.18%
Animals born in rest of Europe		
Animals born in Asia	57	10.4%
Animals born in America		
Animals born in Africa	490	89.42%
Animals born elsewhere		
Total	**548**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	137	25%
F2 or greater	411	75%
Self-sustaining colony		
Total	**548**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	194642	33.56%
Translational and applied research	153743	26.5%
Regulatory use and Routine production	225842	38.93%
Protection of the natural environment in the interests of the health or welfare of human	1697	0.29%

Purpose Category	Number of uses	Percentage
beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1598	0.28%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2538	0.44%
Total	**580060**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	58513	30.06%
Cardiovascular Blood and Lymphatic System	8635	4.44%
Nervous System	74343	38.19%
Respiratory System	1384	0.71%
Gastrointestinal System including Liver	5792	2.98%
Musculoskeletal System	6933	3.56%
Immune System	13667	7.02%
Urogenital/Reproductive System	2830	1.45%
Sensory Organs (skin, eyes and ears)	3892	2%
Endocrine System/Metabolism	4776	2.45%
Multisystemic	3858	1.98%
Ethology / Animal Behaviour /Animal Biology	5028	2.58%
Other basic research	4991	2.56%
Total	**194642**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	46470	30.23%
Human Infectious Disorders	21902	14.25%
Human Cardiovascular Disorders	1852	1.2%
Human Nervous and Mental Disorders	18498	12.03%
Human Respiratory Disorders	16658	10.83%
Human Gastrointestinal Disorders including Liver	2706	1.76%
Human Musculoskeletal Disorders	6007	3.91%
Human Immune Disorders	3875	2.52%
Human Urogenital/Reproductive Disorders	2992	1.95%
Human Sensory Organ Disorders (skin, eyes and ears)	2457	1.6%
Human Endocrine/Metabolism Disorders	3064	1.99%
Other Human Disorders	5288	3.44%
Animal Diseases and Disorders	7228	4.7%
Animal Welfare	918	0.6%
Diagnosis of diseases	13483	8.77%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	345	0.22%
Total	**153743**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	111851	49.53%
Other efficacy and tolerance testing	45856	20.3%
Toxicity and other safety testing including pharmacology	63786	28.24%
Routine production	4349	1.93%
Total	**225842**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	21535	19.25%
Pyrogenicity testing	2717	2.43%
Batch potency testing	84520	75.56%
Other quality controls	3079	2.75%
Total	**111851**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10612	16.64%
Skin irritation/corrosion	820	1.29%
Skin sensitisation	11983	18.79%
Eye irritation/corrosion	93	0.15%
Repeated dose toxicity	8757	13.73%
Carcinogenicity		
Phototoxicity		
Genotoxicity	291	0.46%
Reproductive toxicity	628	0.98%
Developmental toxicity	5554	8.71%
Neurotoxicity	300	0.47%
Kinetics	5976	9.37%
Pharmaco-dynamics (incl safety pharmacology)	1154	1.81%
Ecotoxicity	4224	6.62%
Safety testing in food and feed area	10807	16.94%
Target animal safety	1212	1.9%
Other toxicity/safety testing	1375	2.16%
Total	**63786**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1211	11.41%
Other lethal methods	755	7.11%
Non lethal methods	8646	81.47%
Total	**10612**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4157	47.47%
29 - 90 days	2782	31.77%
> 90 days	1818	20.76%
Total	**8757**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3930	93.04%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	294	6.96%
Total	**4224**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	2861	65.79%
Monoclonal antibody by mouse ascites method		
Other product types	1488	34.21%
Total	**4349**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	143853	63.7%
Legislation on medicinal products for veterinary use and their residues	37188	16.47%
Medical devices legislation	19575	8.67%
Industrial chemicals legislation	8715	3.86%
Plant protection product legislation	595	0.26%
Biocides legislation	624	0.28%
Food legislation including food contact material	11492	5.09%
Feed legislation including legislation for the safety of target animals, workers and environment	1074	0.48%
Cosmetics legislation		
Other legislation	2726	1.21%
Total	**225842**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	209119	92.6%
Legislation satisfying national requirements only [within EU]	3418	1.51%
Legislation satisfying Non-EU requirements only	13305	5.89%
Total	**225842**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	575352	99.19%
Yes	4708	0.81%
Total	**580060**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	31875	5.5%
Mild [up to and including]	281069	48.46%
Moderate	177180	30.55%
Severe	89936	15.5%
Total	**580060**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	571715	98.56%
Yes	8345	1.44%
Total	**580060**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	448697	77.35%
Genetically altered without a harmful phenotype	112874	19.46%
Genetically altered with a harmful phenotype	18489	3.19%
Total	**580060**	**100.00%**

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Latvia

Latvia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2014 competent authority has approved 8 projects, but in 2015 – 9, however since the previous year, animal amount used for scientific purposes have decreased from 13730 in 2014 to 5457 in 2015. During the 2014 active research was performed in 12 projects, but in 2015 – in 16 projects and one project was not realized because the lack of funding. Compeering previous period, in 2015 were realised more small projects with quite a small total animal amount not exceeding number of 100 animals per one project.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 new types of species were used in procedures – dogs (7), domestic fowl (40) and rabbits (35). Comparing 2014 and 2015 data using of pigs have decreased and wild birds have not been use because a lack of funding.

Animal species used in procedures in 2014 and 2015 are exposed on Figure 1. and Figure 2

Figure 1

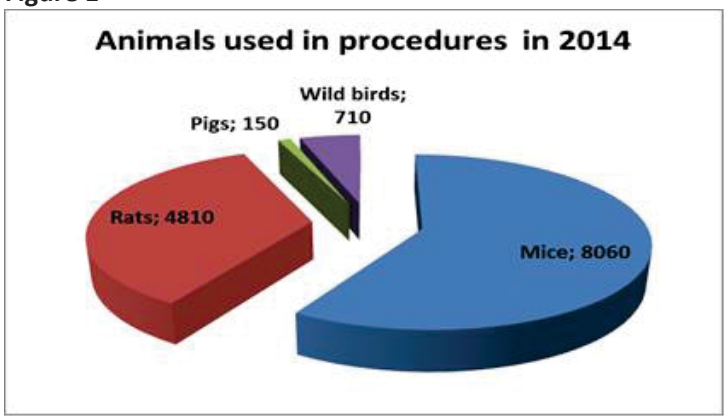
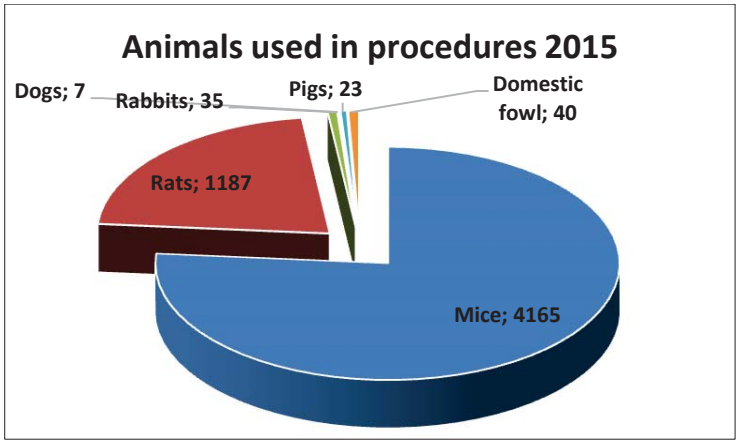


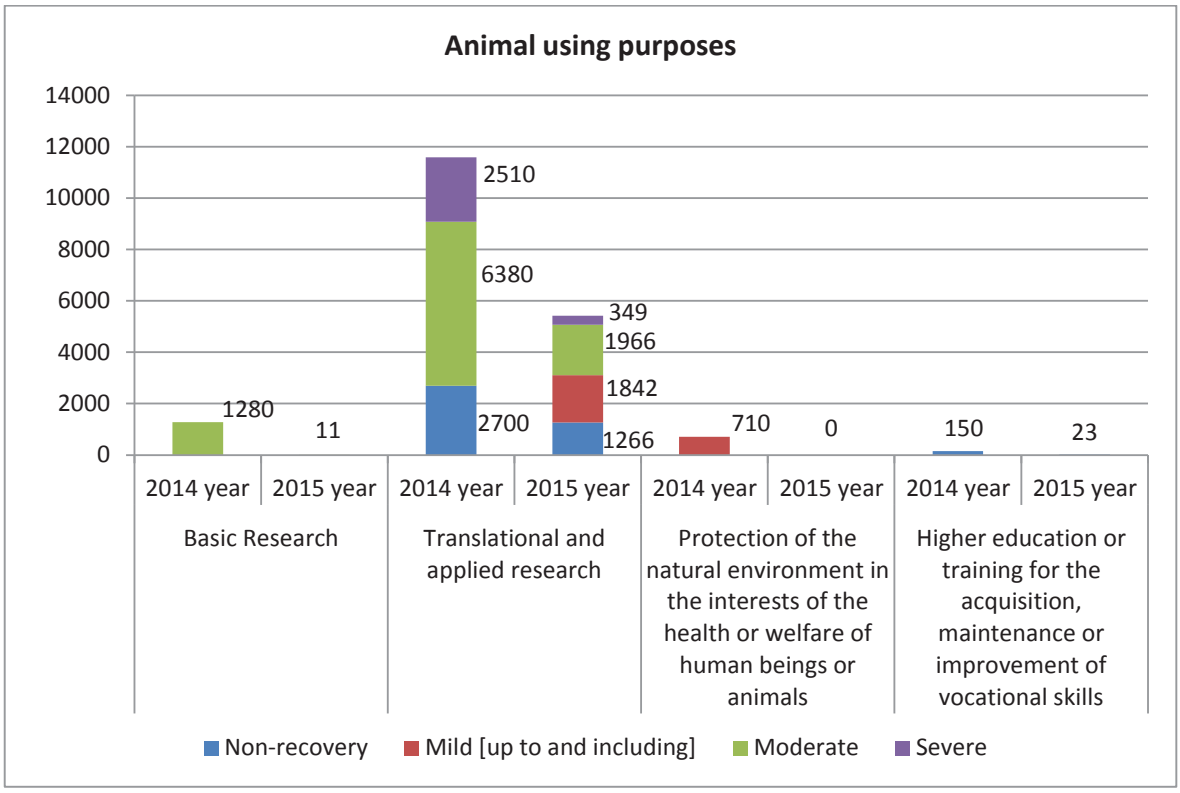
Figure 2



3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and biggest part 98.0% from the registered breeder.

Figure 3



In total 349 animals (6.40%) were used in planned severe procedures, including 81 mice and 182 rats for human nervous and mental disorders research. Procedures were appreciated as sever because of surgical intervention in brain cavity, but animals were not exposed to additional severe or moderate pain in long term. 74 mice and 12 rats from not planned severe procedures actually went through severe procedure because of individual reaction during surgery under anaesthesia (sudden death) and unexpected deterioration of health state (weight loss, hyperglycaemia), however mostly detecting heavier sufferings than were expected, animals were excluded from further steps of procedure and were humanely euthanized.

The biggest part 1977 (36.23%) of animals were exposed to planned moderate procedures, including 739 mice and 94 rats for human nervous and mental disorders research, 48 mice, 69 rats and 20 rabbits for human musculoskeletal disorders, 11 mice for nervous system (basic research), 37 mice for cancer, 78 mice for human immune disorders, 451 mice, 7 dogs and 15 rabbits for animal diseases and 367 mice for non-regulatory toxicology research (see Figure 3). 41 mice from not planned moderate procedures were exposed to moderate procedure because of individual reaction to adjuvant (not completed absorption and forming subcutaneous induration).
In mild procedures were used 1842 (33.75%) animals including 1565 mice for human nervous and mental disorders research, 62 mice for human immunes system disorders and 40 domestic fowl for

animal diseases research; 64 rats exposed to mild surgical intervention (sham operated animals) and 4 mice from procedures with harder character because of not desired effect and pathological state forming were excluded from further research process and underwent only mild manipulations
In non-recovery procedures were used 1289 (23.62%) animals including 520 mice and 746 rats for non-regulatory toxicology and ecotoxicology and 23 pigs for educational purposes
In general observation there are evident changes in the basic research, where animal using were decreased significantly from 1280 (9.32%) in 2014 to 11 (0.20%), also the number of animals used for educational purposes comparing previous year decreased from 150 (1.09%) to 23 (0.42%) in 2015 as well as in 2015 animals were not used in protection of natural environment in the interests of the health animal beings. The highest amount of animal using remain unchanged in translation and applied research. This year reaching 99.38% (5423) of all used animals and increasing for 14.97% comparing with previous year. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.
Reason for animal amount changes mentioned previous is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures and as it is seen from data in some projects animals are not used at all in this year instead of planned.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.
Scientific project authors strive to use *in silico* and *in vitro* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientist doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.
In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training). After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease used animal amount in procedures.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.
During the year 2015 users have reported to competent authority that 8 rats exposed to narcosis unexpectedly died during the surgical manipulation. In 2015 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4165	76.32%
Rats	1187	21.75%

Animal Species	Number of animals	Percentage
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	35	0.64%
Cats		
Dogs	7	0.13%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	23	0.42%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	40	0.73%
Other birds	0	0%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**5457**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5359	98.2%
Animals born in the EU but not at a registered breeder	98	1.8%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5457**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		

NHP Source (origin)	Number of animals	Percentage
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	11	0.2%
Translational and applied research	5423	99.38%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	0	0%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	23	0.42%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5457**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	11	100%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**11**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	52	0.96%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	2763	50.95%
Human Respiratory Disorders		

Translational and applied research	Number of uses	Percentage
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	141	2.6%
Human Immune Disorders	270	4.98%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders	564	10.4%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1633	30.11%
Total	**5423**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

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Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	5457	100%
Yes		
Total	**5457**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1289	23.62%
Mild [up to and including]	1842	33.75%
Moderate	1977	36.23%
Severe	349	6.4%
Total	**5457**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5457	100%
Yes		
Total	**5457**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5457	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**5457**	**100.00%**

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Latvia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

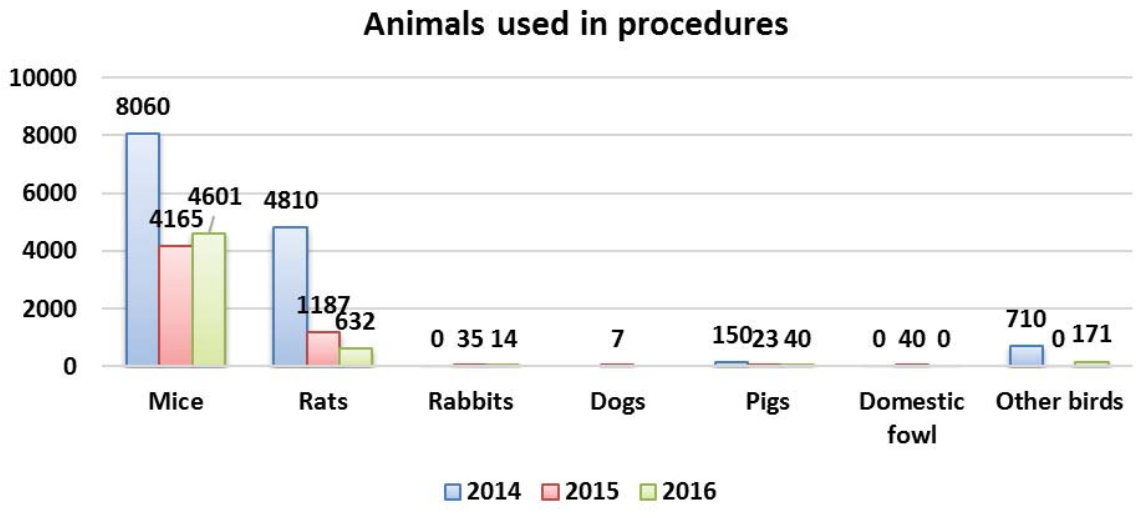
In 2015 competent authority has approved 9 projects, but in 2016 – 3. Since the previous year, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016). During the 2015 active research was performed in 16 projects, but in 2016 – in 17 projects. In 2016 the first time researchers started to use genetically altered animals – 60 mice in moderate procedures for basic research (human nervous system).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Compeering last two years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016, but total amount of used rats have decreased from 21.75% (n=1.187) in 2015 to 11.58% (n=632) in 2016. The reason for these changes is connected with economical (new synthesised substances are very expensive and therefore usually are synthesised in small amounts that leads to great need for smaller animals used in further *in vivo* tests) animal welfare and 3Rs considerations (suggestions from project evaluation commission). In 2016 dogs and domestic fowl were not used because the end of the projects in previous year, but after financial improvement the part of wild nature research project was realized and 171 wild birds were exposed to mild procedure.

Animal species used in procedures in 2014, 2015 and 2016 are exposed on Figure 1.

Figure 1



3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and biggest part 95.9% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2) – 48.3% (n=2637) from which 2516 were used for planned mild procedures, but 121, which came from a control groups and sham

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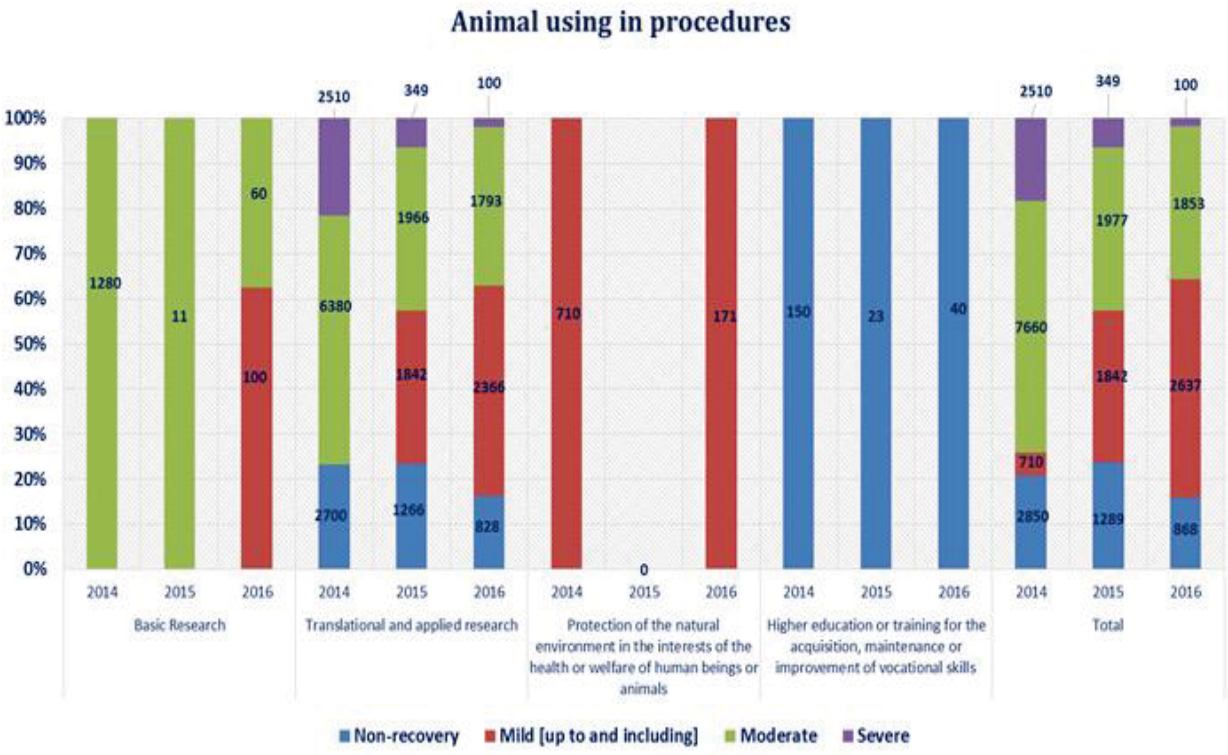
operated groups of cardiovascular disease, human nervous and mental disorders research projects and in general were planned to expose to moderate procedures, but actually underwent easier or not all manipulations comparing to other experimental groups in the same procedure. Therefore previous mentioned animal (n=121) sufferings were evaluated as mild.

Figure 2



In total in 2016 animals were not used in planned severe procedures, but 100 animals (1.8%) in four projects actually went through severe procedure.

1. During mild procedure in human cardiovascular disease research project 4 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.

2. During moderate procedure in human cancer research project 35 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.

3. Because of specific individual features during moderate procedure in human infectious disorders research project 4 mice recovered very hard after long exposing to narcosis during electroporation and therefore animals were humanely killed and were not included in further manipulations.

4. During moderate procedure in human musculoskeletal disorders research project 1 rabbit died. The case was not convinced with procedure, but during the time of procedure previous unknown acquired digestion disorders exacerbated resulting with death.

5. During moderate procedure in animal diseases and disorders research, 56 mice died without previously detectable signs of suffering.

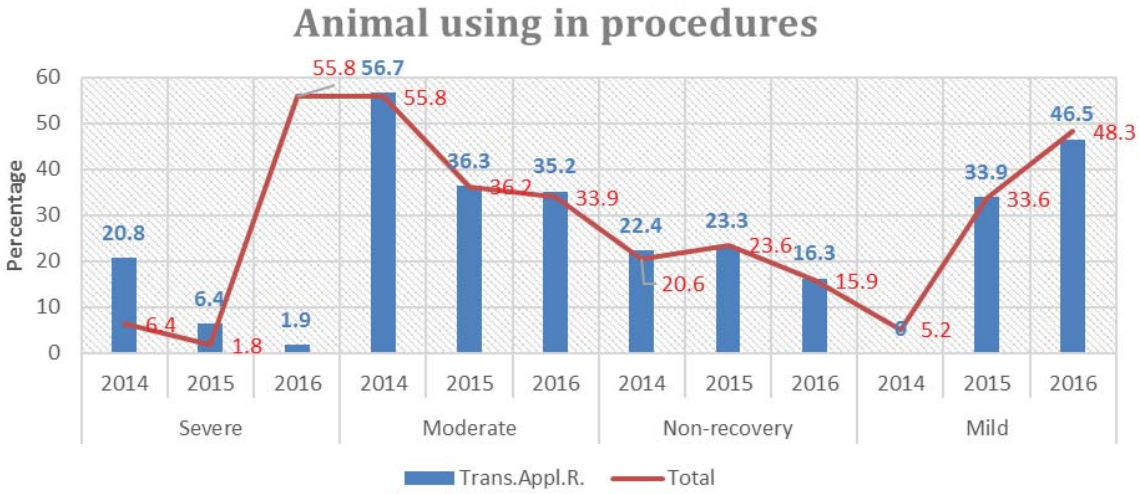
In moderate procedures in 2016 was used 1853 (33.95%) animals from which 1851 animals were exposed to planned moderate procedures, but 2 animals actually went through moderate procedures in human infections diseases research project because after using adjuvant (incomplete Freund's adjuvant) bad absorption in tissue was observed. Tissue thickening was remarked. It disappeared in 3-5days after injection was made. In moderate procedures 563 mice and 24 rats were used for trans/Appl human nervous and mental disorders, 48 mice, 418 mice for animal diseases and disorders research, 60 mice for basic nervous system research, 46 for human infectious and disorders research, 13 rabbits for musculoskeletal diseases and disorders and 158 mice for non-regulatory toxicology and ecotoxicology research (see Figure 3).

In 2016 868 (15.9%) animals were used in non-recovery procedures, including 260 mice and 560 rats in human cardiovascular disorders research projects and 40 pigs for higher education purposes (human and veterinary surgeons training).

In general observation there are evident changes in the basic research, where increased animal using in mild procedures (almost 2/3 form used animals for basic research), but still saving quite small amount – 3.2% (n=160) comparing with other research purposes.

The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect. In this research branch for the last three years decreased animal using, especially in harder procedures (see Fig.3), but increased animal using in mild procedures. In 2014 animals were not used in mild procedures. In 2014 and 2015 biggest amount of animals were used in severe and moderate procedures, but in 2016 – in mild procedures (46.4%) and in the same time animal using in severe procedures were low (1.9%).

Figure 3



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Scientific project authors strive to use *in silico, in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), but in 2016 – 40 pigs. After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease. Increase of pig using in non-recovery procedure probably is associated with more frequent training requests from surgeons.

Compeering previous year, in 2016 171 wild birds were used in wild nature research project. This project was authorized in previous year, but financial difficulties did not allow to realize project in 2015, but in 2016 after improvement of financial position, this project was resumed.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During the year 2016 users have not reported to competent authority that animals exposed to narcosis exceed classified “severe” procedure. In 2016 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4601	84.3%
Rats	632	11.58%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	14	0.26%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	40	0.73%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	171	3.13%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		

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Animal Species	Number of animals	Percentage
Other Fish		
Cephalopods		
Total	5458	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5233	95.88%
Animals born in the EU but not at a registered breeder	225	4.12%
Animals born in rest of Europe		
Animals born in rest of world		
Total	5458	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	160	2.93%
Translational and applied research	5087	93.2%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	171	3.13%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	40	0.73%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	5458	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	160	100%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**160**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	604	11.87%
Human Infectious Disorders	108	2.12%
Human Cardiovascular Disorders	2277	44.76%
Human Nervous and Mental Disorders	1448	28.46%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	14	0.28%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders	478	9.4%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	158	3.11%
Total	**5087**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	5458	100%
Yes		
Total	5458	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	868	15.9%
Mild [up to and including]	2637	48.31%
Moderate	1853	33.95%
Severe	100	1.83%
Total	5458	100.00%

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5458	100%
Yes		
Total	5458	100.00%

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Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5398	98.9%
Genetically altered without a harmful phenotype	60	1.1%
Genetically altered with a harmful phenotype		
Total	**5458**	**100.00%**

Latvia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2015 competent authority has approved 9 projects, in 2016 – 3, but in 2017 - 13. Since the previous years, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016), but slightly decreased – 5289 in 2017. During the 2015 active licence was for 16 projects, in 2016 – for 17, but in 2017 – for 25 projects. However it does not mean that in all projects all procedures were performed and projects realised as planned. In some cases projects or procedures were stopped for a while because the lack of financing or additional research before preclinical trials. Year by year the science quickly develops and that is why researchers after getting new information concerning their research topic uses *in vitro* methodology as much as possible, and it results with decreasing total amount of animals. In most of cases, especially in long lasting projects (5-year projects), researchers use less animals as they have written down in project licence application.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Comparing last three years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016 but in 2017 – decreased 63.0% (3332) (see Fig.1). Total amount of used rats have decreased from 21.75% (n=1187) in 2015 to 11.58% (n=632) in 2016, but increased in 2017 to 33.94% (1795). The reason for these changes is that in 2017 researchers have realized more projects where rats were included. In some specific investigations or testing of new substances rats were preferred because of their size. Rat's bigger size comparing to mice allow researchers to get more biological samples (for example – tissue, blood samples or tumour cells) for *in vitro* testing and in the same time also t allow to use less animals and get more necessary data. Compeering previous years in 2017 wild birds were not used for scientific purposes because of project ending however other wild species – bats (*Pipistrellus nathusii*) were used for mild procedures (basic research for white nose syndrome by taking blood samples for molecular analysis and investigation of their behaviour).

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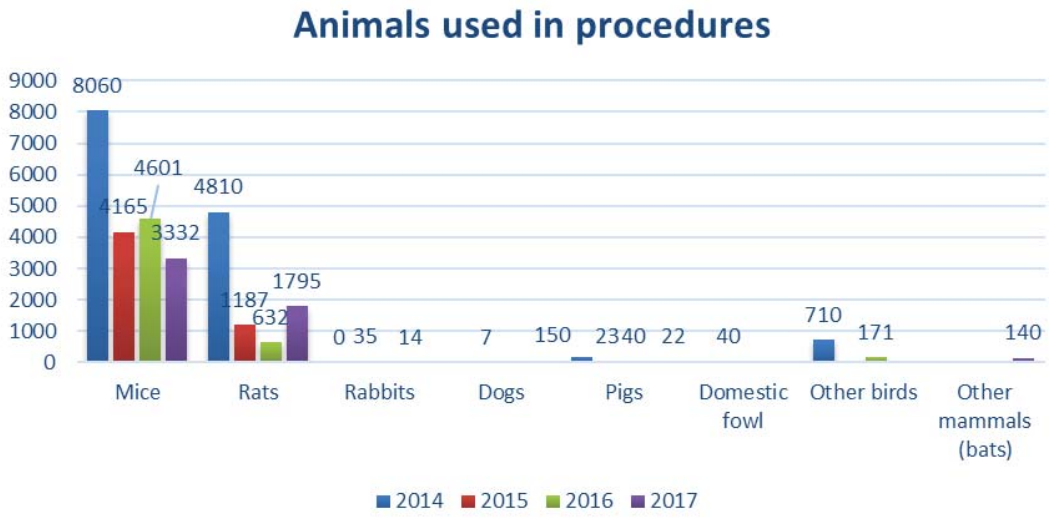
Figure 1



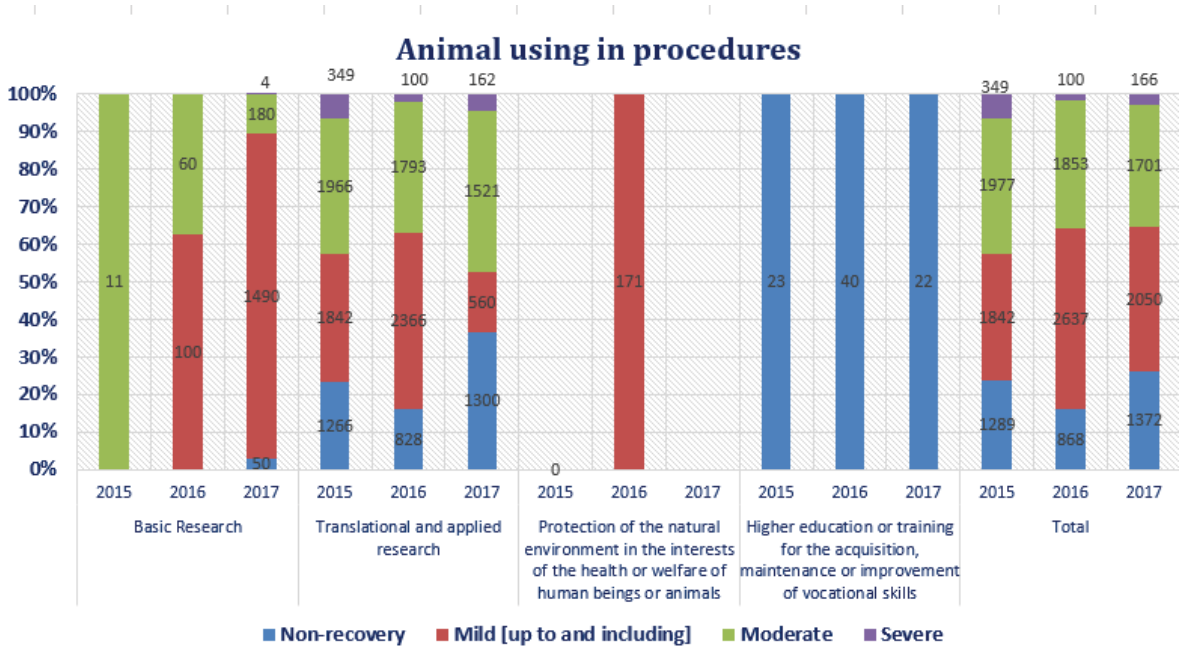
3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and the biggest part 96.4% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2 and Fig. 3) – 38.76% (n=2050) from which 1919 were used for planned mild procedures, but

a) 2 mice because the lack of tumour development were killed before the end of planned moderate procedure ((Trans/Appl Research) Human Cancer) and actually were exposed to mild procedure;
b) 24 rats and 65 mice were used as control group in moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) and were shame operated that finally did not cause further disabilities or dysfunctions except skin cut and finally resulted as mild procedure;
c) 40 rats were used in moderate procedure ((Basic Research) Nervous System) as animals of control group and did not underwent all manipulations comparing to other experimental groups, therefore actually were exposed to mild procedure.

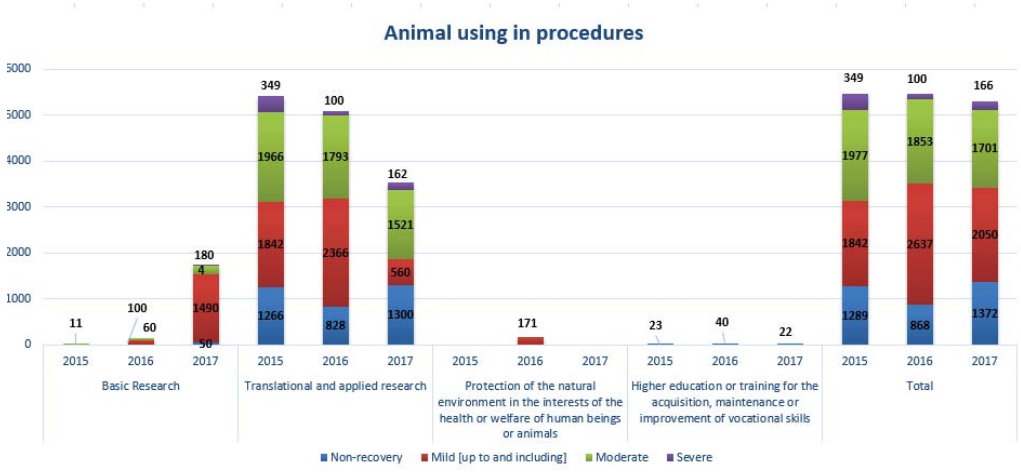
Figure 2



In total 166 (3.14%) animals in 2017 were used in severe procedures from which 114 animal were used for planned severe procedures (4 mice for (Basic Research) Oncology, and 110 mice for (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology) but 52 mice and 2 rats from three projects went through severe not planned procedure.

1. During moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) 18 mice died during the surgical manipulations and did not wake up after anaesthesia.
2. During moderate procedure ((Trans/Appl Research) Human Cancer) 34 animals lost weight more then 25% and therefore animals were humanely killed and were not included in further manipulations.

Figure 3

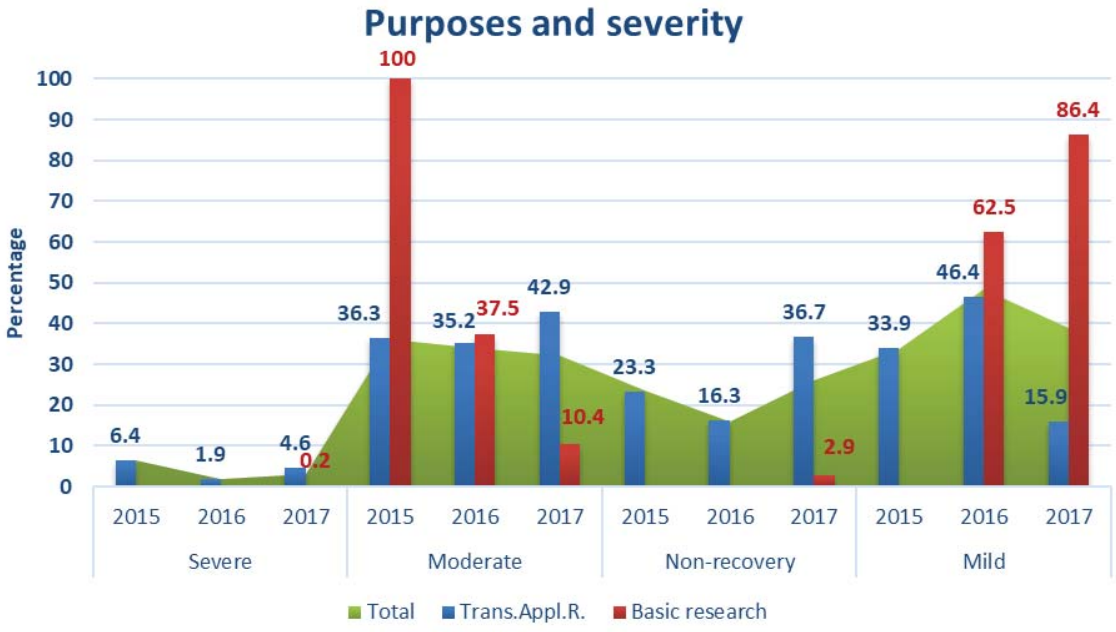


In moderate procedures in 2017 was used 1701 (32.16%) animals from which 804 mice were used in (Trans/Appl Research) Human Cancer research, 249 mice and 94 rats for (Trans/Appl Research) Human Nervous and Mental Disorders research, 59 rats for (Basic Research) Nervous System research and 374 mice for (Trans/Appl Research) Animal Diseases and Disorders research.

In 2017 1372 (25.94%) animals were used in non-recovery procedures, including 1300 rats for (Trans/Appl Research) Human Cardiovascular Disorders, 50 mice for (Basic Research) Nervous System and 22 pigs for Higher education or training for the acquisition, maintenance or improvement of vocational skills (human and veterinary surgeons training).

In general observation there are evident changes in severity of procedures. Comparing previous years in 2017 increased animal using in severe and non-recovery procedures. That is explained by long lasting projects (5-year projects) that were stopped for one or two year period for various reasons (lack of financing, additional *in vitro* research) but realized in 2017.
The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.
In this research branch for the last two years decreased animal using, especially in harder procedures (see Fig. 4), but in 2017 increased animal using in non-recovery, severe and moderate procedures.

Figure 4



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures in 2015 and 2016) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuous scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation

commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests. However increasing of animal using in non-recovery, moderate and severe procedures in 2017 is explained with interruption of long lasting projects (5-year lasting projects) and not fully realization during the time of first years authorization because of additional *in vitro* research and/or lack of finances.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Authors of scientific projects strive to use *in silico, in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan. If there are any possibility to decrease animal sufferings or to decrease a total amount of animals in procedures, applicants are strictly obligated to make changes in project before authorization. In addition – during inspections each project is checked according to approved methodology.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), 40 pigs – in 2016 and 22 pigs in 2017. After procedure (surgical intervention) pigs were euthanized. As much as possible manipulations (cuts, trainings of surgical techniques) were done with each animal under anaesthesia and narcosis to decrease a total amount of animals. Decrease of pig using in non-recovery procedure probably is associated with less frequent training requests from surgeons. In 2017 140 bats (*Pipistrellus nathusii*) were used for basic research (animal behaviour and infectious disease) in mild procedures. The procedure involved such a manipulations as blood and skin biopsy sample taking and observation of behaviour after animals were freed.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During the year 2017 users have reported two cases were animals did not awake after surgical intervention and narcosis (26 mice) and one case where 34 mice in cancer research where euthanized before the end of procedure because of weight lost more than 25%.

In 2017 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

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Latvia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3332	63%
Rats	1795	33.94%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	22	0.42%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	140	2.65%
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**5289**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5127	96.94%
Animals born in the EU but not at a registered breeder	162	3.06%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5289**	**100.00%**

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Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1724	32.6%
Translational and applied research	3543	66.99%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	22	0.42%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5289**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4	0.23%
Cardiovascular Blood and Lymphatic System		
Nervous System	1580	91.65%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology	140	8.12%
Other basic research		
Total	**1724**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	840	23.71%
Human Infectious Disorders	135	3.81%
Human Cardiovascular Disorders	1406	39.68%
Human Nervous and Mental Disorders	605	17.08%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders	70	1.98%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	0	0%
Other Human Disorders		
Animal Diseases and Disorders	377	10.64%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	110	3.1%
Total	**3543**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		

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Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		

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Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	5289	100%
Yes		
Total	**5289**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1372	25.94%
Mild [up to and including]	2050	38.76%
Moderate	1701	32.16%
Severe	166	3.14%
Total	**5289**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5289	100%
Yes		
Total	**5289**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5229	98.87%
Genetically altered without a harmful phenotype	60	1.13%
Genetically altered with a harmful phenotype		
Total	**5289**	**100.00%**

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Lithuania

Lithuania: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, there were 2451 laboratory animals employed for animal studies and other scientific purposes in Lithuania. In comparison to the previous year ~ 1000 less animals were used for the projects. Reduction can be justified due to the expiry date of more than 32 % projects in 2015.

The number of users increased from 8 in 2013 to 12 in 2015, however some establishments finished some projects in 2015.

Increase in use of birds is noticed.

Significant decrease in use of animals for the procedures classified as non-recovery.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The total number of animals used in specific areas is affected by many factors (i.e. active projects, funding, international projects ect.)

i. e. increase in use of animals for the purpose „Protection of the natural environment in the interests of the health or welfare of human beings or animals“ was directly related to one project where other birds (*Serinus canaria*) were used.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Most part of the animals (~64 %) were used for the procedures classified as mild [up to and including] severity, (~ 32 %) as moderate and (~4 %) as non-recovery.

Only Directive 2010/63/EU contains the requirement that all procedures should be classified, and no analogous to the system used in the Directives was introduced in the national legislation before, so this required additional input from users.

So significant decrease in use of animals for the procedures classified as non-recovery is mostly due to a better understanding of classification and better reporting of the actual severities by the users in 2015.

There was no exceeding of the ‘severe’ classification reported in 2015, because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

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4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category “Other”, only other birds (*Serinus canaria*) were used for one project during the reporting period.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period. No exemptions under article 6(4)(a) of the Directive 2010/63/EU were granted in 2015, either

Lithuania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1591	64.91%
Rats	572	23.34%
Guinea-Pigs	85	3.47%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	122	4.98%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	13	0.53%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		

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Animal Species	Number of animals	Percentage
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	64	2.61%
Reptiles	4	0.16%
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**2451**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2245	91.6%
Animals born in the EU but not at a registered breeder	206	8.4%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**2451**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2041	83.27%
Translational and applied research	302	12.32%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	64	2.61%

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Purpose Category	Number of uses	Percentage
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	44	1.8%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	2451	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	388	19.01%
Cardiovascular Blood and Lymphatic System	275	13.47%
Nervous System	180	8.82%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	537	26.31%
Immune System	540	26.46%
Urogenital/Reproductive System	3	0.15%
Sensory Organs (skin, eyes and ears)	30	1.47%
Endocrine System/Metabolism		
Multisystemic	60	2.94%
Ethology / Animal Behaviour /Animal Biology		
Other basic research	28	1.37%
Total	2041	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	22	7.28%
Human Infectious Disorders		
Human Cardiovascular Disorders	16	5.3%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	62	20.53%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	20	6.62%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	182	60.26%
Total	302	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		

Regulatory use and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	2451	100%
Yes		
Total	**2451**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	96	3.92%
Mild [up to and including]	1574	64.22%
Moderate	781	31.86%
Severe		
Total	**2451**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2451	100%
Yes		
Total	**2451**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2451	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**2451**	**100.00%**

Lithuania: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, there were 2660 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~200 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and (or) started performing projects. The number of users increased from 8 in 2013 to 14 in 2016.

The clearest trends in 2016 were increase in the use of farm animals for the purposes “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and “Regulatory use and Routine production“.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Almost 4 % of all the animals were used directly for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and it was almost twice as many in comparison to the previous year. Increase of animals used for this activity was related to an increased number of hospital type training centers due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2016 and other started or continued new projects in the end of the previous year.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Increase in use of animals for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” was partly related to the increased number of animals used for procedures classified as non-recovery.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

Substantial attention was given to 3R principles in personnel training. Training programmes were amended in terms of 3R theoretical and practical activities related to the search of animal alternatives by the organisers and approved by the competent authority.

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5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category "Other", no other animals were used during the reporting period.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2016 as well as in 2015.

Lithuania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1759	66.13%
Rats	744	27.97%
Guinea-Pigs	30	1.13%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	51	1.92%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	48	1.8%
Goats		
Sheep	28	1.05%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		

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Animal Species	Number of animals	Percentage
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	2660	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2602	97.82%
Animals born in the EU but not at a registered breeder	58	2.18%
Animals born in rest of Europe		
Animals born in rest of world		
Total	2660	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2212	83.16%
Translational and applied research	117	4.4%
Regulatory use and Routine production	230	8.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	101	3.8%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**2660**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	567	25.63%
Cardiovascular Blood and Lymphatic System	58	2.62%
Nervous System	69	3.12%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	534	24.14%
Immune System	248	11.21%
Urogenital/Reproductive System	214	9.67%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	400	18.08%
Multisystemic	122	5.52%
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**2212**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	18	15.38%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	27	23.08%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	72	61.54%
Total	**117**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Toxicity and other safety testing including pharmacology	95	41.3%
Routine production	135	58.7%
Total	**230**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	40	42.11%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	15	15.79%
Pharmaco-dynamics (incl safety pharmacology)	40	42.11%
Total	**95**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	40	100%
Total	**40**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	135	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**135**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	175	76.09%
Legislation on medicinal products for veterinary use and their residues	55	23.91%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**230**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	230	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**230**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2660	100%
Yes		
Total	**2660**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	141	5.3%
Mild [up to and including]	1812	68.12%
Moderate	707	26.58%
Severe		
Total	**2660**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2660	100%
Yes		
Total	**2660**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2660	100%
Genetically altered without a harmful phenotype	0	0%
Genetically altered with a harmful phenotype		
Total	**2660**	**100.00%**

Lithuania: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, there were 2766 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~100 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and started performing projects. The number of users increased from 8 in 2013 to 12 in 2015 and to 14 in 2017.

The clearest trends in 2017 were the large increase in the use of fish for research, increase of use of farm animals (pigs) and use of animals for the purposes "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and "Translational and applied research".

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The most common primary purpose for using animals was basic research (in Immune System, Oncology, Nervous System) (~ 60 %), then (~ 22 %), for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and (~ 18 %) for the purpose "Translational and applied research".

Increase in use of animals for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" is noticed from ~ 4 % to ~ 22 %. Increase of animals used for this activity was related to increased number of hospital type training centres due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2017 and other started or continued new projects in the end of the previous year.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Most part of the animals (~79 %) were used for the procedures classified as mild [up to and including] severity, (~18 %) for the procedures classified as moderate and (~ 3 %) for non-recovery severity.

Decrease in use of animals for the procedures classified as moderate and non-recovery during year 2017-2015 is related to the fact that some establishment did not perform any projects due to reconstruction of premises for some time, so more animals were used for the procedures classified as mild.

There were no exceeding of the 'severe' classification reported in 2017 and previous year because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

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4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category "Other", other birds (~ 1 %) and fish (~ 19 %) were used during the reporting period (~ 20 %) in total comparing to total amount of animals used in 2017.

The clearest trend in 2017 was the large increase in the use of fish for research. The main reason is, that new user was established and started performing projects with specific focus on fish.

Some other birds (Serinus canaria) were used.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2017.

Lithuania: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1718	62.11%
Rats	391	14.14%
Guinea-Pigs	15	0.54%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	13	0.47%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	68	2.46%
Goats		
Sheep	15	0.54%

Animal Species	Number of animals	Percentage
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	26	0.94%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	520	18.8%
Cephalopods		
Total	**2766**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2683	97%
Animals born in the EU but not at a registered breeder	83	3%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**2766**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1659	59.98%
Translational and applied research	501	18.11%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	606	21.91%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**2766**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	337	20.31%
Cardiovascular Blood and Lymphatic System	20	1.21%
Nervous System	284	17.12%
Respiratory System	103	6.21%
Gastrointestinal System including Liver		
Musculoskeletal System	10	0.6%
Immune System	873	52.62%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic	32	1.93%
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**1659**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	102	20.36%
Human Cardiovascular Disorders	8	1.6%
Human Nervous and Mental Disorders	107	21.36%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	17	3.39%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	267	53.29%
Total	**501**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	2766	100%
Yes		
Total	2766	100.00%

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Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	83	3%
Mild [up to and including]	2186	79.03%
Moderate	497	17.97%
Severe		
Total	**2766**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2766	100%
Yes		
Total	**2766**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2766	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**2766**	**100.00%**

Luxembourg

Luxembourg: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg an increase of about 50% of the use of animals was observed. Furthermore comparing the statistic of 2015, in 2015 the species “rat” was used in procedures.

More explanation will be indicated in part 2 of this questionnaire.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased during the last years. This trend will continue when reporting the following year (2016).

In Luxembourg two main institutions lead the laboratories and both modernised and increased their facilities during the last years. For example in 2016 a further facility was authorised, this will have a further impact on the number of animals used due to the fact of the little number of facilities (6 facilities) and the small size of the country.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 the first time the actual severity “severe” was reported. Initially for the concerned project the severity “mild” was prospected and consequently the responsible person stopped this project and they didn’t demanded any authorisation for modification .

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The particular efforts taken to promote the principle of the Three Rs were notably the enforcement and obligation of the training and the increased impact from the national committee.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

There is no significant proportion reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During 2015 there was no case an exceedance of the ‘severe’ classification.

Luxembourg: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3078	87.34%
Rats	73	2.07%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	373	10.58%
Other Fish		
Cephalopods		
Total	**3524**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	3452	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**3452**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3484	98.86%
Translational and applied research	40	1.14%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**3524**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	764	21.93%
Cardiovascular Blood and Lymphatic System	373	10.71%
Nervous System	1736	49.83%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	611	17.54%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**3484**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	39	97.5%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1	2.5%
Total	**40**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		

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Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		

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Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3452	97.96%
Yes	72	2.04%
Total	**3524**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	151	4.28%
Mild [up to and including]	1654	46.94%
Moderate	1679	47.64%
Severe	40	1.14%
Total	**3524**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3524	100%
Yes		
Total	**3524**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1721	48.84%
Genetically altered without a harmful phenotype	1657	47.02%
Genetically altered with a harmful phenotype	146	4.14%
Total	**3524**	**100.00%**

Luxembourg: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg there was an increase in the total number of uses from 3.524 in 2015 to 21.472 total uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total of 3.660 mammals were used in procedures in 2016. These figures represent an increase of 6% of the total use of mammals from 2015 to 2016.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015 to a total of 21.472 uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg, the two main institutions involved in animal testing both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2016.

Due to the small number of parties involved (6 facilities in total), this had a strong impact on the total number of animals used.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 the actual severity “severe” was reported the first time, when 1,14% of the uses were severe. In 2016 0,52% of the actual severities where classified as severe. As to the actual severities, no trend was observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics.

The particular efforts taken to promote the principle of the Three Rs were:

the focus on the education of the users,

the organisation of a workshop on the severity assessment and reporting

and additional care taken during the project evaluation.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category “other” was not reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

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In 2016 there was no case where the ‘severe-classification‘ has been exceeded.

Luxembourg: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3493	16.27%
Rats	167	0.78%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	17812	82.95%
Other Fish		
Cephalopods		
Total	**21472**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	20987	98.81%
Animals born in the EU but not at a registered breeder	253	1.19%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**21240**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	21017	97.88%
Translational and applied research	455	2.12%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**21472**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	946	4.5%
Cardiovascular Blood and Lymphatic System	429	2.04%
Nervous System	18511	88.08%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	1131	5.38%
Urogenital/Reproductive System		

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	21017	100.00%

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	372	81.76%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	83	18.24%
Total	455	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		

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Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	21240	98.92%
Yes	232	1.08%
Total	**21472**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	341	1.59%
Mild [up to and including]	18628	86.75%
Moderate	2392	11.14%
Severe	111	0.52%
Total	**21472**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	21472	100%
Yes		
Total	**21472**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	18178	84.66%
Genetically altered without a harmful phenotype	1980	9.22%
Genetically altered with a harmful phenotype	1314	6.12%
Total	**21472**	**100.00%**

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Luxembourg: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg there was an increase in the total number of uses from 3.524 total uses in 2015, 21.472 total uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total number of 5.668 mammals were used in procedures in 2017. These figures represent an increase of 54,86% of the total uses of mammals from 2016 to 2017.

Regarding the purpose of the animal uses, no trends ware observed during the last year. The main category is basic research, followed by translational and applied research, maintenance of colonies and higher education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015, 21.472 uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg two main institutions are involved in animal testing. Both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2017.

Due to the small number of the parties involved in animal experiments (6 facilities in total), the development of the animal facilities has a strong impact on the total number of animals used. In particular the majority of the animal uses (19.410 zebrafish larvae) represent a few projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Comparing the actual severities from 2016 to 2017 no trend were observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The particular efforts taken to promote the principle of the Three Rs have been:

- The focus is put on the education of the users. Notably additional minimum requirements have been adopted for the personal involved in animal experiment,

- A workshop on the severity assessment and reporting took place,

- Refinement of the housing and care of the animals is ensured, inter alia, by modernisation of the animal facilities and by a new animal facility. Another point is the environment enrichment of the cages

or aquariums, in particular, providing animals with appropriate housing that allows the expression of species-specific behaviours, such as nesting opportunities for mice.

- During the inspection attention is put on points such as that the staff follows the project protocol and in particularly that the humane endpoints are respected and the score sheets are reviewed. When procedures are conducted which involve pain or invasive procedures, it is verified that these procedures are carried out under general or local anaesthesia and that analgesia or another method is used to ensure that pain, suffering and distress are kept to a minimum.

- Additional care is taken during the project evaluation , inter alia, a review of the referenced literatures, a check of the most up to date references have been considered, a check whether there are alternative methods in place and the statistical calculation is reviewed. Regarding the alternative methods, it is checked if all measures are taken to reduce pain, suffering or lasting harms, if the humane endpoints are appropriate, if the housing, health checks of the animals are appropriate etc.

-Regarding the Reduction the national research institutes are collaborating with other research groups and are sharing data and resources (animals, tissue, organs and equipment) between research groups. Furthermore one institute owns an IRM, which enables longitudinal studies in the same animals and which is put at the disposal of the other institutes

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category “other” was not reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 there was no case where the severe-classification has been exceeded.

Luxembourg: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	5572	21.56%
Rats	96	0.37%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		

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Animal Species	Number of animals	Percentage
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	20173	78.07%
Other Fish		
Cephalopods		
Total	**25841**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	25617	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**25617**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	24562	95.05%
Translational and applied research	888	3.44%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	144	0.56%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	247	0.96%
Total	**25841**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1861	7.58%
Cardiovascular Blood and Lymphatic System	374	1.52%
Nervous System	20265	82.51%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	2062	8.4%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**24562**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	526	59.23%
Human Infectious Disorders	326	36.71%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	36	4.05%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**888**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

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First uses and re-uses

Re-use	Number of uses	Percentage
No	25617	99.13%
Yes	224	0.87%
Total	**25841**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	519	2.01%
Mild [up to and including]	21938	84.9%
Moderate	3213	12.43%
Severe	171	0.66%
Total	**25841**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	25764	99.7%
Yes	77	0.3%
Total	**25841**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	22113	85.57%
Genetically altered without a harmful phenotype	3660	14.16%
Genetically altered with a harmful phenotype	68	0.26%
Total	**25841**	**100.00%**

Malta

Malta: Narrative 2015

1. **General information on any changes in trends observed since the previous reporting period.**

   During this year no changes have been observed in trends noted during the past years. This is due to the complete absence of scientific works involving animals.

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   N/A

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   N/A

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   N/A

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   N/A

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A

Malta: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	0	
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		

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Animal Species	Number of animals	Percentage
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	0	100.00%

Malta: Narrative 2016

1. **General information on any changes in trends observed since the previous reporting period.**

   No changes have been noted from the previous year, so no animal experimentation have been carried out.

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   Not applicable

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   No

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   No

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   N/A

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A

Malta: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	0	
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		

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Animal Species	Number of animals	Percentage
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	0	100.00%

Malta: Narrative 2017

1. **General information on any changes in trends observed since the previous reporting period.**

   This year an application has been received by the Competent authority and the approval has been granted to carry out research on fish (sea bass).

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   The research program took to an increase in the number of animals used, from 0 to 250 fish.

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   No severe procedures are involved in the study carried out.

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   All the fish had to be been euthanized and incinerated.

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   A significant proportion of animals is not used therefore it is not applicable

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A. This was an host specific parasite study interaction and did not involve severe procedures.

Malta: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice		
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		

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Animal Species	Number of animals	Percentage
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	250	100%
Cephalopods		
Total	**250**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder		
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe	250	100%
Animals born in rest of world		
Total	**250**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

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Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research		
Translational and applied research	250	100%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**250**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System		
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total		

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders	250	100%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**250**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

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First uses and re-uses

Re-use	Number of uses	Percentage
No	250	100%
Yes		
Total	**250**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	250	100%
Moderate		
Severe		
Total	**250**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	250	100%
Yes		
Total	**250**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	250	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**250**	**100.00%**

Netherlands

Netherlands: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2014 and 2015, the Dutch collection of statistical information on the use of animals in procedures, was carried out according to the common format of Commission Implementing Decision 2012/707/EU. There are a big differences between the new data categories and the former Dutch data format. This makes it very difficult to compare the statistics of 2014 and 2015 with the data from previous years.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 528.159 animals were used in procedures. This is 92.868 (-14.9%) less than in 2014.

A decrease in numbers of animals has been observed in almost all data categories. Especially the number of mice (-32.701), cattle (-6.646), domestic fowl (-34.289), pigs (-4.777), rhesus monkeys (-47), and cats (-18) was reduced. In 2015 127.813 (26,7%) genetically altered animals were used in procedures, this is 17.574 (-12.1%) animals less than in 2014.

In 2015 animals were 8.514 times reused, which is 2.195 (+34.7%) more than in 2014 (6.319).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 1.971 (+12.9%) more procedures were reported in the severity category ‘severe’, compared to 2014. This increase was especially seen in the categories Translational and applied research (human) (+16.5%), Animal diseases and disorders / animal welfare (+6.3%), Higher education or training for the acquisition, maintenance or improvement of vocational skills (+0.5%), and Testing by legislation/feed legislation including legislation for the safety of target animals, works and environment (+1%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands continuous efforts have been taken to promote the principles of the 3R’s. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Alures we have provided information on the ‘other’ categories in the required fields. Dutch users were asked to provide more information on the selected category when these information appeared to be insufficient. In some cases the users did realize that they could reclassify the animals uses in the predefined data categories. This is a continuous process of creating awareness to the authorized users.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2015 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	244804	51.05%
Rats	99602	20.77%
Guinea-Pigs	3433	0.72%
Hamsters (Syrian)	1518	0.32%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	1031	0.21%
Rabbits	9899	2.06%
Cats	61	0.01%
Dogs	750	0.16%
Ferrets	396	0.08%
Other carnivores	410	0.09%
Horses, donkeys and cross-breeds	213	0.04%
Pigs	8402	1.75%
Goats	239	0.05%
Sheep	2126	0.44%
Cattle	5240	1.09%
Prosimians		
Marmoset and tamarins	91	0.02%
Cynomolgus monkey	47	0.01%
Rhesus monkey	96	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	14	0%
Domestic fowl	51386	10.71%
Other birds	18248	3.8%
Reptiles	851	0.18%
Rana		
Xenopus	1181	0.25%
Other Amphibians	562	0.12%
Zebra fish	4909	1.02%
Other Fish	24071	5.02%
Cephalopods		
Total	**479580**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	378128	80.3%
Animals born in the EU but not at a registered breeder	90414	19.2%
Animals born in rest of Europe		
Animals born in rest of world	2350	0.5%
Total	**470892**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	166	95.4%
Animals born in rest of Europe		
Animals born in Asia	8	4.6%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**174**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	3	1.72%
F2 or greater	8	4.6%
Self-sustaining colony	163	93.68%
Total	**174**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	126592	26.4%
Translational and applied research	142675	29.75%
Regulatory use and Routine production	137291	28.63%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	364	0.08%
Preservation of species	1729	0.36%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	19628	4.09%
Forensic enquiries	42	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	51259	10.69%
Total	**479580**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	36560	28.88%
Cardiovascular Blood and Lymphatic System	12259	9.68%
Nervous System	20523	16.21%
Respiratory System	1763	1.39%
Gastrointestinal System including Liver	3499	2.76%
Musculoskeletal System	1890	1.49%
Immune System	15280	12.07%
Urogenital/Reproductive System	2261	1.79%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	234	0.18%
Endocrine System/Metabolism	6450	5.1%
Multisystemic	3318	2.62%
Ethology / Animal Behaviour /Animal Biology	17705	13.99%
Other basic research	4850	3.83%
Total	**126592**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13203	9.25%
Human Infectious Disorders	19623	13.75%
Human Cardiovascular Disorders	4985	3.49%
Human Nervous and Mental Disorders	11760	8.24%
Human Respiratory Disorders	3942	2.76%
Human Gastrointestinal Disorders including Liver	2677	1.88%
Human Musculoskeletal Disorders	1921	1.35%
Human Immune Disorders	3075	2.16%
Human Urogenital/Reproductive Disorders	965	0.68%
Human Sensory Organ Disorders (skin, eyes and ears)	281	0.2%
Human Endocrine/Metabolism Disorders	5034	3.53%
Other Human Disorders	882	0.62%
Animal Diseases and Disorders	42449	29.75%
Animal Welfare	28642	20.07%
Diagnosis of diseases	1877	1.32%
Plant diseases	436	0.31%
Non-regulatory toxicology and ecotoxicology	923	0.65%
Total	**142675**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	65122	47.43%
Other efficacy and tolerance testing	1023	0.75%
Toxicity and other safety testing including pharmacology	70723	51.51%
Routine production	423	0.31%
Total	**137291**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3162	4.86%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	61960	95.14%
Total	**65122**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1020	1.44%
Skin irritation/corrosion	316	0.45%
Skin sensitisation	3777	5.34%
Eye irritation/corrosion	85	0.12%
Repeated dose toxicity	6928	9.8%
Carcinogenicity	1538	2.17%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Genotoxicity	733	1.04%
Reproductive toxicity	23926	33.83%
Developmental toxicity	19323	27.32%
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Kinetics	986	1.39%
Ecotoxicity	9292	13.14%
Safety testing in food and feed area	960	1.36%
Target animal safety	1839	2.6%
Total	**70723**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	120	11.76%
Other lethal methods	425	41.67%
Non lethal methods	475	46.57%
Total	**1020**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	5024	72.52%
29 - 90 days	1904	27.48%
> 90 days		
Total	**6928**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	7821	84.17%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity	720	7.75%
Bioaccumulation	751	8.08%
Other ecotoxicity		
Total	**9292**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	294	69.5%
Monoclonal antibody by mouse ascites method		
Other product types	129	30.5%
Total	**423**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	44052	32.09%
Legislation on medicinal products for veterinary use and their residues	33821	24.63%
Medical devices legislation	2	0%
Industrial chemicals legislation	45992	33.5%
Plant protection product legislation	2764	2.01%
Biocides legislation		
Food legislation including food contact material	740	0.54%
Feed legislation including legislation for the safety of target animals, workers and environment	1045	0.76%
Cosmetics legislation		
Other legislation	8875	6.46%
Total	**137291**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	127695	93.01%
Legislation satisfying national requirements only [within EU]	521	0.38%
Legislation satisfying Non-EU requirements only	9075	6.61%
Total	**137291**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	471066	98.22%
Yes	8514	1.78%
Total	**479580**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	23323	4.86%
Mild [up to and including]	346271	72.2%
Moderate	92789	19.35%
Severe	17197	3.59%
Total	**479580**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	469439	97.89%
Yes	10141	2.11%
Total	**479580**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	351767	73.35%
Genetically altered without a harmful phenotype	63088	13.15%
Genetically altered with a harmful phenotype	64725	13.5%
Total	**479580**	**100.00%**

Netherlands: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period

In 2016, the Dutch registered establishments reported 403.370 animals used in procedures. This is 76.210 (-18.9%) less than in 2015. Especially the number of mice (-82.826), sheep (-1688), rabbits (-1320) and cattle (-1167) was reduced.

In 2016 animals were 10.819 times reused, which is which is 2305 more than in 2015 (8.514).
Reuse mainly takes place for the purpose of education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2016, 78.209 procedures were reported with the use of genetically altered animals. This is a decrease of 49.604 animals compared to 2015. This decrease in use of genetically altered animals can partially be explained with the observation that in the previous years a large numbers of lines of genetically altered animals were established. This after completion of a welfare assessment with a minimum of two generations. For a substantial amount of genetically altered lines, it was concluded in the welfare assessment that they are not expected to have a harmful phenotype. Therefore, breeding of these lines no longer needs to be reported.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severities reported in 2016 (mild 68.7%, moderate 21.7% severe 3.3%, and non-recovery: 6.3%) are generally in line with the actual severities reported in 2015 (non-recovery 4.9%, mild 72.2%, moderate 19.3% and severe 3.6%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R's. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other carnivores (main categories): European pine marten (*Martes martes*), harbour seals (*Phoca vitulina*), European (Russian) minks (*Mustela lutreola*), Toepaja (*Tupaia belangeri*), and wild boars (*Sus scrofa*).

Other birds (main categories): 4803 (23.8%) *Parus Major* (great tit), 3654 (18.1%) *Anas plathyrynchos* (common mallard), 1572 (7.8%) *Gallus gallus* (red junglefowl), 1363 (6.8%) *Limosa limosa (*black tailed godwit), 1055 (5.2%) *Cyanistes caeruleus* (Eurasian blue tit).

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Other fish (main categories): 3087 (23.8%) *Anguilla Anguilla* (European eel), 2909 (22.5%) *Pimephales promelas* (fathead minnow), 2780 (21.5%) *Cyprinus carpio* (common carp)

All procedures (3257) reported in de category 'other basic research' were used for cell biology-research.

2756 out of 5008 procedures in the category 'other efficacy and tolerance testing' were used for tests concerning the European pharmacopeia.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2016 exceedance of the severity classification 'severe' has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	148406	38.38%
Rats	106876	27.64%
Guinea-Pigs	2763	0.71%
Hamsters (Syrian)	1443	0.37%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	472	0.12%
Rabbits	8579	2.22%
Cats	89	0.02%
Dogs	656	0.17%
Ferrets	294	0.08%
Other carnivores	216	0.06%
Horses, donkeys and cross-breeds	146	0.04%
Pigs	10129	2.62%
Goats	152	0.04%
Sheep	438	0.11%
Cattle	4073	1.05%
Prosimians		
Marmoset and tamarins	16	0%
Cynomolgus monkey	34	0.01%
Rhesus monkey	70	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1	0%
Domestic fowl	52237	13.51%
Other birds	20143	5.21%
Reptiles	207	0.05%

Animal Species	Number of animals	Percentage
Rana	20	0.01%
Xenopus	431	0.11%
Other Amphibians	63	0.02%
Zebra fish	15804	4.09%
Other Fish	12942	3.35%
Cephalopods		
Total	**386700**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	288771	76.84%
Animals born in the EU but not at a registered breeder	82417	21.93%
Animals born in rest of Europe		
Animals born in rest of world	4612	1.23%
Total	**375800**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	58	71.6%
Animals born in rest of Europe		
Animals born in Asia	23	28.4%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**81**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	25	30.86%
Self-sustaining colony	56	69.14%
Total	**81**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	115211	29.79%
Translational and applied research	107466	27.79%
Regulatory use and Routine production	142733	36.91%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	24	0.01%
Preservation of species	4257	1.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	14714	3.81%
Forensic enquiries	677	0.18%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1618	0.42%
Total	**386700**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	43795	38.01%
Cardiovascular Blood and Lymphatic System	7531	6.54%
Nervous System	17046	14.8%
Respiratory System	1498	1.3%
Gastrointestinal System including Liver	3351	2.91%
Musculoskeletal System	848	0.74%
Immune System	13063	11.34%
Urogenital/Reproductive System	1653	1.43%
Sensory Organs (skin, eyes and ears)	316	0.27%
Endocrine System/Metabolism	3670	3.19%
Multisystemic	3598	3.12%
Ethology / Animal Behaviour /Animal Biology	15585	13.53%
Other basic research	3257	2.83%
Total	**115211**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14122	13.14%
Human Infectious Disorders	18775	17.47%
Human Cardiovascular Disorders	4564	4.25%
Human Nervous and Mental Disorders	9646	8.98%
Human Respiratory Disorders	2664	2.48%
Human Gastrointestinal Disorders including Liver	2186	2.03%
Human Musculoskeletal Disorders	917	0.85%
Human Immune Disorders	2024	1.88%
Human Urogenital/Reproductive Disorders	107	0.1%
Human Sensory Organ Disorders (skin, eyes and ears)	430	0.4%
Human Endocrine/Metabolism Disorders	2444	2.27%
Other Human Disorders	30	0.03%
Animal Diseases and Disorders	18186	16.92%
Animal Welfare	29363	27.32%
Diagnosis of diseases	1339	1.25%
Plant diseases	43	0.04%
Non-regulatory toxicology and ecotoxicology	626	0.58%
Total	**107466**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	54947	38.5%
Other efficacy and tolerance testing	5008	3.51%
Toxicity and other safety testing including pharmacology	82616	57.88%
Routine production	162	0.11%
Total	**142733**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2603	4.74%
Pyrogenicity testing		
Batch potency testing	52206	95.01%
Other quality controls	138	0.25%
Total	**54947**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1903	2.3%
Skin irritation/corrosion	124	0.15%
Skin sensitisation	4086	4.95%
Eye irritation/corrosion	107	0.13%
Repeated dose toxicity	6386	7.73%
Carcinogenicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Genotoxicity	660	0.8%
Reproductive toxicity	25780	31.2%
Developmental toxicity	35853	43.4%
Kinetics	1001	1.21%
Ecotoxicity	4917	5.95%
Safety testing in food and feed area	1792	2.17%
Target animal safety	7	0.01%
Total	**82616**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods	112	5.89%
Non lethal methods	1791	94.11%
Total	**1903**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2047	32.05%
29 - 90 days	3679	57.61%
> 90 days	660	10.34%
Total	**6386**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3777	76.82%
Chronic toxicity		
Reproductive ecotoxicity	240	4.88%
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	900	18.3%
Other ecotoxicity		
Total	**4917**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	2	1.23%
Monoclonal antibody by mouse ascites method		
Other product types	160	98.77%
Total	**162**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	38543	27%
Legislation on medicinal products for veterinary use and their residues	30184	21.15%
Medical devices legislation	62	0.04%
Industrial chemicals legislation	68172	47.76%
Plant protection product legislation	310	0.22%
Biocides legislation	86	0.06%
Food legislation including food contact material	438	0.31%
Feed legislation including legislation for the safety of target animals, workers and environment	2182	1.53%
Cosmetics legislation		
Other legislation	2756	1.93%
Total	**142733**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	140100	98.16%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	2633	1.84%
Total	**142733**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	375881	97.2%
Yes	10819	2.8%
Total	**386700**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	8732	2.26%
Mild [up to and including]	277205	71.68%
Moderate	87429	22.61%
Severe	13334	3.45%
Total	**386700**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	378070	97.77%
Yes	8630	2.23%
Total	**386700**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	308491	79.78%
Genetically altered without a harmful phenotype	67451	17.44%
Genetically altered with a harmful phenotype	10758	2.78%
Total	**386700**	**100.00%**

Netherlands: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

In 2017, the Dutch registered establishments reported 477.550 animals used in procedures. This is 74.180 (+18.4%) more than in 2016. Especially the number of mice (+44.015), and zebrafish (+36.220) was increased. The number of rats (-18.052) was reduced.

In 2017 animals were 11.138 times reused, which is 319 animal more than in 2016 (10.819). Reuse mainly takes place for the purpose of education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2017 more experiments with zebrafish were carried out in the context of intensifying research into new possibilities for the screening of anti-cancer drugs. In addition, more experiments with zebrafish have been carried out as a result of research into hormone-disrupting substances in the context of a larger EU project.

In 2017, 133.365 procedures were reported with the use of genetically altered animals. This is a increase of 55.156 animals compared to 2016. Most animal testing on genetically modified animals have carried out on mice (84,908, 63.7% of the number of animal tests for genetically modified animals animals) and zebrafish (45,941, 34.4%).

After a significant increase in number of animal uses in 2014 and a temporary decrease in 2016, the number of animals uses appears to be stabilizing in 2017 and has reached the same level as in the reporting years 2013 and 2015. These fluctuations seem to be caused mainly by the adaptation of the user community to the new reporting and licensing system, introduced in 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severities reported in 2017 (mild 64,9%, moderate 25,5%, severe 3.0%, and non-recovery: 6.6%) are generally in line with the actual severities reported in 2016 (mild 68.7%, moderate 21.7%, severe 3.3%, and non-recovery 6.3%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R's. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other carnivores (main categories): 257 European (Russian) minks (Mustela lutreola), 6 harbour seals (Phoca vitulina), 6 badgers (Meles meles), and 2 European pine marten (Martes martes).

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Other birds (main categories): 4618 Parus Major (great tit), 3822 Anas plathyrynchos (common mallard), 3160 Gallus gallus (red junglefowl), 1580 Limosa limosa (black tailed godwit).

Other fish (main categories): 5318 Pleuronectes platessa (European plaice), 4467 Anguilla Anguilla (European eel), 3571 Limanda limanda (common dab).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	205993	43.14%
Rats	91537	19.17%
Guinea-Pigs	5816	1.22%
Hamsters (Syrian)	1035	0.22%
Hamsters (Chinese)	12	0%
Mongolian gerbil		
Other Rodents	736	0.15%
Rabbits	9764	2.04%
Cats	200	0.04%
Dogs	909	0.19%
Ferrets	680	0.14%
Other carnivores	270	0.06%
Horses, donkeys and cross-breeds	173	0.04%
Pigs	9738	2.04%
Goats	259	0.05%
Sheep	558	0.12%
Cattle	3833	0.8%
Prosimians		
Marmoset and tamarins	41	0.01%
Cynomolgus monkey	42	0.01%
Rhesus monkey	234	0.05%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	3315	0.69%
Domestic fowl	55371	11.59%
Other birds	18322	3.84%
Reptiles	294	0.06%
Rana	9	0%
Xenopus	438	0.09%

Animal Species	Number of animals	Percentage
Other Amphibians	60	0.01%
Zebra fish	52024	10.89%
Other Fish	15887	3.33%
Cephalopods		
Total	**477550**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	363141	77.89%
Animals born in the EU but not at a registered breeder	94773	20.33%
Animals born in rest of Europe	44	0.01%
Animals born in rest of world	8263	1.77%
Total	**466221**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	189	98.95%
Animals born in rest of Europe		
Animals born in Asia	2	1.05%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**191**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	2	1.05%
Self-sustaining colony	189	98.95%
Total	**191**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	199245	41.72%
Translational and applied research	127385	26.67%
Regulatory use and Routine production	122247	25.6%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	873	0.18%
Preservation of species	3698	0.77%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	22074	4.62%
Forensic enquiries	361	0.08%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1667	0.35%
Total	**477550**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	94460	47.41%
Cardiovascular Blood and Lymphatic System	6868	3.45%

Basic Research	Number of uses	Percentage
Nervous System	18175	9.12%
Respiratory System	758	0.38%
Gastrointestinal System including Liver	3203	1.61%
Musculoskeletal System	692	0.35%
Immune System	16582	8.32%
Urogenital/Reproductive System	1199	0.6%
Sensory Organs (skin, eyes and ears)	1030	0.52%
Endocrine System/Metabolism	4351	2.18%
Multisystemic	4115	2.07%
Ethology / Animal Behaviour /Animal Biology	20617	10.35%
Other basic research	27195	13.65%
Total	**199245**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13920	10.93%
Human Infectious Disorders	22913	17.99%
Human Cardiovascular Disorders	5882	4.62%
Human Nervous and Mental Disorders	9692	7.61%
Human Respiratory Disorders	2410	1.89%
Human Gastrointestinal Disorders including Liver	2555	2.01%
Human Musculoskeletal Disorders	1587	1.25%
Human Immune Disorders	4179	3.28%
Human Urogenital/Reproductive Disorders	814	0.64%
Human Sensory Organ Disorders (skin, eyes and ears)	575	0.45%
Human Endocrine/Metabolism Disorders	2423	1.9%
Other Human Disorders	235	0.18%
Animal Diseases and Disorders	31368	24.62%
Animal Welfare	22221	17.44%
Diagnosis of diseases	1115	0.88%
Plant diseases	8	0.01%
Non-regulatory toxicology and ecotoxicology	5488	4.31%
Total	**127385**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	50082	40.97%
Other efficacy and tolerance testing	3235	2.65%
Toxicity and other safety testing including pharmacology	68753	56.24%
Routine production	177	0.14%
Total	**122247**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1948	3.89%
Pyrogenicity testing		
Batch potency testing	47934	95.71%
Other quality controls	200	0.4%
Total	**50082**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1886	2.74%
Skin irritation/corrosion	47	0.07%
Skin sensitisation	2378	3.46%
Eye irritation/corrosion	59	0.09%
Repeated dose toxicity	8739	12.71%
Carcinogenicity		
Neurotoxicity		
Other toxicity/safety testing		
Genotoxicity	106	0.15%
Reproductive toxicity	36568	53.19%
Developmental toxicity	9944	14.46%
Kinetics	1635	2.38%
Pharmaco-dynamics (incl safety pharmacology)	8	0.01%
Phototoxicity	4	0.01%
Ecotoxicity	4101	5.96%
Safety testing in food and feed area	2104	3.06%
Target animal safety	1174	1.71%
Total	**68753**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	1886	100%
Total	**1886**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3875	44.34%
29 - 90 days	4131	47.27%
> 90 days	733	8.39%
Total	**8739**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1368	33.36%
Chronic toxicity	2329	56.79%
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	404	9.85%
Other ecotoxicity		
Total	4101	100.00%

Routine production

Routine production	Number of uses	Percentage
Blood based products	6	3.39%
Monoclonal antibody by mouse ascites method		
Other product types	171	96.61%
Total	177	100.00%

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	30227	24.73%
Legislation on medicinal products for veterinary use and their residues	31915	26.11%
Medical devices legislation		
Industrial chemicals legislation	57024	46.65%
Plant protection product legislation	312	0.26%
Biocides legislation	92	0.08%
Food legislation including food contact material	447	0.37%
Feed legislation including legislation for the safety of target animals, workers and environment	2164	1.77%
Cosmetics legislation		
Other legislation	66	0.05%
Total	122247	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	119545	97.79%
Legislation satisfying national requirements only [within EU]	8	0.01%
Legislation satisfying Non-EU requirements only	2694	2.2%
Total	122247	100.00%

First uses and re-uses

Re-use	Number of uses	Percentage
No	466412	97.67%
Yes	11138	2.33%
Total	477550	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	31611	6.62%
Mild [up to and including]	310002	64.92%
Moderate	121739	25.49%
Severe	14198	2.97%
Total	477550	100.00%

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	466582	97.7%
Yes	10968	2.3%
Total	**477550**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	344185	72.07%
Genetically altered without a harmful phenotype	123939	25.95%
Genetically altered with a harmful phenotype	9426	1.97%
Total	**477550**	**100.00%**

Poland

Poland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The report is the first submitted under the new rules.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The report is the first submitted under the new rules.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The report is the first submitted under the new rules.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Propagation and awareness of the need for replacement, reduction and refinement (3R) is one of the primary aims Polish National Ethics Committee on Animal Experimentation and is governed by a legal act of the highest importance, the Act on Experiments on Animals of 15 January 2015, in accordance to the Directive 2010/63/EU on the protection of animals used for scientific purposes.
Propagation of list of alternative methods designed to replace some routine animal tests and reduction of number of animals in routine testing is accessible at the webpage of the Committee.
Application of alternative methods to replace animals from routine tests is one of the major criteria in assessment of animal study applications by the Local Ethics Committees in Poland. Description of replacement, reduction and refinement application is also an indispensable part of each application.
The Committee supports the 3R courses for scientists and caretakers, which are obligatory to receive any permission to perform or plan experiments. All these issues are also propagate during the meetings organized with the local committees and disseminate to the bodies on animal welfare, which operate in all breeders, suppliers and users. At the webpage of the Committee there are documents concerning 3R rules prepared by European Commission and the guides prepared by the Committee describing how to assess the invasiveness procedures and how to make them milder to animals. All these documents are publicly accessible.
In our opinion, it is too early to assess its impacts on statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In the 2015 report under the category "other animals" there are:

- Other carnivores (other Carnivora) are Meles meles, Mustela nivalis, Neovison vison, Nyctereutes procyonoides, Ursus arctos, Vulpes vulpes used in the purposes of Ethology /

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Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals. They represent 96,24 % of all carnivores.

- Other birds (other Aves) are Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Calidris alba, Calidris ferruginea, Calidris canutus, Canistes caerules, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Cisticola chubbi, Coturnix japonica, Columba livia, Cyanistes caeruleus, Dromaiinae, Emberiza hortulana, Falco peregrinus, Fulica atra, Gerygone flavolateralis, Hirundo rustica, Laniarus atroflavus, Larus canus, Meleagris gallopavo gallopavo var. Domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sternula albiforns, Sterna hirundo, Sylvia communis, Turdus philomelos, Taeniopygia guttata, , Turdus merula used in the purposes of Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, Higher education or training for the acquisition, maintenance or improvement of vocational skills. They represent 34,31% of all birds.

- Other fish (other Pisces) are Acipenser baeri, Acipenser guldenstaedtii, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Carassius carassius, Cobitis taenia, Coregonus lavaretus, Cyprinus carpio, Gasterosteus aculeatus, Leuciscus idus, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Platichthys flesus, Poecilia reticulata, Poecilia sphenops, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta, Salmonidae, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Tinca tinca used in the purposes of (Regulatory use/Toxicity and../Ecotoxicity) Acute toxicity, (Basic Research) Immune System, (Basic Research) Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, (Basic Research) Urogenital/Reproductive System, (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology, Higher education or training for the acquisition, maintenance or improvement of vocational skills, Preservation of species, (Basic Research) Multisystemic , (Trans/Appl Research) Animal Welfare. They represent 94,85 % of all fish.

- Other amphibians (other Amphibia) are Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus, Slalamandra salamandra, used in the purposes of Basic Research: Urogenital/Reproductive System and Ethology / Animal Behaviour /Animal Biology. They represent 36,7 % of all amphibians.

In Regulatory use / Routine production as „Other" are specified medicinal products and quality controls.

In Regulatory use as „Other efficacy and tolerance testing" are specified study of local tolerance and study of skin sensitization.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There are no such cases.

Poland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	88776	50.16%
Rats	36073	20.38%
Guinea-Pigs	5756	3.25%
Hamsters (Syrian)	22	0.01%
Hamsters (Chinese)		
Mongolian gerbil	178	0.1%
Other Rodents	8445	4.77%
Rabbits	1606	0.91%
Cats	8	0%
Dogs	24	0.01%
Ferrets		
Other carnivores	818	0.46%
Horses, donkeys and cross-breeds	232	0.13%
Pigs	1718	0.97%
Goats	8	0%
Sheep	566	0.32%
Cattle	1637	0.92%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1195	0.68%
Domestic fowl	11099	6.27%
Other birds	5798	3.28%
Reptiles	110	0.06%
Rana	224	0.13%
Xenopus	102	0.06%
Other Amphibians	189	0.11%
Zebra fish	639	0.36%
Other Fish	11757	6.64%
Cephalopods		
Total	**176980**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	145779	83.75%
Animals born in the EU but not at a registered breeder	27864	16.01%
Animals born in rest of Europe	21	0.01%
Animals born in rest of world	398	0.23%
Total	**174062**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	126089	71.24%
Translational and applied research	14826	8.38%
Regulatory use and Routine production	29475	16.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3126	1.77%
Preservation of species	664	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2688	1.52%
Forensic enquiries	100	0.06%
Maintenance of colonies of established genetically altered animals, not used in other procedures	12	0.01%
Total	**176980**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	9925	7.87%
Cardiovascular Blood and Lymphatic System	7537	5.98%
Nervous System	53294	42.27%
Respiratory System	236	0.19%
Gastrointestinal System including Liver	4076	3.23%
Musculoskeletal System	1107	0.88%
Immune System	6579	5.22%
Urogenital/Reproductive System	5662	4.49%
Sensory Organs (skin, eyes and ears)	495	0.39%
Endocrine System/Metabolism	3322	2.63%
Multisystemic	15835	12.56%
Ethology / Animal Behaviour /Animal Biology	6463	5.13%
Other basic research	11558	9.17%
Total	**126089**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2906	19.6%
Human Infectious Disorders	468	3.16%
Human Cardiovascular Disorders	207	1.4%
Human Nervous and Mental Disorders	2399	16.18%
Human Respiratory Disorders	80	0.54%
Human Gastrointestinal Disorders including Liver	244	1.65%
Human Musculoskeletal Disorders	164	1.11%
Human Immune Disorders	338	2.28%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	410	2.77%
Human Endocrine/Metabolism Disorders	96	0.65%
Other Human Disorders	429	2.89%
Animal Diseases and Disorders	1642	11.08%
Animal Welfare	2418	16.31%
Diagnosis of diseases	577	3.89%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	2448	16.51%
Total	**14826**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16708	56.69%
Other efficacy and tolerance testing	36	0.12%
Toxicity and other safety testing including pharmacology	11766	39.92%
Routine production	965	3.27%
Total	**29475**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4710	28.19%
Pyrogenicity testing	234	1.4%
Batch potency testing	10089	60.38%
Other quality controls	1675	10.03%
Total	**16708**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	5385	45.77%
Skin irritation/corrosion	259	2.2%
Skin sensitisation	1284	10.91%
Eye irritation/corrosion	50	0.42%
Repeated dose toxicity	183	1.56%
Carcinogenicity	140	1.19%
Developmental toxicity		
Genotoxicity		
Kinetics		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Reproductive toxicity	1425	12.11%
Neurotoxicity	142	1.21%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	164	1.39%
Ecotoxicity	2718	23.1%
Other toxicity/safety testing	16	0.14%
Total	**11766**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4525	84.03%
Other lethal methods		
Non lethal methods	860	15.97%
Total	**5385**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	183	100%
29 - 90 days		
> 90 days		
Total	**183**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2718	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**2718**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	383	39.69%
Monoclonal antibody by mouse ascites method		
Other product types	582	60.31%
Total	**965**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19733	66.95%
Legislation on medicinal products for veterinary use and their residues	3025	10.26%
Medical devices legislation	867	2.94%
Industrial chemicals legislation	2022	6.86%
Plant protection product legislation	3150	10.69%
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	12	0.04%

Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation	666	2.26%
Total	**29475**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	28709	97.4%
Legislation satisfying national requirements only [within EU]	607	2.06%
Legislation satisfying Non-EU requirements only	159	0.54%
Total	**29475**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	174062	98.35%
Yes	2918	1.65%
Total	**176980**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	16523	9.34%
Mild [up to and including]	67288	38.02%
Moderate	64396	36.39%
Severe	28773	16.26%
Total	**176980**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	176187	99.55%
Yes	793	0.45%
Total	**176980**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	166850	94.28%
Genetically altered without a harmful phenotype	6489	3.67%
Genetically altered with a harmful phenotype	3641	2.06%
Total	**176980**	**100.00%**

Poland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The 2016 report is only the second one made in accordance with the new rules. This makes it impossible to identify real trends in the use of animals for experiments. In addition, the drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. On the one hand, this has resulted in an increase in the number of animals used, due to rapidly completed 'old' experiments. On the other hand, some experiments which are not considered procedures under the new rules continue to take place (and be reported). The reports for 2015 could also contain errors resulting from a misunderstanding of the new rules and reporting rules. Users' awareness is increasing thanks to numerous training courses held in 2015-2016 and other forms of disseminating information, with the consequence that subsequent reports are correct and more consistent.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The observed differences in the number of animals used in each area, as reflected in the 2015 and 2016 reports, may be the consequence of the trends described above. In addition, they seem to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016, a clear decline is observed in the number of mice used in 'non-recovery' experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes. Certainty of the accuracy of the data reported was only achieved in the subsequent report for 2016.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website.
When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for

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authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged by law to set up monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users' reporting in this area on an annual basis.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the 'other' group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2016, the animal species included in the 'other' category were:

- 'Other' species of carnivore (other Carnivora), namely Mustela nivalis and Neovison vison. These are used in fundamental research relating to biology and species behaviour and translational research on animal welfare. They account for 18.25% of all carnivorous animal species used in research.
- 'Other' bird species (other Aves), namely Acrocephalus arundinaceus, Acrocephalus dumetorum, Acrocephalus palustris, Acrocephalus schoenobaenus, Acrocephalus scirpaceus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris ferruginea, Canistes caerules, Chlidonias hybrid, Columba livia, Coturnix japonica, Cyanistes caeruleus, Dromaiinae, Ficedula hypoleuca, Fringilla coelebs, Hippolais icterina, Hirundo rustica, Lanius collurio, Larus canus, Locustella fluviatilis, Locustella luscinioides, Locustella naevia, Meleagris gallopavo gallopavo var. domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sterna albifrons, Sterna hirundo, Sylvia borin, Sylvia communis, Sylvia curruca, Sylvia nisoria, Tetrao urogallus, Turdus merula and Turdus philomelos. These are mainly used in fundamental research relating to biology and species behaviour, tests of gastrointestinal systems, including liver and multisystemic tests, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 66.61% of all bird species used in research.
- 'Other' fish species (other Pisces), namely Acipenser baeri, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Barbus barbus, Carassius auratus, Carassius carassius, Carassius gibelio, Chondrostoma nasus, Clarias gariepinus, Cobitis taenia, Cobitis elongatoides, Cobitis hybrids, Coregonus albula, Coregonus lavaretus, Cyprinus carpio, Esox lucius, Gasterosteus aculeatus, Gymnocephalus cernua, Neogobius fluviatilis, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Poecilia reticulate, Platichthys flesus, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta m. trutta, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Squalius cephalus and Tinca tinca. These are mainly used in fundamental research relating to biology and species behaviour, tests of immune systems,

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reproductive systems and multisystemic tests, translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature, but also in some acute toxicity studies. They account for 97.16% of all fish species used in research.

- 'Other' amphibian species (other Amphibia), namely Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus and Slalamandra salamandra. These are used in fundamental research relating to biology and species behaviour and reproductive system tests, and translational research on animal diseases and disorders. They account for 97.32% of all amphibian species used in research.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees.

Poland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	89105	47.22%
Rats	32370	17.15%
Guinea-Pigs	6639	3.52%
Hamsters (Syrian)	212	0.11%
Hamsters (Chinese)		
Mongolian gerbil	88	0.05%
Other Rodents	1263	0.67%
Rabbits	998	0.53%
Cats	15	0.01%
Dogs	88	0.05%
Ferrets		
Other carnivores	23	0.01%
Horses, donkeys and cross-breeds	220	0.12%
Pigs	1068	0.57%
Goats	36	0.02%
Sheep	1143	0.61%
Cattle	492	0.26%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	578	0.31%
Domestic fowl	3612	1.91%

Animal Species	Number of animals	Percentage
Other birds	7207	3.82%
Reptiles	526	0.28%
Rana	20	0.01%
Xenopus		
Other Amphibians	727	0.39%
Zebra fish	1203	0.64%
Other Fish	41086	21.77%
Cephalopods		
Total	**188719**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	129825	69.26%
Animals born in the EU but not at a registered breeder	57519	30.69%
Animals born in rest of Europe		
Animals born in rest of world	104	0.06%
Total	**187448**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	142463	75.49%
Translational and applied research	17140	9.08%
Regulatory use and Routine production	26157	13.86%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	321	0.17%
Preservation of species	893	0.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1597	0.85%
Forensic enquiries	30	0.02%
Maintenance of colonies of established genetically altered animals, not used in other procedures	118	0.06%
Total	**188719**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	7378	5.18%
Cardiovascular Blood and Lymphatic System	5558	3.9%
Nervous System	52700	36.99%
Respiratory System	134	0.09%
Gastrointestinal System including Liver	5032	3.53%
Musculoskeletal System	843	0.59%
Immune System	6012	4.22%
Urogenital/Reproductive System	3597	2.52%
Sensory Organs (skin, eyes and ears)	193	0.14%
Endocrine System/Metabolism	7697	5.4%
Multisystemic	7232	5.08%
Ethology / Animal Behaviour /Animal Biology	40710	28.58%
Other basic research	5377	3.77%
Total	**142463**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	5061	29.53%
Human Infectious Disorders	1207	7.04%
Human Cardiovascular Disorders	505	2.95%
Human Nervous and Mental Disorders	2261	13.19%
Human Respiratory Disorders	10	0.06%
Human Gastrointestinal Disorders including Liver	160	0.93%
Human Musculoskeletal Disorders	70	0.41%
Human Immune Disorders	115	0.67%
Human Urogenital/Reproductive Disorders	31	0.18%
Human Sensory Organ Disorders (skin, eyes and ears)	178	1.04%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	30	0.18%
Animal Diseases and Disorders	398	2.32%
Animal Welfare	3287	19.18%
Diagnosis of diseases	3325	19.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	502	2.93%
Total	**17140**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	18221	69.66%
Other efficacy and tolerance testing	363	1.39%
Toxicity and other safety testing including pharmacology	7261	27.76%
Routine production	312	1.19%
Total	**26157**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3876	21.27%
Pyrogenicity testing	202	1.11%
Batch potency testing	13177	72.32%
Other quality controls	966	5.3%
Total	**18221**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1721	23.7%
Skin irritation/corrosion	195	2.69%
Skin sensitisation	1571	21.64%
Eye irritation/corrosion	50	0.69%
Repeated dose toxicity	120	1.65%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Developmental toxicity	164	2.26%
Kinetics	40	0.55%
Pharmaco-dynamics (incl safety pharmacology)	38	0.52%
Ecotoxicity	3338	45.97%
Other toxicity/safety testing	24	0.33%
Total	**7261**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	371	21.56%
Other lethal methods		
Non lethal methods	1350	78.44%
Total	**1721**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	120	100%
> 90 days		
Total	**120**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3123	93.56%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity	215	6.44%
Total	**3338**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	312	100%
Total	**312**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	18178	69.5%
Legislation on medicinal products for veterinary use and their residues	2651	10.13%
Medical devices legislation	310	1.19%
Industrial chemicals legislation	265	1.01%
Plant protection product legislation	4597	17.57%
Biocides legislation	122	0.47%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	34	0.13%
Cosmetics legislation		
Other legislation		
Total	**26157**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	25604	97.89%
Legislation satisfying national requirements only [within EU]	487	1.86%
Legislation satisfying Non-EU requirements only	66	0.25%
Total	**26157**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	187448	99.33%
Yes	1271	0.67%
Total	**188719**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	7963	4.22%
Mild [up to and including]	87965	46.61%
Moderate	47593	25.22%
Severe	45198	23.95%
Total	**188719**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	188426	99.84%
Yes	293	0.16%
Total	**188719**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	180608	95.7%
Genetically altered without a harmful phenotype	5577	2.96%
Genetically altered with a harmful phenotype	2534	1.34%
Total	**188719**	**100.00%**

Poland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. This is the case because some experiments which are not considered procedures under the new rules continue to take place and be reported. Despite this, the number of animals used decreased markedly in 2017. Thanks to the training provided, a better understanding can be seen of the definition of a procedure and the reporting rules, resulting in the more precise identification of animal numbers. One example is that the number of fish other than zebrafish used in 2017 fell significantly.
A steady and significant decrease was also noted in the number of animals reused.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The observed variation in the number of animals used of certain species seems to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties. One good example is the appearance in 2017 of a group of 17 monkeys from Ceboidea and Cercopitecoidea species used in connection with a single experiment on their behaviour in zoo conditions. It is also likely that single experiments on dogs and horses ended in 2017 for this same reason, and the number of dogs and horses used therefore decreased significantly.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2017, a decrease is observed in the number of rats used in 'non-recovery' experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website, and organises training for LECs once per year.

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When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged to set up by law monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users' reporting in this area on an annual basis.
In 2017 the NEC also took the initiative to organise a cooperation network between units and bodies involved in the implementation of alternative methods.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the 'other' group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2017, the animal species included in the 'other' category were:

- 'Other' species of carnivore (other Carnivora), namely Mustela nivalis and Mustela lutreola. These are used mainly in fundamental research relating to biology and species behaviour. They account for 92.86% of all carnivorous animal species used in research.

- 'Other' bird species (other Aves), namely Acrocephalus paludicola, Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris alpine, Calidris canutus, Calidris falcinellus, Calidris ferruginea, Calidris minuta, Calidris pugnax, Charadrius dubius, Charadrius hiaticula, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Columba livia, Coturnix japonica, Cyanistes caeruleus, Cygnus olor, Ficedula hypoleuca, Fringilla coelebs, Fulica atra, Gallinago gallinago, Haliaeetus albicilla, Hirundo rustica, Meleagris gallopavo, Motacilla alba, Motacilla flava, Lanius collurio, Larus canus, Parus major, Passer domesticus, Passer montanus, Phasianus colchicus, Serinus canaria, Sterna hirundo, Taeniopygia guttata, Tetrao urogallus, Tringa erythropus, Tringa glareola, Tringa nebularia, Tringa ochropus, Tringa totanus, Turdus merula and Vanellus vanellus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 56.44% of all bird species used in research.

- 'Other' fish species (other Pisces), namely Acipenser baeri, Acipenser gueldenstadtii, Acipenser ruthenus, Babka gymnotrachelus, Coregonus lavaretus, Cottus gobio, Cyprinus carpio, Eudontomyzon mariae, Gobio gobio, Lampetra planeri, Neogobius fluviatilis, Oncorhynchus mykiss, Perca fluviatilis, Poecilia reticulata, Proterorhinus semilunaris, Rutilus rutilus, Sander

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lucioperca and Scardinius erythrophthalmus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders, and also in some acute toxicity studies. They account for 84.99% of all fish species used in research.

- 'Other' amphibian species (other Amphibia), namely Bufotes viridis in the adult and larval stages, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus. These are mainly used in fundamental research relating to reproductive and metabolism studies, and translational research on animal diseases and disorders, as well as population genetics and phylogeography. They account for 95.8% of all amphibian species used in research.

- 'Other' monkey species, namely 17 monkeys from Ceboidea and Cercopithecoidea species used in connection with a single experiment on their behaviour in zoo conditions.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees.

Poland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	89880	57.53%
Rats	28982	18.55%
Guinea-Pigs	5235	3.35%
Hamsters (Syrian)	150	0.1%
Hamsters (Chinese)		
Mongolian gerbil	120	0.08%
Other Rodents	8108	5.19%
Rabbits	820	0.52%
Cats		
Dogs	10	0.01%
Ferrets		
Other carnivores	130	0.08%
Horses, donkeys and cross-breeds	73	0.05%
Pigs	1517	0.97%
Goats	24	0.02%
Sheep	1301	0.83%
Cattle	413	0.26%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		

Animal Species	Number of animals	Percentage
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	14	0.01%
Other species of New World Monkeys (Ceboidea)	3	0%
Apes		
Other Mammals	700	0.45%
Domestic fowl	5067	3.24%
Other birds	6566	4.2%
Reptiles	314	0.2%
Rana	20	0.01%
Xenopus		
Other Amphibians	456	0.29%
Zebra fish	950	0.61%
Other Fish	5381	3.44%
Cephalopods		
Total	**156234**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	135878	87.43%
Animals born in the EU but not at a registered breeder	18496	11.9%
Animals born in rest of Europe	361	0.23%
Animals born in rest of world	674	0.43%
Total	**155409**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	17	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**17**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	17	100%
Self-sustaining colony		
Total	**17**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	113639	72.74%
Translational and applied research	16135	10.33%
Regulatory use and Routine production	24762	15.85%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	43	0.03%
Preservation of species	25	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational	1129	0.72%

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Purpose Category	Number of uses	Percentage
skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	501	0.32%
Total	**156234**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	8173	7.19%
Cardiovascular Blood and Lymphatic System	6727	5.92%
Nervous System	52548	46.24%
Respiratory System	784	0.69%
Gastrointestinal System including Liver	3070	2.7%
Musculoskeletal System	673	0.59%
Immune System	7755	6.82%
Urogenital/Reproductive System	2929	2.58%
Sensory Organs (skin, eyes and ears)	225	0.2%
Endocrine System/Metabolism	5992	5.27%
Multisystemic	5956	5.24%
Ethology / Animal Behaviour /Animal Biology	10531	9.27%
Other basic research	8276	7.28%
Total	**113639**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3081	19.1%
Human Infectious Disorders	366	2.27%
Human Cardiovascular Disorders	815	5.05%
Human Nervous and Mental Disorders	1176	7.29%
Human Respiratory Disorders	943	5.84%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	64	0.4%
Human Immune Disorders	120	0.74%
Human Urogenital/Reproductive Disorders	44	0.27%
Human Sensory Organ Disorders (skin, eyes and ears)	20	0.12%
Human Endocrine/Metabolism Disorders	316	1.96%
Other Human Disorders	35	0.22%
Animal Diseases and Disorders	678	4.2%
Animal Welfare	3852	23.87%
Diagnosis of diseases	3088	19.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1537	9.53%
Total	**16135**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16493	66.61%
Other efficacy and tolerance testing	195	0.79%
Toxicity and other safety testing including pharmacology	7784	31.44%
Routine production	290	1.17%
Total	**24762**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3982	24.14%
Pyrogenicity testing	236	1.43%
Batch potency testing	11482	69.62%
Other quality controls	793	4.81%
Total	**16493**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1050	13.49%
Skin irritation/corrosion	139	1.79%
Skin sensitisation	707	9.08%
Eye irritation/corrosion	9	0.12%
Repeated dose toxicity	807	10.37%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Reproductive toxicity	669	8.59%
Developmental toxicity	1694	21.76%
Kinetics	30	0.39%
Ecotoxicity	2364	30.37%
Other toxicity/safety testing	315	4.05%
Total	**7784**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	180	17.14%
Other lethal methods		
Non lethal methods	870	82.86%
Total	**1050**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	387	47.96%
29 - 90 days	420	52.04%
> 90 days		
Total	**807**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2364	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total	2364	100.00%

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	290	100%
Total	290	100.00%

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16523	66.73%
Legislation on medicinal products for veterinary use and their residues	2251	9.09%
Medical devices legislation	916	3.7%
Industrial chemicals legislation	2652	10.71%
Plant protection product legislation	2276	9.19%
Biocides legislation	24	0.1%
Food legislation including food contact material	120	0.48%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	24762	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	24221	97.82%
Legislation satisfying national requirements only [within EU]	514	2.08%
Legislation satisfying Non-EU requirements only	27	0.11%
Total	24762	100.00%

First uses and re-uses

Re-use	Number of uses	Percentage
No	155426	99.48%
Yes	808	0.52%
Total	156234	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	4791	3.07%
Mild [up to and including]	50260	32.17%
Moderate	50013	32.01%
Severe	51170	32.75%
Total	156234	100.00%

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	155876	99.77%
Yes	358	0.23%
Total	**156234**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	146889	94.02%
Genetically altered without a harmful phenotype	5905	3.78%
Genetically altered with a harmful phenotype	3440	2.2%
Total	**156234**	**100.00%**

Portugal

Portugal: Narrative 2015 – no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	13175	63.88%
Rats	2399	11.63%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats	46	0.22%
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	250	1.21%
Other Fish	4752	23.04%
Cephalopods	1	0%
Total	**20623**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	16287	85.59%
Animals born in the EU but not at a registered breeder	1896	9.96%
Animals born in rest of Europe		
Animals born in rest of world	847	4.45%
Total	**19030**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	11853	57.47%
Translational and applied research	7288	35.34%
Regulatory use and Routine production	1382	6.7%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3	0.01%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	97	0.47%
Total	**20623**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	266	2.24%
Cardiovascular Blood and Lymphatic System	576	4.86%
Nervous System	1859	15.68%
Respiratory System		
Gastrointestinal System including Liver	230	1.94%
Musculoskeletal System	330	2.78%
Immune System	5965	50.32%
Urogenital/Reproductive System	19	0.16%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	100	0.84%
Endocrine System/Metabolism		
Multisystemic	8	0.07%
Ethology / Animal Behaviour /Animal Biology	347	2.93%
Other basic research	2153	18.16%
Total	**11853**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	10	0.14%
Human Infectious Disorders	1019	13.98%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	2002	27.47%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	88	1.21%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	350	4.8%
Human Endocrine/Metabolism Disorders	89	1.22%
Other Human Disorders	230	3.16%
Animal Diseases and Disorders		
Animal Welfare	3500	48.02%
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**7288**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	1382	100%
Total	**1382**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	200	14.47%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	750	54.27%
Safety testing in food and feed area	432	31.26%
Total	**1382**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	200	100%
Total	**200**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity	750	100%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**750**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation	750	54.27%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	632	45.73%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**1382**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]	1382	100%
Legislation satisfying Non-EU requirements only		
Total	**1382**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	19030	92.28%
Yes	1593	7.72%
Total	**20623**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	213	1.03%
Mild [up to and including]	11207	54.34%
Moderate	6832	33.13%
Severe	2371	11.5%
Total	**20623**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	20573	99.76%
Yes	50	0.24%
Total	**20623**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	15339	74.38%
Genetically altered without a harmful phenotype	2116	10.26%
Genetically altered with a harmful phenotype	3168	15.36%
Total	**20623**	**100.00%**

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Portugal: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	28892	91.11%
Rats	2251	7.1%
Guinea-Pigs	4	0.01%
Hamsters (Syrian)	6	0.02%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	39	0.12%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	451	1.42%
Other Fish	69	0.22%
Cephalopods		
Total	**31712**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	30784	97.64%
Animals born in the EU but not at a registered breeder	623	1.98%
Animals born in rest of Europe		
Animals born in rest of world	120	0.38%
Total	**31527**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	14894	46.97%
Translational and applied research	9548	30.11%
Regulatory use and Routine production	185	0.58%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	37	0.12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	102	0.32%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	6946	21.9%
Total	**31712**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	680	4.57%
Cardiovascular Blood and Lymphatic System	159	1.07%
Nervous System	2982	20.02%
Respiratory System	95	0.64%
Gastrointestinal System including Liver	307	2.06%
Musculoskeletal System	240	1.61%
Immune System	7543	50.64%
Urogenital/Reproductive System	90	0.6%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	562	3.77%
Multisystemic	92	0.62%
Ethology / Animal Behaviour /Animal Biology	1074	7.21%
Other basic research	1070	7.18%
Total	**14894**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	505	5.29%
Human Infectious Disorders	5782	60.56%
Human Cardiovascular Disorders	300	3.14%
Human Nervous and Mental Disorders	477	5%
Human Respiratory Disorders	82	0.86%
Human Gastrointestinal Disorders including Liver	161	1.69%
Human Musculoskeletal Disorders	72	0.75%
Human Immune Disorders	784	8.21%
Human Urogenital/Reproductive Disorders	10	0.1%
Human Sensory Organ Disorders (skin, eyes and ears)	221	2.31%
Human Endocrine/Metabolism Disorders	151	1.58%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare	99	1.04%
Diagnosis of diseases	904	9.47%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**9548**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	185	100%
Total	**185**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	185	100%
Total	**185**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	185	100%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**185**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	185	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**185**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	31527	99.42%
Yes	185	0.58%
Total	**31712**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	369	1.16%
Mild [up to and including]	14043	44.28%
Moderate	9487	29.92%
Severe	7813	24.64%
Total	**31712**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	31438	99.14%
Yes	274	0.86%
Total	**31712**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19723	62.19%
Genetically altered without a harmful phenotype	9795	30.89%
Genetically altered with a harmful phenotype	2194	6.92%
Total	**31712**	**100.00%**

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Portugal: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	46107	88.04%
Rats	3135	5.99%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	140	0.27%
Rabbits	36	0.07%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	155	0.3%
Goats		
Sheep	30	0.06%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	32	0.06%
Domestic fowl	120	0.23%
Other birds	56	0.11%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	1280	2.44%
Other Fish	829	1.58%
Cephalopods	450	0.86%
Total	**52370**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	49301	96.09%
Animals born in the EU but not at a registered breeder	1678	3.27%
Animals born in rest of Europe		
Animals born in rest of world	329	0.64%
Total	**51308**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	36663	70.01%
Translational and applied research	5202	9.93%
Regulatory use and Routine production	298	0.57%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	392	0.75%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	9815	18.74%
Total	**52370**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3230	8.81%
Cardiovascular Blood and Lymphatic System	1205	3.29%
Nervous System	4952	13.51%
Respiratory System	83	0.23%
Gastrointestinal System including Liver	683	1.86%
Musculoskeletal System	173	0.47%
Immune System	20968	57.19%
Urogenital/Reproductive System	36	0.1%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	1437	3.92%
Multisystemic	153	0.42%
Ethology / Animal Behaviour /Animal Biology	1277	3.48%
Other basic research	2466	6.73%
Total	**36663**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	162	3.11%
Human Infectious Disorders	403	7.75%
Human Cardiovascular Disorders	68	1.31%
Human Nervous and Mental Disorders	2058	39.56%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	102	1.96%
Human Musculoskeletal Disorders	127	2.44%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	233	4.48%
Human Endocrine/Metabolism Disorders	36	0.69%
Other Human Disorders		
Animal Diseases and Disorders	3	0.06%
Animal Welfare	604	11.61%
Diagnosis of diseases	914	17.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	492	9.46%
Total	**5202**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	298	100%
Total	**298**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	126	42.28%
Safety testing in food and feed area	172	57.72%
Total	**298**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	126	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**126**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues	126	42.28%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	172	57.72%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**298**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	298	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**298**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	51308	97.97%
Yes	1062	2.03%
Total	**52370**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2017	3.85%
Mild [up to and including]	27397	52.31%
Moderate	12540	23.95%
Severe	10416	19.89%
Total	**52370**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	51836	98.98%
Yes	534	1.02%
Total	**52370**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	30557	58.35%
Genetically altered without a harmful phenotype	20466	39.08%
Genetically altered with a harmful phenotype	1347	2.57%
Total	**52370**	**100.00%**

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Romania

Romania: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Compared to the last report, the one from 2014, there was a decrease in the number of total animals used for scientific purposes, with 0,53%, from 19735 in 2014 to 19632 in 2015.

To the purpose of use has been a decrease in the use of animals for higher education or training and an increased use of animals in research.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The difference between 2014 and 2015 is minim, given the fact that is less de 1%.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Some changes were observed in severity trend. 26% severe in 2015 vs 0.05% in 2014. 0.59% non-recovery in 2015 vs 17.31% in 2014. 39.27% mild in 2015 vs 62.344 in 2014. 34.14% moderate vs 20.30% in 2014.

The reason is that now, in this year, our colleague learned to done a severity assessment.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The animals use under “other" categories are 0.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Such a kind of analysis was not made yet.

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Romania: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	10876	55.4%
Rats	6322	32.2%
Guinea-Pigs	1108	5.64%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	380	1.94%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs	10	0.05%
Goats		
Sheep	167	0.85%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	565	2.88%
Other birds		
Reptiles		
Rana	200	1.02%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**19632**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	18162	94.22%
Animals born in the EU but not at a registered breeder	1115	5.78%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**19277**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	7752	39.49%
Translational and applied research	3240	16.5%
Regulatory use and Routine production	7498	38.19%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1142	5.82%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**19632**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3499	45.14%
Cardiovascular Blood and Lymphatic System	800	10.32%
Nervous System	289	3.73%
Respiratory System	200	2.58%
Gastrointestinal System including Liver	20	0.26%
Musculoskeletal System	188	2.43%
Immune System	162	2.09%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic	84	1.08%
Ethology / Animal Behaviour /Animal Biology	50	0.64%
Other basic research	2460	31.73%
Total	**7752**	**100.00%**

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Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	32	0.99%
Human Infectious Disorders	20	0.62%
Human Cardiovascular Disorders	110	3.4%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	85	2.62%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	69	2.13%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	30	0.93%
Animal Diseases and Disorders	102	3.15%
Animal Welfare	66	2.04%
Diagnosis of diseases	2726	84.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**3240**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	6184	82.48%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	927	12.36%
Routine production	387	5.16%
Total	**7498**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	5456	88.23%
Pyrogenicity testing	58	0.94%
Batch potency testing	670	10.83%
Other quality controls		
Total	**6184**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	187	20.17%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		

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Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	740	79.83%
Total	**927**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	187	100%
Total	**187**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	740	100%
29 - 90 days		
> 90 days		
Total	**740**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	321	82.95%
Monoclonal antibody by mouse ascites method		
Other product types	66	17.05%
Total	**387**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	6404	85.41%
Legislation on medicinal products for veterinary use and their residues	731	9.75%
Medical devices legislation	363	4.84%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**7498**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7438	99.2%
Legislation satisfying national requirements only [within EU]	2	0.03%
Legislation satisfying Non-EU requirements only	58	0.77%
Total	**7498**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	19277	98.19%
Yes	355	1.81%
Total	**19632**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	88	0.45%
Mild [up to and including]	9958	50.72%
Moderate	5550	28.27%
Severe	4036	20.56%
Total	**19632**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	19632	100%
Yes		
Total	**19632**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19032	96.94%
Genetically altered without a harmful phenotype	600	3.06%
Genetically altered with a harmful phenotype		
Total	**19632**	**100.00%**

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Romania: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Compared to the last report, the one from 2015, there was a decrease in the number of total animals used for scientific purposes (around 20.000 in 2015 and around 13.000 in 2016).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

To the purpose of use has been a decrease in the use of animals for higher education or training and diagnosis of the disease and an increased use of animals in research.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Some changes were observed in severity trend. The main category of severity was moderate followed by mild and severe. It have been reduced non - recovery category.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The animals use under “other" categories are not in a significant proportion.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Such a kind of analysis was not made yet.

Romania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	9079	64.08%
Rats	2685	18.95%
Guinea-Pigs	1076	7.59%
Hamsters (Syrian)	146	1.03%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	222	1.57%

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Animal Species	Number of animals	Percentage
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs		
Goats		
Sheep	211	1.49%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	555	3.92%
Other birds		
Reptiles		
Rana	190	1.34%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**14168**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12592	90.95%
Animals born in the EU but not at a registered breeder	1253	9.05%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**13845**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	4011	28.31%
Translational and applied research	3183	22.47%
Regulatory use and Routine production	5402	38.13%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1572	11.1%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**14168**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	935	23.31%
Cardiovascular Blood and Lymphatic System	485	12.09%
Nervous System	190	4.74%
Respiratory System		
Gastrointestinal System including Liver	261	6.51%
Musculoskeletal System	92	2.29%
Immune System	334	8.33%
Urogenital/Reproductive System	170	4.24%
Sensory Organs (skin, eyes and ears)	120	2.99%
Endocrine System/Metabolism	70	1.75%
Multisystemic	884	22.04%
Ethology / Animal Behaviour /Animal Biology	200	4.99%
Other basic research	270	6.73%
Total	**4011**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	15	0.47%
Human Infectious Disorders	4	0.13%
Human Cardiovascular Disorders	86	2.7%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		

Translational and applied research	Number of uses	Percentage
Other Human Disorders		
Animal Diseases and Disorders	277	8.7%
Animal Welfare		
Diagnosis of diseases	2742	86.15%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	59	1.85%
Total	**3183**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4913	90.95%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	171	3.17%
Routine production	318	5.89%
Total	**5402**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4260	86.71%
Pyrogenicity testing	27	0.55%
Batch potency testing	584	11.89%
Other quality controls	42	0.85%
Total	**4913**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	74	43.27%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	97	56.73%
Total	**171**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	74	100%
Total	**74**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	303	95.28%
Monoclonal antibody by mouse ascites method		
Other product types	15	4.72%
Total	**318**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3992	73.9%
Legislation on medicinal products for veterinary use and their residues	1096	20.29%
Medical devices legislation	314	5.81%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**5402**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	5364	99.3%
Legislation satisfying national requirements only [within EU]	11	0.2%
Legislation satisfying Non-EU requirements only	27	0.5%
Total	**5402**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	13845	97.72%
Yes	323	2.28%
Total	**14168**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	169	1.19%
Mild [up to and including]	7693	54.3%
Moderate	5498	38.81%
Severe	808	5.7%
Total	**14168**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	14168	100%
Yes		
Total	**14168**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	13885	98%
Genetically altered without a harmful phenotype	283	2%
Genetically altered with a harmful phenotype		
Total	**14168**	**100.00%**

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Romania: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Since the previous reporting year, there was a slight increase in the number of total animals used for scientific purposes, from 14168 in 2016 to 14642 in 2017.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a significant decrease in the diagnosis of diseases within the translational and applied research due to the reduced number of samples received.

There was a decrease in regulatory use and routine production, with a significant drop in blood based products and batch safety testing and an increase in batch potency testing. The latter occurred due to an increase in the vaccines production

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There were some variations in terms of severity, namely a decrease in mild and an increase in non-recovery, according to those who evaluated the projects.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There was a joint effort from the competent authority and the scientific organizations to promote the principle of replacement, reduction and refinement through briefings and workshops.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No significant proportion of animal use was reported under “other" categories.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were not cases where “severe” classification was exceeded.

Romania: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	7975	54.47%
Rats	4367	29.83%
Guinea-Pigs	792	5.41%
Hamsters (Syrian)	150	1.02%
Hamsters (Chinese)		

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Animal Species	Number of animals	Percentage
Mongolian gerbil		
Other Rodents		
Rabbits	504	3.44%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs	58	0.4%
Goats		
Sheep	209	1.43%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	330	2.25%
Other birds	23	0.16%
Reptiles		
Rana	230	1.57%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**14642**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12356	86.54%
Animals born in the EU but not at a registered breeder	1922	13.46%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**14278**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	5381	36.75%
Translational and applied research	5500	37.56%
Regulatory use and Routine production	2522	17.22%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1239	8.46%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**14642**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1525	28.34%
Cardiovascular Blood and Lymphatic System	539	10.02%
Nervous System	634	11.78%
Respiratory System		
Gastrointestinal System including Liver	165	3.07%
Musculoskeletal System	339	6.3%
Immune System	1349	25.07%
Urogenital/Reproductive System	70	1.3%
Sensory Organs (skin, eyes and ears)	10	0.19%
Endocrine System/Metabolism	318	5.91%
Multisystemic	342	6.36%
Ethology / Animal Behaviour /Animal Biology	90	1.67%
Other basic research		
Total	**5381**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	114	2.07%
Human Cardiovascular Disorders	211	3.84%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	286	5.2%
Human Musculoskeletal Disorders	260	4.73%
Human Immune Disorders	275	5%

Translational and applied research	Number of uses	Percentage
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	121	2.2%
Human Endocrine/Metabolism Disorders	690	12.55%
Other Human Disorders		
Animal Diseases and Disorders	74	1.35%
Animal Welfare		
Diagnosis of diseases	3040	55.27%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	429	7.8%
Total	**5500**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1789	70.94%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	106	4.2%
Routine production	627	24.86%
Total	**2522**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	721	40.3%
Pyrogenicity testing	234	13.08%
Batch potency testing	753	42.09%
Other quality controls	81	4.53%
Total	**1789**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	20	18.87%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	86	81.13%
Total	**106**	**100.00%**

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Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	20	100%
Total	**20**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	86	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**86**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	587	93.62%
Monoclonal antibody by mouse ascites method		
Other product types	40	6.38%
Total	**627**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1078	42.74%
Legislation on medicinal products for veterinary use and their residues	1253	49.68%
Medical devices legislation	170	6.74%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	20	0.79%
Feed legislation including legislation for the safety of target animals, workers and environment	1	0.04%
Cosmetics legislation		
Other legislation		
Total	**2522**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2138	84.77%
Legislation satisfying national requirements only [within EU]	2	0.08%
Legislation satisfying Non-EU requirements only	382	15.15%
Total	**2522**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	14278	97.51%
Yes	364	2.49%
Total	**14642**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2110	14.41%
Mild [up to and including]	5061	34.56%
Moderate	6094	41.62%
Severe	1377	9.4%
Total	**14642**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	14642	100%
Yes		
Total	**14642**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	14289	97.59%
Genetically altered without a harmful phenotype	353	2.41%
Genetically altered with a harmful phenotype		
Total	**14642**	**100.00%**

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Slovakia

Slovakia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

New information on keeping GM (genetically modified) animal lines appeared in the Report from year 2015. In SK the new GM lines were not established, just were kept on the basis of approved Project.

In comparison to the previous year, 3213 less animals were used in the projects. It was caused also by the fact, that more of the approved establishments did not perform any projects in 2015. Some of the establishments informed in advance about the closure of their establishment, because they were not able to assure the compliance with the requirements for placing and treatment of the animals, appointed by the Directive.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Red numbers appeared in the column "other birds" of the Report, in particular in Zebra finch (Taeniopygia guttata) species, with the information on consumption of used animals of 13,95 % , which compared to the previous year, is more. It concerns one approved project for one applicant, approved for performance from15.05.2014 to 31.12.2017. Each year, the applicant consumed 36 birds on the average. It is allowed to use 80 male and 15 female animals within this approved project. By the time of duration of the project, 72 animals were already used. In comparison to the previous year, we did not record significant increase in use of the animals of this category in the project. The same number of animals were used in 2015 as in previous year 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

During year 2015, any significant changes in evaluation of cruelty did not appear in the projects, comparing to the year 2014.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Observance of 3R principles is established in our legislation, it is required to observe 3R principles in performance of the projects and breeding and treating of the animals. Great attention is given to 3R principles in trainings of the assigned persons, stated in Article 23 of the Directive.

5. Further breakdown on the use of "other"categories if a significant proportion of animal use is reported under this category.

In SK any other more significant animal categories are used, just those already stated in the Report.

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6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In SK, there is an Act (No.: 71/67 Coll. on Administrative Order), establishing that the issued decisions are obligatory for the applicant. Any kind of arbitrary change against the project is illegal. This defect, according to the its importance, can be considered as an administrative offence and a penalty can be imposed for it. Each project is classified according to the level of severity, due to the Annex VIII of the Directive. The level of severity of the procedures is stated in the Decision for authorisation of the projects. In SK any situation of arbitrary change of the level of severity towards it increase, cannot appear. It is not possible to use in the projects a different number of animals as those approved, without permission. Within annual reports, CA would see the changes of the levels of severity and the numbers of used animals on the contrary to the Decisions for authorisation of the projects, issued by CA. There is also feed-back in performance of the controls in the approved establishments.

Slovakia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6046	44.66%
Rats	5841	43.15%
Guinea-Pigs	1026	7.58%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	33	0.24%
Other Rodents		
Rabbits	228	1.68%
Cats	29	0.21%
Dogs	34	0.25%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	16	0.12%
Goats		
Sheep	26	0.19%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	222	1.64%

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Animal Species	Number of animals	Percentage
Other birds	36	0.27%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	13537	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	13537	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	13537	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	9870	72.91%
Translational and applied research	788	5.82%
Regulatory use and Routine production	2048	15.13%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8	0.06%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	823	6.08%
Total	13537	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	796	8.06%
Cardiovascular Blood and Lymphatic System	1371	13.89%
Nervous System	2192	22.21%
Respiratory System	992	10.05%
Gastrointestinal System including Liver	194	1.97%
Musculoskeletal System	106	1.07%
Immune System	421	4.27%
Urogenital/Reproductive System	2596	26.3%
Sensory Organs (skin, eyes and ears)	40	0.41%
Endocrine System/Metabolism	496	5.03%
Multisystemic	138	1.4%
Ethology / Animal Behaviour /Animal Biology	11	0.11%
Other basic research	517	5.24%
Total	**9870**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	134	17.01%
Human Infectious Disorders		
Human Cardiovascular Disorders	79	10.03%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	314	39.85%
Human Urogenital/Reproductive Disorders	80	10.15%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders	75	9.52%
Animal Diseases and Disorders	62	7.87%
Animal Welfare		
Diagnosis of diseases	44	5.58%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**788**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1462	71.39%
Other efficacy and tolerance testing	6	0.29%
Toxicity and other safety testing including pharmacology	580	28.32%
Routine production		
Total	**2048**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1262	86.32%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	200	13.68%
Total	**1462**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	253	43.62%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	35	6.03%
Repeated dose toxicity	292	50.34%
Total	**580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	253	100%
Other lethal methods		
Non lethal methods		
Total	**253**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	90	30.82%
> 90 days	202	69.18%
Total	**292**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1385	67.63%
Legislation on medicinal products for veterinary use and their residues	126	6.15%
Medical devices legislation	90	4.39%
Industrial chemicals legislation	245	11.96%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	202	9.86%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**2048**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2048	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2048**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	13537	100%
Yes		
Total	**13537**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1402	10.36%
Mild [up to and including]	8226	60.77%
Moderate	3639	26.88%
Severe	270	1.99%
Total	**13537**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	13537	100%
Yes		
Total	**13537**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	12679	93.66%
Genetically altered without a harmful phenotype	99	0.73%
Genetically altered with a harmful phenotype	759	5.61%
Total	**13537**	**100.00%**

Slovakia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, in SK 5% less animals were used in the projects than in 2015. From the total number of used animals the most were used rats (46, 6%). There were 40, 9% of mice, 7,4% of guinea-pigs, 2,8% of rabbits, 2% of poultry used. As many as 96% of rodentials were used in the scientific programs. The rest was poultry. On 31 December 2016, the transition period for implementation of the requirements established in Annex III of the Directive 2010/63/EU finished.
Since 2013, in SK re-accreditation of all approved establishments of the users, breeders and suppliers, according to new legislative requirements, was carried out. In 2016, 4 (four) establishments of the users asked the Competent Authority for their withdrawal and discard from the list of approved establishments of the users, for the reason of technical and economical demandingness. 5 (five) users asked for withdrawal of the approval of their establishment for the reason of change of the legal person and the change of address in order to merge into one legal subject. In SK, general reconstruction of several establishments for placement of animals used in the procedures or kept for the reason of their use in the procedures, was carried out. Therefore, the total number of used procedures and subsequently the number of used animals has decreased. In comparison to 2015, the number of approved establishments has changed. In 2015, 54 establishments overall were approved and in 2016, only 40 establishments were approved. Therefore, only 79 projects were approved in 2016 in comparison to 2015, when SVFA SR as the competent authority has issued 102 decisions on the approval of the projects. The most common use of the animals was the basic research (71,3%), subsequently the use in regulated projects with common production (23,4%), then (3,1%) was used in keeping of GMO breeding colonies, and (2,2%) in translation/applied research. In frame of the basic research, mainly nervous system (30%), reproductive system (16%) and immunity system (14%) were declared as the common research areas. 99,67% of used animals were kept/breeded within EU. None of the animals were reused again. 93% of the used animals were without GM and 7% of all used animals were GM.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In comparison to 2015, the changes in % are as follows: the number of used mice has decreased by 13% and quinea-pigs by 7%. Increase of the number of used rats has been proved by 2% and rabbits by 59%. In 2016 comparing to the last year, domestic dogs have not been used in any of the procedures. In 2015, 34 dogs were used. The number of used cats decreased from 29 to 11 cats only. In comparison to the last year, the use of other mammals (cattle, pigs, sheep) decreased by 80%. According to withdrawal of the decisions for approval of some of the users establishments and with respect to reduction or stopping of the procedures of some of the users establishments, a significant decrease of the animals used in the procedures namely in mice and quinea-pigs occurred. Decreased number of used mice and quinea-pigs is related to the research procedures of some establishments, which ceased or suspended from their activities by the reason of reconstruction in 2016. The cause is also that minimum 5 users have merged into one legal subject and they had to abolish their establishments. Reconstructions of the establishments had been performed in the establishments using dogs and cats, therefore their number has been reduced or decreased to minimum.

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3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016, 52% of projects were classified as “non-recovery” or “,mild”, 46% of the total number were projects classified as ”moderate”, (in 2015, the “moderate” projects were represented only by 27% of all approved establishments), and projects classified as “severe” were represented by 1,2% of the total number of the approved projects. The number of severe projects decreased from 2% in 2015. The reason of increased number of the projects classified as “moderate” can be that the applicants for the approval of projects, performing projects classified as “severe” last year, have refined their procedures, therefore their projects automatically came into category “moderate”.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The obligation to comply with 3R principles is established by the legislation. This topics is presented in details at trainings of staff carrying functions referred to in Article 23 of the Directive. During controls of the establishments of the users, breeders and suppliers carried out in a frequency established by the law, a great attention is taken to observance of the 3R principles during performance of the projects and in animal placement and animal care. There is a great space in SK for the performance of “in-vitro” projects, using alternative methods and providing information of 3R principles, also declared in up-dating of the activities in the table due to the Article 47 of the Directive, published on web site of the Competent Authority SVFA SR.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In the category „other basic research” a significant increase of the used animals has occurred. The number of 517 animals from 2015 increased to 1875 animals in 2016, which represents almost 20% more animals used in this area. It was found out after the additional control, that some users have incorrectly assigned the objective of the project to the concerned performed type of the project. No significant increase of the number of used animals was recorded in other areas.

In category “other birds” increased number of used animals by 12,45% in comparison to the last year was indicated. 32 pcs of Zebra finch was used in the approved project in 2016. This is not a significant increase whereas the project is approved for the period of 5 (five) years and annualy approximately 30-40 birds are used

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In the process of authorisation of the project of the user, breeder or supplier in SK, an Authorization Decision is issued. In the Authorization Decision all necessary detailed information, including classification of severity, authorized exemptions within the frame of performance of the project or breeding or animal supplies are specified. According to the seriousness of the infringement it is

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possible to resolve the infringement of any type of the decision either by issuing veterinary measures in the administrative procedure, or by issuing veterinary measures on site. A penalty on site or financial penalty through administrative procedure can also be imposed. If shortcomings are not eliminated up to the stated deadline, it is possible to increase the penalty, or abolish the decision on authorization of the project or establishment.

Such a case has not happened in SK yet. All establishments are regularly controlled due to the specified frequency. In 2016, altogether 38 controls of the establishments were carried out. Included 2 controls which were follow-up – additional for the purpose of control of elimination of found shortcomings. 29 controls were carried out for the purpose of authorisation of the establishments of the users, breeders or suppliers and 7 controls for the reason of control of the compliance of requirements in the approved establishments. During retrospective assessment, an Advisory Body and the Competent Authority reviewed that each of the projects intended for the reverse control was resent and evaluated. In each "severe" project, several available possibilities for its refinement were used in order to assure that the animals would not feel cruelty/severity. In several projects submitted to the reverse assessment was found out that after their severity was classified as "moderate". If a pain classified as "severe" occurred, all available possible measures were carried out for its refinement

Slovakia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	5263	41.01%
Rats	5973	46.55%
Guinea-Pigs	955	7.44%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	14	0.11%
Other Rodents		
Rabbits	358	2.79%
Cats	11	0.09%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	1	0.01%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		

Animal Species	Number of animals	Percentage
Apes		
Other Mammals		
Domestic fowl	225	1.75%
Other birds	32	0.25%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	12832	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12789	99.66%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world	43	0.34%
Total	12832	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	8366	65.2%
Translational and applied research	1085	8.46%
Regulatory use and Routine production	2987	23.28%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other	394	3.07%

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Purpose Category	Number of uses	Percentage
procedures		
Total	**12832**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	146	1.75%
Cardiovascular Blood and Lymphatic System	808	9.66%
Nervous System	2746	32.82%
Respiratory System	478	5.71%
Gastrointestinal System including Liver	58	0.69%
Musculoskeletal System	52	0.62%
Immune System	1350	16.14%
Urogenital/Reproductive System	1454	17.38%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	230	2.75%
Multisystemic	23	0.27%
Ethology / Animal Behaviour /Animal Biology	40	0.48%
Other basic research	981	11.73%
Total	**8366**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	40	3.69%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	72	6.64%
Human Musculoskeletal Disorders		
Human Immune Disorders	103	9.49%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	57	5.25%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	7	0.65%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	806	74.29%
Total	**1085**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1533	51.32%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	1412	47.27%
Routine production	42	1.41%
Total	**2987**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1298	84.67%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	235	15.33%
Total	**1533**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	388	27.48%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	632	44.76%
Repeated dose toxicity	392	27.76%
Total	**1412**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	388	100%
Other lethal methods		
Non lethal methods		
Total	**388**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	392	100%
29 - 90 days		
> 90 days		
Total	**392**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	42	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	42	100.00%

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1340	44.86%
Legislation on medicinal products for veterinary use and their residues	235	7.87%
Medical devices legislation		
Industrial chemicals legislation	1002	33.55%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	410	13.73%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	2987	100.00%

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2987	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	2987	100.00%

First uses and re-uses

Re-use	Number of uses	Percentage
No	12832	100%
Yes		
Total	12832	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1149	8.95%
Mild [up to and including]	5588	43.55%
Moderate	5947	46.35%
Severe	148	1.15%
Total	12832	100.00%

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	12832	100%
Yes		
Total	**12832**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	11920	92.89%
Genetically altered without a harmful phenotype	43	0.34%
Genetically altered with a harmful phenotype	869	6.77%
Total	**12832**	**100.00%**

Slovakia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the number of animals used in projects increased by 17,66% for the different reasons. The first reason was authorisation of two big establishments of users breeding animals for their own need, offering their establishments for performing projects also for the other users. Thereby, the space for performance of the projects in the Slovak Republic has amplified. The second reason was that by the end of year 2016, all existing establishments of users, breeders, suppliers have finished reconstructions in their establishments and therefore in 2017 they could involve in performing of the projects. In 2016, all existing establishments were newly authorised in compliance with Annex 3 of the Directive 2010/63/EU. Since 2017, scientific activities have fully developed, all authorised establishments have started to perform them. Project Agencies in SK (VEGA, APVV) have allocated financial grants for realisation of several projects authorised by the Competent Authority of SR in the area of protection of animals used for scientific purposes. Increased number of animals used in 2017 is deeply connected with this. After finishing transition period for standards of treating and housing animals until 01.01.2017, performance of the projects in establishments has developed in SK. Purpose of the projects in performance of regulated projects has increased. In comparison to year 2016, in performance of the project with the purpose non-regulatory toxicology and ecotoxicology was not reported in 2017. In the area of regulatory use and routine production a type of regulated project - reproductive toxicity occurred and a test with 29-90 days period of administration was added in the area of repeated dose toxicity. Due to the Act, in vitro methods or alternative methods are used preferentially in the regulated projects. In vivo project shall be carried out only if it is not possible to use an alternative method, if there is any. The reason is that the tested substance e.g. is not dissoluble in the dissolution reagent determined for given alternative method.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2017, the number of animals used in the projects increased by 17, 66% in comparison to the year 2016. This relates also to the increase of use animals in particular areas or their decrease depending on the area of the research. Significant increase occurred in use of „other birds“, whereas in the approved project No. 2982/17-221 apart from the species Zebra finch the other species Bangalese finch has also started to be used, whereby the number of use animals increased by 7,8%. The number of animals used for maintenance GM animal colonies without their further use in the project increased by 3%. The number of used animals in basic research in the area multisystemic has increased. A project with use of 782 (7,23%) of animals for the purpose of carcinogenicity research was authorised. The project was focused on safety testing of genetically modified plants by means of toxicology methods. The number of animals used in translational and applied research has increased significantly by 50, 48%, whereas in 2016 no project with this purpose had been carried out. The number of used animals in Animal Diseases and Disorders has increased by 36 % relating to increased number of used animals in one year. In 2017, the purpose of regulated projects increased and simultaneously, the number of animals used in regulated projects decreased in general by 5%. At the same time, the number of animals used in the

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basic research increased by 4 % related to starting research activities of several useres establishments of the Slovak Academy of Science and Universities.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In comparison to the year 2016, significant increase occured in classification of severity. The number of animals used in category „mild“ decreased by 10%, whereas the number of animals used in category „moderate“ increased by 11%. This is also related to the purpose of executed projects which have increased significantly in the basic research mainly in the area of „other basic research“, as stated in the table for obligatory report of the Member States. The projects in „other basic reaserch“ had been carried out for the purposes of microbiology, virology and diabetes. By using these methods also the level of severity is increasing.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Slovak Republic annually completes and sends referred templates of the tables for reporting of support and achievements in the area of observing the principles of 3R. The tables are published at the web site of the State Veterinary and Food Administration of SR. Applicants for any kind of authorisation, whether the establishment or the project, in compliance with the Act, are obliged to describe observance of 3R principles. During controls of establishments in the area of observance of legislative requirements, inspectors of animal protection are focused mainly on the area of observance of 3R in keeping and using animals. Several users attend trainings for implementation of in vitro methods in performance of the regulated projects. In 2017, Slovakia organized an International Conference of in vitro methods EUROTOX. The subject of the observance of 3R principles is highly emphasized at the obligational training of specified functions carried out by the staff of authorised establishments of users, breeders and suppliers. Moreover, the members of Animal Welfare Body, which is established in each establishment or its services are used externally, have to supervise the compliance of these principles in the establishments.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The number of used animals has changed significantly in basic research in the area „ other basic research“ as listed in the purpose of projects in the table for obligatory report of the Member States. The projects in „other basic research“ were carried out in the area of microbiology, virology and diabetes. Simultaneously, increase of animals category „ other birds“ from 32 in 2016 to 59 in 2017 was notified. It was caused by the use of other bird species, i.e. Bengalese finch (Lonchura striata domestica).

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The Competent Authority of the Slovak Republic does not register exceed of classification specified as „severe“ in 2017. In the Slovak Republic the projects classified as „severe“ are authorised. The real number of animals that have experienced pain in the projects classified as „severe“ is notified in every obligatory report sent to EU Commission. Exceed is not possible because the establishments are annually controlled by a physical control on site in the establishments by inspectors of animal protection of the District Veterinary and Food Administrations. At the same time, users are obliged to notify real severity caused to animals in the projects according to the submitted template of the tables from EU Commission. The Competent Authority of SR has got all relevant information about the projects and in case of suspicion can impose execution of a targeted control in the establishment of the respective user. Inspector of animal protection shall carry out control focused on observance of severity in the project in comparison to the Decision of authorisation of the project. In case of found incompliances, the veterinary measures or penalties are imposed.

Slovakia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6087	39.01%
Rats	7939	50.88%
Guinea-Pigs	1036	6.64%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	9	0.06%
Other Rodents		
Rabbits	226	1.45%
Cats	11	0.07%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	2	0.01%
Cattle	1	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	233	1.49%
Other birds	59	0.38%
Reptiles		
Rana		

Animal Species	Number of animals	Percentage
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	15603	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	15565	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	15565	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	10819	69.34%
Translational and applied research	1046	6.7%
Regulatory use and Routine production	2822	18.09%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	56	0.36%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	860	5.51%
Total	15603	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	316	2.92%
Cardiovascular Blood and Lymphatic System	932	8.61%
Nervous System	4076	37.67%
Respiratory System	607	5.61%
Gastrointestinal System including Liver	180	1.66%
Musculoskeletal System	19	0.18%
Immune System	424	3.92%
Urogenital/Reproductive System	1175	10.86%
Sensory Organs (skin, eyes and ears)	9	0.08%
Endocrine System/Metabolism	610	5.64%
Multisystemic	782	7.23%
Ethology / Animal Behaviour /Animal Biology	595	5.5%
Other basic research	1094	10.11%
Total	**10819**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	20	1.91%
Human Nervous and Mental Disorders	528	50.48%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	21	2.01%
Human Urogenital/Reproductive Disorders	10	0.96%
Human Sensory Organ Disorders (skin, eyes and ears)	27	2.58%
Human Endocrine/Metabolism Disorders	60	5.74%
Other Human Disorders		
Animal Diseases and Disorders	374	35.76%
Animal Welfare		
Diagnosis of diseases	6	0.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1046**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1014	35.93%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	1777	62.97%
Routine production	31	1.1%
Total	**2822**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	867	85.5%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	147	14.5%
Total	**1014**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	653	36.75%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	542	30.5%
Repeated dose toxicity	460	25.89%
Reproductive toxicity	122	6.87%
Total	**1777**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	603	92.34%
Other lethal methods		
Non lethal methods	50	7.66%
Total	**653**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	280	60.87%
29 - 90 days	180	39.13%
> 90 days		
Total	**460**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	31	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**31**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1300	46.07%
Legislation on medicinal products for veterinary use and their residues	133	4.71%
Medical devices legislation	64	2.27%
Industrial chemicals legislation	946	33.52%
Plant protection product legislation	9	0.32%
Biocides legislation		
Food legislation including food contact material	190	6.73%
Feed legislation including legislation for the safety of target animals, workers and environment	180	6.38%
Cosmetics legislation		
Other legislation		
Total	**2822**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2822	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2822**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	15565	99.76%
Yes	38	0.24%
Total	**15603**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1101	7.06%
Mild [up to and including]	5185	33.23%
Moderate	8963	57.44%
Severe	354	2.27%
Total	**15603**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	15603	100%
Yes		
Total	**15603**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	14104	90.39%
Genetically altered without a harmful phenotype	260	1.67%
Genetically altered with a harmful phenotype	1239	7.94%
Total	**15603**	**100.00%**

Slovenia

Slovenia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Number of animals used for scientific purposes in 2015 is slightly lower in comparison with numbers reported in 2014. In 2014, approximately 12.000 animals were used and in 2015, the number of animals used for scientific purposes is slightly over 9.000.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

More than 95% of all used animals in 2015 are rodents and rabbits. Mice is the most commonly used species (95%), following rats (2%) and rabbits (1, 4%). 477 animals (rodents) were reported as GA animals, 58 of them with a harmful phenotype (39 mice and 19 rats). Animals were used in basic research (endocrine system/metabolism and cardiovascular/lymphatic system).
No cats, dogs and non-human primates were used for scientific purposes in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The majority of all animals (74,17%) were used for the purpose of regulatory use and routine production. Out of this percentage, over 40% of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, 57 fish (*Onchorhynchus mykiss*) were used in higher education or training for the acquisition, maintenance or improvement of vocational skills. Severity of procedures was classified as non-recovery or mild.

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

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No information submitted.

Slovenia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	8621	95.63%
Rats	184	2.04%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	127	1.41%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.02%
Pigs	8	0.09%
Goats		
Sheep	3	0.03%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	13	0.14%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	57	0.63%
Cephalopods		
Total	**9015**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5400	98.58%
Animals born in the EU but not at a registered breeder	78	1.42%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5478**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	963	10.68%
Translational and applied research	1177	13.06%
Regulatory use and Routine production	6757	74.95%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	118	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9015**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	125	12.98%
Cardiovascular Blood and Lymphatic System	68	7.06%
Nervous System		
Respiratory System		
Gastrointestinal System including Liver	15	1.56%
Musculoskeletal System	35	3.63%
Immune System	174	18.07%
Urogenital/Reproductive System	74	7.68%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	472	49.01%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**963**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1002	85.13%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	24	2.04%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	112	9.52%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	39	3.31%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1177**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	6717	99.41%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	40	0.59%
Total	**6757**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	175	2.61%
Pyrogenicity testing	111	1.65%
Batch potency testing	6431	95.74%
Other quality controls		
Total	**6717**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Kinetics	40	100%
Total	**40**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	6757	100%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**6757**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6757	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6757**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	5478	60.77%
Yes	3537	39.23%
Total	**9015**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	105	1.16%
Mild [up to and including]	8559	94.94%
Moderate	351	3.89%
Severe		
Total	**9015**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9015	100%
Yes		
Total	**9015**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	8538	94.71%
Genetically altered without a harmful phenotype	419	4.65%
Genetically altered with a harmful phenotype	58	0.64%
Total	**9015**	**100.00%**

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Slovenia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Number of animals used for scientific purposes in 2016 has dropped significantly in comparison with numbers reported in 2015. In 2015, approximately 9.000 animals were used and in 2016, the number of animals used for scientific purposes is around 6.800. The highest drop in the number of used animals was in regulatory use and routine production.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As every year, more than 95% of all used animals are rodents and rabbits. Mice is the most commonly used species (95%), following rats (1, 36 %) and rabbits (less than 1%).
66 animals (rodents) were reported as GA animals, all without a harmful phenotype (50 mice and 16 rats). Those animals were used in basic research (oncology and cardiovascular blood and lymphatic system). No cats, dogs and non-human primates were used for scientific purposes in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Almost 86 % off all animals were used for the purpose of regulatory use and routine production. Out of this percentage, around 26 % of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.
1,54 % of all uses were classified as non – recovery (animals used for the purpose of translational and applied research and higher education). Almost 91% of all uses were mild, 4,5 % moderate and 3 % were classified as severe, where all uses were for the purpose of basic research (mice used for immune system research).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No information submitted.

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6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No information submitted.

Slovenia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6542	97.28%
Rats	93	1.38%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	45	0.67%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	32	0.48%
Goats		
Sheep	3	0.04%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	10	0.15%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**6725**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4920	99.8%
Animals born in the EU but not at a registered breeder	10	0.2%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**4930**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	419	6.23%
Translational and applied research	1762	26.2%
Regulatory use and Routine production	4491	66.78%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	53	0.79%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**6725**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	50	11.93%
Cardiovascular Blood and Lymphatic System	16	3.82%
Nervous System		
Respiratory System		
Gastrointestinal System including Liver	24	5.73%
Musculoskeletal System	32	7.64%
Immune System	224	53.46%
Urogenital/Reproductive System	49	11.69%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research	24	5.73%
Total	**419**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1603	90.98%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	17	0.96%
Human Urogenital/Reproductive Disorders	10	0.57%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	122	6.92%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	10	0.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1762**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4491	100%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology		
Total	**4491**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	70	1.56%
Pyrogenicity testing	40	0.89%
Batch potency testing	4381	97.55%
Other quality controls		
Total	**4491**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4491	100%

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**4491**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4491	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**4491**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	4930	73.31%
Yes	1795	26.69%
Total	**6725**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	16	0.24%
Mild [up to and including]	6183	91.94%
Moderate	318	4.73%
Severe	208	3.09%
Total	**6725**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	6725	100%
Yes		
Total	**6725**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	6659	99.02%
Genetically altered without a harmful phenotype	66	0.98%
Genetically altered with a harmful phenotype		
Total	**6725**	**100.00%**

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Slovenia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the number of animals used for scientific purposes has been reduced in comparison with numbers reported in previous years. The number is around 5.000 animals. The highest drop in the number of used animals was in regulatory use and routine production, where almost 50% less animals were used compared to previous years. The reason is the replacement of in vivo methods, which follows the 3R principle of replacement. Further more, the reason can be found in the termination of certain projects for certain markets, which leads in reduction of use of animals for regulatory purposes. Not negligible is also the fact, that the principle of reduction is followed as much as possible and animals are being re-used.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As every year, more than 95% of all used animals are rodents (mice and rats) and rabbits. Mice is the most commonly used species (88%), following rats (4, 40 %) and rabbits (less than 2,63%).
There is an increase of animals used in basic research where, in comparison with previous year almost 1.000 rodents (mice in rats) were used. The number was less than 400 rodents (mice and rats) in 2016. Animals were mainly used in research for the purpose of oncology, endocrine system, immune system and gastrointestinal system including liver. The highest number of rodents was used for the research of endocrine system.
A slight increase can be observed also in the use of GA animals. While there were 66 animals reported as GA in 2016, 351 GA animals were reported in 2017. This number represent 6,70 % of all used animals in Slovenia in 2017. Out of this 351 GA animals, 288 mice were reported as GA without a harmful phenotype and 63 mice with harmful phenotype. In 2016 no GA animal with harmful phenotype was reported.
Pyrogenicity testing is still used on rabbits for the purpose of quality control including batch safety and potency testing, but only when the alternative method (in vitro method) gives doubtful results.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Majority of procedures in Slovenia are still classified as mild (over 85%), around 12% are moderate and less than 2% severe, where all uses were for basic research for the purpose of immune system research.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory use - quality control, as prescribed and validated parameters were achieved with the re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

No cats, dogs and non-human primates were used in procedures in 2017.

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5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No information submitted.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No information submitted.

Slovenia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4563	88.74%
Rats	226	4.4%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	135	2.63%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.04%
Pigs	80	1.56%
Goats		
Sheep	28	0.54%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	10	0.19%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	98	1.91%

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Animal Species	Number of animals	Percentage
Cephalopods		
Total	5142	100.00%

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4569	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	4569	100.00%

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1035	20.13%
Translational and applied research	1786	34.73%
Regulatory use and Routine production	2183	42.45%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	16	0.31%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	122	2.37%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	5142	100.00%

Basic Research

Basic Research	Number of uses	Percentage
Oncology	149	14.4%
Cardiovascular Blood and Lymphatic System		
Nervous System	70	6.76%
Respiratory System		
Gastrointestinal System including Liver	150	14.49%
Musculoskeletal System	34	3.29%
Immune System	102	9.86%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	375	36.23%
Multisystemic	59	5.7%
Ethology / Animal Behaviour /Animal Biology	48	4.64%
Other basic research	48	4.64%
Total	**1035**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1552	86.9%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	65	3.64%
Other Human Disorders	55	3.08%
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	114	6.38%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1786**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2101	96.24%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	82	3.76%
Total	**2183**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	272	12.95%
Pyrogenicity testing	59	2.81%
Batch potency testing	1770	84.25%
Other quality controls		
Total	**2101**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Kinetics	82	100%
Total	**82**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2183	100%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**2183**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2183	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2183**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	4569	88.86%
Yes	573	11.14%
Total	**5142**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	44	0.86%
Mild [up to and including]	4372	85.03%
Moderate	637	12.39%
Severe	89	1.73%
Total	**5142**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5087	98.93%
Yes	55	1.07%
Total	**5142**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	4791	93.17%
Genetically altered without a harmful phenotype	288	5.6%
Genetically altered with a harmful phenotype	63	1.23%
Total	**5142**	**100.00%**

Spain

Spain: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture, Fisheries, Food and the Environment (MAGRAMA) designed an IT application which was used for the first time this past year. Its purpose is to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The information is provided by the authorised centres, which input the reports from each centre in the system. The authorised centres are overseen by the competent authorities of the various Autonomous Communities which report to MAGRAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. It was therefore necessary to adapt both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This affects how the information about uses in 2014 compare with the same information in 2015. This problem should be resolved with the experience gained as future reports are created. This means that comparisons between years will be more reliable, and it will be possible to evaluate the trends which, for the moment, cannot be evaluated.

In 2015, there was a significant effort to improve the classification of uses under the corresponding headings and, as far as possible, to avoid using 'others'.

In addition, analysis of the data showed that the severity classification 'non-recovery' had at times been interpreted incorrectly. For this reason, there is a change in the proportions of the various severity classifications, which is largely due to better understanding of the meaning of each category. It is also partly due to the generally accepted practice of applying the precautionary principle. As a result, where there is uncertainty between two levels of severity, the higher level of actual severity is assigned to a use.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

In the report on uses in 2015, there were uses of new species not used in 2014. Nevertheless, this is not considered highly significant as such uses are associated with projects that use such species on an occasional basis (for example, frogs).

The proportion of 'other animal species' is high as there are several registered users that work with wildlife.

In 2015, several lines of research associated with zootechnics were developed. This can be seen in the use of 'production animals', although it is partially obscured by the reduction in the use of sheep.

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In addition, a new user conducting research in the field of animal nutrition has been using relatively large groups of animals. This is because the user is working in commercial conditions, which significantly increases the figures reported.

The field of aquaculture, and the development of technologies to extend the practice, requires the use of 'non-habitual' species of fish, such as cephalopods, in significant numbers. The main species used are sea-bream, sea-bass, turbot and trout. The notable increase in the use of cephalopods has the same [...].

The increase in genetically altered mice is notable: this is a global trend on account of the wide range of options offered by the use of such animals.

Finally, with regard to the purposes for which animals are used, there is a notable decrease in uses in basic research in parallel with the increase in applied research. A reduction is apparent in the use of animals for regulatory purposes. This is partly due to better classification of the purposes for which animals are used. The significant increase in maintaining genetically altered lines is due to the increase in altered lines and, largely, to the fact that genotyping by invasive methods was considered a procedure. The emphasis placed on the need for thorough education and training in new surgical techniques was reflected in the increase in animals intended for training and teaching.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In Spain, assignment of severity to the procedures is one of the most significant new features of the Directive. It was done for the first time following the application of the Directive.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced. In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific procedure.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - [and] by the assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose, along with the competent authorities themselves. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

The points on which the greatest effort is being made are: disseminating reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, cadavers etc., and finally with animals for which the severity of the procedures must not exceed the classification of 'mild'. However, this situation is not apparent in the statistics because of the increase in the number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

In the category 'other animals', the majority corresponds to 'other fishes', for two main reasons. The first is that the range of options for this group is limited to two options. This means that 'other fishes' in reality represents 'fishes other than zebrafish'. Secondly, in Spain there are several centres dedicated to researching the biology and needs of fish in aquaculture, for example trout, sea-bream, sea-bass, turbot etc. These represent a significant number of animals.

Furthermore, there are centres that work with wildlife, also for the purpose of thoroughly understanding their biology and behaviour.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This situation has not arisen in Spain.

Spain: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	483689	57.65%
Rats	57616	6.87%
Guinea-Pigs	7760	0.92%
Hamsters (Syrian)	665	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	193	0.02%
Rabbits	30408	3.62%
Cats	361	0.04%
Dogs	860	0.1%
Ferrets	94	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	210	0.03%
Pigs	9262	1.1%
Goats	389	0.05%

Animal Species	Number of animals	Percentage
Sheep	1980	0.24%
Cattle	519	0.06%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	289	0.03%
Rhesus monkey	4	0%
Vervets (Chlorocebus spp.)		
Baboons	18	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	607	0.07%
Domestic fowl	98444	11.73%
Other birds	4585	0.55%
Reptiles	302	0.04%
Rana	14	0%
Xenopus	1304	0.16%
Other Amphibians	2267	0.27%
Zebra fish	44543	5.31%
Other Fish	76709	9.14%
Cephalopods	15848	1.89%
Total	**838940**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	744953	90.26%
Animals born in the EU but not at a registered breeder	76558	9.28%
Animals born in rest of Europe		
Animals born in rest of world	3802	0.46%
Total	**825313**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	21	8.61%
Animals born in rest of Europe		
Animals born in Asia	78	31.97%
Animals born in America		
Animals born in Africa	145	59.43%
Animals born elsewhere		
Total	**244**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	9	3.69%
F2 or greater	185	75.82%
Self-sustaining colony	50	20.49%
Total	**244**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	433171	51.63%
Translational and applied research	217468	25.92%
Regulatory use and Routine production	133876	15.96%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	17306	2.06%
Preservation of species	13	0%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	13922	1.66%
Forensic enquiries	1	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	23183	2.76%
Total	**838940**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	46399	10.71%
Cardiovascular Blood and Lymphatic System	35069	8.1%
Nervous System	83966	19.38%
Respiratory System	2755	0.64%
Gastrointestinal System including Liver	49205	11.36%
Musculoskeletal System	13259	3.06%
Immune System	24368	5.63%
Urogenital/Reproductive System	6680	1.54%
Sensory Organs (skin, eyes and ears)	7809	1.8%
Endocrine System/Metabolism	29287	6.76%
Multisystemic	41201	9.51%
Ethology / Animal Behaviour /Animal Biology	18301	4.22%
Other basic research	74872	17.28%
Total	**433171**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	62970	28.96%
Human Infectious Disorders	22693	10.44%
Human Cardiovascular Disorders	5317	2.44%
Human Nervous and Mental Disorders	17719	8.15%
Human Respiratory Disorders	5243	2.41%
Human Gastrointestinal Disorders including Liver	2286	1.05%
Human Musculoskeletal Disorders	3072	1.41%
Human Immune Disorders	3342	1.54%
Human Urogenital/Reproductive Disorders	1563	0.72%
Human Sensory Organ Disorders (skin, eyes and ears)	13873	6.38%
Human Endocrine/Metabolism Disorders	16953	7.8%
Other Human Disorders	1048	0.48%
Animal Diseases and Disorders	35315	16.24%
Animal Welfare	18539	8.52%
Diagnosis of diseases	5540	2.55%
Plant diseases	14	0.01%
Non-regulatory toxicology and ecotoxicology	1981	0.91%
Total	**217468**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	71438	53.36%
Other efficacy and tolerance testing	288	0.22%
Toxicity and other safety testing including pharmacology	59672	44.57%
Routine production	2478	1.85%
Total	**133876**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	16585	23.22%
Pyrogenicity testing	9960	13.94%
Batch potency testing	41617	58.26%
Other quality controls	3276	4.59%
Total	**71438**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16447	27.56%
Skin irritation/corrosion	103	0.17%
Skin sensitisation	630	1.06%
Eye irritation/corrosion	39	0.07%
Repeated dose toxicity	5172	8.67%
Carcinogenicity		
Phototoxicity		
Reproductive toxicity		
Genotoxicity	60	0.1%
Developmental toxicity	90	0.15%
Neurotoxicity	8400	14.08%
Kinetics	2069	3.47%
Pharmaco-dynamics (incl safety pharmacology)	3849	6.45%
Ecotoxicity	133	0.22%
Safety testing in food and feed area	19301	32.35%
Target animal safety	3331	5.58%
Other toxicity/safety testing	48	0.08%
Total	**59672**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	14047	85.41%
Other lethal methods	75	0.46%
Non lethal methods	2325	14.14%
Total	**16447**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3244	62.72%
29 - 90 days	1129	21.83%
> 90 days	799	15.45%
Total	**5172**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	57	42.86%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	76	57.14%
Other ecotoxicity		
Total	**133**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1759	70.98%
Monoclonal antibody by mouse ascites method	719	29.02%
Other product types		
Total	**2478**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	33313	24.88%
Legislation on medicinal products for veterinary use and their residues	65403	48.85%
Medical devices legislation	501	0.37%
Industrial chemicals legislation	510	0.38%
Plant protection product legislation	10	0.01%
Biocides legislation		
Food legislation including food contact material	21626	16.15%
Feed legislation including legislation for the safety of target animals, workers and environment	2368	1.77%
Cosmetics legislation		
Other legislation	10145	7.58%
Total	**133876**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	112896	84.33%
Legislation satisfying national requirements only [within EU]	3371	2.52%
Legislation satisfying Non-EU requirements only	17609	13.15%
Total	**133876**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	825557	98.4%
Yes	13383	1.6%
Total	**838940**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	72630	8.66%
Mild [up to and including]	382421	45.58%
Moderate	325697	38.82%
Severe	58192	6.94%
Total	**838940**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	814686	97.11%
Yes	24254	2.89%
Total	**838940**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	573795	68.4%
Genetically altered without a harmful phenotype	234380	27.94%
Genetically altered with a harmful phenotype	30765	3.67%
Total	**838940**	**100.00%**

Spain: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently throughout the reporting periods.

This can affect data patterns. We therefore believe that it is too early to draw conclusions regarding trends.

In 2016, efforts were maintained to improve the classification of uses under the corresponding headings, with the identification and correction of errors in the assignment of uses to the various categories available in the data collection form and, as far as possible, avoidance of using the heading 'others'.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The report on uses in 2016 includes species which are new, while others that appeared in previous reports have disappeared. Nevertheless, it is understood that these variations are not significant as they are associated with the implementation or completion of projects that use such species on an occasional basis.

The trend in increased use of genetically modified mice continues as the ability to design them to order makes them ideal experimental models for a multitude of studies.

The number of uses of fish continues to increase. This is due in part to the adaptation of the models that use zebrafish, which are being developed in an increasing number of fields, and in part to research concerning fish in aquaculture in Spain.

The proportion of 'other animal species' is high as there are several registered users that work with wildlife. Furthermore, as stated in the previous paragraph, the field of aquaculture, and the

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development of technologies to extend the practice, requires the use of 'non-habitual' species of fish, such as cephalopods, in significant numbers. The main species used are sole, sea-bream, sea-bass, turbot and trout.

The increase in 'maintaining genetically modified lines' continues. This is due both to the greater presence of the genetically modified lines themselves, and to the fact that, as of this report, genotyping by invasive methods was considered a procedure.

The need for thorough education and training in new surgical techniques was reflected in an increase in animals intended for training and teaching, making it possible to refine post-research activity.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific use.

The apparent fall in the proportion of 'non-recovery' uses continues. However this variation can be attributed to correct information as a result of the concept of 'non-recovery use' being clarified rather than to any real variation in the type of procedures carried out.

Uses classified as severe, while increasing in absolute figures, remain unchanged (8% of uses) in comparison with last year when their relative importance is compared with the total uses.

The greatest severities can be seen to be associated with uses required by European Union legislation, in the category 'regulatory use', and to a lesser extent in studies on animal diseases.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - and by the

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assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

Bearing in mind that the staff who work with the animals are one of the key aspects, more thorough and up-to-date training results not only in knowledge of more tools but also in greater motivation to use them.

The points on which the greatest effort is being made are: dissemination of reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

Improvements in training and in the instruments available enable progress in refining procedures.

However, this situation is obscured in the overall statistical figures by the significant increase of those... [text unclear] not apparent in the statistics because of the increased number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

In the 'other animals' section, a significant number of uses refer to 'other birds'. These are limited to centres working to gain detailed knowledge of the biology and behaviour of wildlife. Almost all of these uses (96%) have been classified as 'mild'.

However, the vast majority (95% of uses under 'other species') corresponds to fish other than zebrafish. In this case, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sole, trout, sea-bream, sea-bass and turbot.

A significant effort was made to avoid the classification of 'others' for the purposes of the uses of animals. As a result, the number fell dramatically.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This situation has not arisen.

Spain: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	539959	61%
Rats	54910	6.2%
Guinea-Pigs	7223	0.82%
Hamsters (Syrian)	734	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	322	0.04%
Rabbits	28035	3.17%
Cats	358	0.04%
Dogs	1083	0.12%
Ferrets	74	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	91	0.01%
Pigs	9434	1.07%
Goats	269	0.03%
Sheep	2695	0.3%
Cattle	888	0.1%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	272	0.03%
Rhesus monkey	2	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	383	0.04%
Domestic fowl	89795	10.14%
Other birds	2400	0.27%
Reptiles	684	0.08%
Rana	30	0%
Xenopus	1091	0.12%
Other Amphibians	110	0.01%
Zebra fish	68562	7.75%
Other Fish	67324	7.61%
Cephalopods	8444	0.95%
Total	**885172**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	840339	95.88%
Animals born in the EU but not at a registered breeder	34299	3.91%
Animals born in rest of Europe		
Animals born in rest of world	1804	0.21%
Total	**876442**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	115	66.47%
Animals born in America		
Animals born in Africa	58	33.53%
Animals born elsewhere		
Total	**173**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	1	0.58%
F2 or greater	172	99.42%
Self-sustaining colony		
Total	**173**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	442337	49.97%
Translational and applied research	256090	28.93%
Regulatory use and Routine production	132505	14.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8115	0.92%
Preservation of species	137	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	12261	1.39%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	33727	3.81%
Total	**885172**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	50747	11.47%
Cardiovascular Blood and Lymphatic System	52032	11.76%
Nervous System	82046	18.55%
Respiratory System	2184	0.49%
Gastrointestinal System including Liver	10033	2.27%
Musculoskeletal System	11870	2.68%
Immune System	28232	6.38%
Urogenital/Reproductive System	11156	2.52%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	9328	2.11%
Endocrine System/Metabolism	16138	3.65%
Multisystemic	86591	19.58%
Ethology / Animal Behaviour /Animal Biology	77993	17.63%
Other basic research	3987	0.9%
Total	**442337**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	98730	38.55%
Human Infectious Disorders	14506	5.66%
Human Cardiovascular Disorders	4516	1.76%
Human Nervous and Mental Disorders	23096	9.02%
Human Respiratory Disorders	3141	1.23%
Human Gastrointestinal Disorders including Liver	5094	1.99%
Human Musculoskeletal Disorders	3317	1.3%
Human Immune Disorders	4513	1.76%
Human Urogenital/Reproductive Disorders	3142	1.23%
Human Sensory Organ Disorders (skin, eyes and ears)	16927	6.61%
Human Endocrine/Metabolism Disorders	19038	7.43%
Other Human Disorders		
Animal Diseases and Disorders	39324	15.36%
Animal Welfare	11045	4.31%
Diagnosis of diseases	8568	3.35%
Plant diseases	10	0%
Non-regulatory toxicology and ecotoxicology	1123	0.44%
Total	**256090**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	74344	56.11%
Other efficacy and tolerance testing	7999	6.04%
Toxicity and other safety testing including pharmacology	49667	37.48%
Routine production	495	0.37%
Total	**132505**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	20368	27.4%
Pyrogenicity testing	9878	13.29%
Batch potency testing	39956	53.74%
Other quality controls	4142	5.57%
Total	**74344**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	12920	26.01%
Skin irritation/corrosion	99	0.2%
Skin sensitisation	794	1.6%
Eye irritation/corrosion	39	0.08%
Repeated dose toxicity	2032	4.09%
Carcinogenicity	146	0.29%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Genotoxicity	50	0.1%
Reproductive toxicity	530	1.07%
Developmental toxicity	166	0.33%
Neurotoxicity	2406	4.84%
Kinetics	2739	5.51%
Pharmaco-dynamics (incl safety pharmacology)	3679	7.41%
Phototoxicity		
Ecotoxicity	104	0.21%
Safety testing in food and feed area	18437	37.12%
Target animal safety	5523	11.12%
Other toxicity/safety testing	3	0.01%
Total	**49667**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10946	84.72%
Other lethal methods	56	0.43%
Non lethal methods	1918	14.85%
Total	**12920**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	791	38.93%
29 - 90 days	437	21.51%
> 90 days	804	39.57%
Total	**2032**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	104	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**104**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	140	28.28%
Monoclonal antibody by mouse ascites method	309	62.42%
Other product types	46	9.29%
Total	**495**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	35421	26.73%
Legislation on medicinal products for veterinary use and their residues	67169	50.69%
Medical devices legislation	376	0.28%
Industrial chemicals legislation	3374	2.55%
Plant protection product legislation	1172	0.88%
Biocides legislation	264	0.2%
Food legislation including food contact material	20105	15.17%
Feed legislation including legislation for the safety of target animals, workers and environment	4599	3.47%
Cosmetics legislation		
Other legislation	25	0.02%
Total	**132505**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	111915	84.46%
Legislation satisfying national requirements only [within EU]	4092	3.09%
Legislation satisfying Non-EU requirements only	16498	12.45%
Total	**132505**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	876615	99.03%
Yes	8557	0.97%
Total	**885172**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	50237	5.68%
Mild [up to and including]	471092	53.22%
Moderate	300645	33.96%
Severe	63198	7.14%
Total	**885172**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	855372	96.63%
Yes	29800	3.37%
Total	**885172**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	520719	58.83%
Genetically altered without a harmful phenotype	319969	36.15%
Genetically altered with a harmful phenotype	44484	5.03%
Total	**885172**	**100.00%**

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Spain: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently in the reports from different periods.

This can affect data patterns and make it difficult to interpret possible trends in animal use.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures for uses of animals.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

In 2017, the number of uses of animals for scientific purposes fell among all species except rats, carnivores, goats and cattle, reptiles and 'other amphibians'.

In the case of rats, the greatest increase was in the area of applied research in relation to research on the gastro-intestinal system, the nervous system and the sensory organs.

Use of carnivores increased by around 45% in comparison with 2016, especially in diagnosis of diseases but also in regulatory use (mainly in kinetics and efficiency controls).

There was an increase in the use of species of farm animals for studies on diseases in such animals as target species for such diseases.

As in previous years, reptiles are mainly used in biology and ethology studies.

The common badger was used for the first time, in a study of animal diseases, as was the common spadefoot toad in studies of animal biology.

In assessing the figures on uses, it must be taken into account that there are users conducting research in the field of animal nutrition. They use relatively large groups of animals because they are working in conditions similar to commercial conditions. This significantly increases the figures reported, as can be seen in the studies carried out in the area of nutrition in chickens for fattening. This is also the reason

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for the significant reduction in the use of cephalopods given that, in 2017, this type of study was no longer being conducted.

The overall use of mice fell significantly, however their use increased in applied research in cancer, respiratory diseases and diseases of the nervous system.

The number of uses of fish fell by almost 40%. Nevertheless, there was a significant increase in the number of uses of genetically modified fish with a harmful phenotype, also partly due to a better understanding of the behaviour and biology of the fish, making it possible to identify the signs of the aforementioned harmful phenotype.

The proportion of 'other animal species' remains high as there are several registered users that work with wildlife, in particular mammals and birds. Furthermore, the field of aquaculture, and the development of technologies to extend the practice, requires the use of 'non-habitual' species of fish in significant numbers. The main species used are sea-bream, sea-bass, turbot, salmon and trout.

In 2017, an increase was apparent in the reuse of animals although it is difficult to evaluate the actual trend as the concept of 'reuse' has not always been interpreted consistently by reporters. The increase is especially clear in the reuse of dogs, cats and primates.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In 2017, as in previous years, the apparent fall in the proportion of 'non-recovery' uses continues. However this variation can be attributed to an improvement in the quality of the information as a result of the concept of 'non-recovery' use being clarified rather than to changes in the characteristics of the studies.

In 2017, an increase is apparent in the severity observed, especially in the procedures carried out with fish. This is due not only to the characteristics of the projects, but also to more training in identifying welfare indicators in this group of animals.

Nevertheless, the relative increase continues in uses with 'mild' severity with a corresponding decrease in 'moderate'. This is presumably due to the application of measures to refine procedures.

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As in previous years, the greatest severities are associated with regulatory uses of animals required by European Union legislation. To a lesser extent, to studies on animal diseases [...]

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - and by the assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

The consultative committees established by some competent authorities conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that undergo this level of suffering.

Staff training involves both initial skills training in order to be able to work with animals and ongoing training. It is a basic tool for correctly applying the alternative strategies to the use of live animals in research and teaching. Proper training confers not only knowledge of the techniques, approaches and tools that can be useful, but also greater motivation for using them.

The user centres are working to optimise the sharing of animal models, and of the animals themselves, especially their cadavers in order to avoid the unnecessary killing of animals.

In order to reduce the number of animals and adapt the project designs, pilot studies are being carried out to enable research to be directed to much more specific procedures.

One of the areas in which the greatest effort is being made is in dissemination of reference tools and databases, along with access to articles, publications and guides related to the application of the three 'Rs', using emails to centres and sector organisations.

As in previous years, efforts continue in the field of teaching with increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

The inclusion of statistical experts in the teams represents an improvement in the design of procedures, making it possible to reduce the number of animals used.

Furthermore in their applications for project authorisation, project managers are required to provide increasingly detailed information with regard to strategies for applying the three 'Rs'.

In tissue sampling, this involves improving or substituting certain techniques, for example avoiding genotyping by tail-docking.

5. **Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.**

As in previous years, the number of uses of 'other species' is very high, totalling almost 50,000 uses.

The vast majority (90% of uses under 'other species') corresponds to fish other than zebrafish. As in previous years, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sea-bream, sea-bass, turbot, salmon and trout.

Of these 'other animals', 5% are birds used in the study of biology, behaviour and pathologies in wild birds.

In the case of 'other purposes', in basic research the majority are concerned with the field of animal nutrition, and of aquaculture, and in toxicology other quality controls, especially in conducting checks for absence of external viruses, duration of immunity and categorisation of active principles.

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

This situation has not arisen in Spain.

Spain: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	523467	65.19%
Rats	56036	6.98%
Guinea-Pigs	6747	0.84%
Hamsters (Syrian)	599	0.07%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	141	0.02%
Rabbits	25931	3.23%
Cats	531	0.07%
Dogs	1476	0.18%
Ferrets	164	0.02%
Other carnivores	25	0%
Horses, donkeys and cross-breeds	61	0.01%
Pigs	8656	1.08%
Goats	369	0.05%
Sheep	1953	0.24%
Cattle	1700	0.21%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	451	0.06%
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		

Animal Species	Number of animals	Percentage
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	99	0.01%
Domestic fowl	82107	10.23%
Other birds	2535	0.32%
Reptiles	1003	0.12%
Rana	18	0%
Xenopus	1204	0.15%
Other Amphibians	1996	0.25%
Zebra fish	41020	5.11%
Other Fish	44667	5.56%
Cephalopods	20	0%
Total	**802976**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	745928	94.13%
Animals born in the EU but not at a registered breeder	45911	5.79%
Animals born in rest of Europe	33	0%
Animals born in rest of world	606	0.08%
Total	**792478**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	104	42.28%
Animals born in America		
Animals born in Africa	142	57.72%
Animals born elsewhere		
Total	**246**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	2	0.81%
F2 or greater	244	99.19%
Self-sustaining colony		
Total	**246**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	329508	41.04%
Translational and applied research	281870	35.1%
Regulatory use and Routine production	120192	14.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6048	0.75%
Preservation of species	371	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	11785	1.47%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	53202	6.63%
Total	**802976**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	28417	8.62%
Cardiovascular Blood and Lymphatic System	26264	7.97%
Nervous System	78970	23.97%
Respiratory System	2457	0.75%
Gastrointestinal System including Liver	8885	2.7%
Musculoskeletal System	6997	2.12%
Immune System	24659	7.48%
Urogenital/Reproductive System	6548	1.99%
Sensory Organs (skin, eyes and ears)	10283	3.12%
Endocrine System/Metabolism	22634	6.87%
Multisystemic	37812	11.48%
Ethology / Animal Behaviour /Animal Biology	73215	22.22%
Other basic research	2367	0.72%
Total	**329508**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	116597	41.37%
Human Infectious Disorders	13579	4.82%
Human Cardiovascular Disorders	6440	2.28%
Human Nervous and Mental Disorders	21394	7.59%
Human Respiratory Disorders	2713	0.96%
Human Gastrointestinal Disorders including Liver	8755	3.11%
Human Musculoskeletal Disorders	2052	0.73%
Human Immune Disorders	5093	1.81%
Human Urogenital/Reproductive Disorders	1160	0.41%
Human Sensory Organ Disorders (skin, eyes and ears)	15801	5.61%
Human Endocrine/Metabolism Disorders	15652	5.55%
Other Human Disorders	1651	0.59%
Animal Diseases and Disorders	50632	17.96%
Animal Welfare	8413	2.98%
Diagnosis of diseases	9848	3.49%
Plant diseases	10	0%
Non-regulatory toxicology and ecotoxicology	2080	0.74%
Total	**281870**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68653	57.12%
Other efficacy and tolerance testing	2121	1.76%
Toxicity and other safety testing including pharmacology	48164	40.07%
Routine production	1254	1.04%
Total	**120192**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	23330	33.98%
Pyrogenicity testing	9472	13.8%
Batch potency testing	31416	45.76%
Other quality controls	4435	6.46%
Total	**68653**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	11069	22.98%
Skin irritation/corrosion	43	0.09%
Skin sensitisation	616	1.28%
Eye irritation/corrosion	11	0.02%
Repeated dose toxicity	6225	12.92%
Carcinogenicity	56	0.12%
Genotoxicity	22	0.05%
Phototoxicity		
Reproductive toxicity		
Developmental toxicity	759	1.58%
Neurotoxicity	2017	4.19%
Kinetics	3364	6.98%
Pharmaco-dynamics (incl safety pharmacology)	1476	3.06%
Ecotoxicity	156	0.32%
Safety testing in food and feed area	21778	45.22%
Target animal safety	486	1.01%
Other toxicity/safety testing	86	0.18%
Total	**48164**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10180	91.97%
Other lethal methods		
Non lethal methods	889	8.03%
Total	**11069**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1906	30.62%
29 - 90 days	3714	59.66%
> 90 days	605	9.72%
Total	**6225**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	124	79.49%
Chronic toxicity		
Reproductive ecotoxicity	32	20.51%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**156**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	54	4.31%
Monoclonal antibody by mouse ascites method	55	4.39%
Other product types	1145	91.31%
Total	**1254**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	32566	27.09%
Legislation on medicinal products for veterinary use and their residues	62289	51.82%
Medical devices legislation	138	0.11%
Industrial chemicals legislation	3194	2.66%
Plant protection product legislation	28	0.02%
Biocides legislation	56	0.05%
Food legislation including food contact material	21850	18.18%
Feed legislation including legislation for the safety of target animals, workers and environment	68	0.06%
Cosmetics legislation		
Other legislation	3	0%
Total	**120192**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	107209	89.2%
Legislation satisfying national requirements only [within EU]	4112	3.42%
Legislation satisfying Non-EU requirements only	8871	7.38%
Total	**120192**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	792724	98.72%
Yes	10252	1.28%
Total	**802976**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	41203	5.13%
Mild [up to and including]	415094	51.69%
Moderate	280781	34.97%
Severe	65898	8.21%
Total	**802976**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	779035	97.02%
Yes	23941	2.98%
Total	**802976**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	512735	63.85%
Genetically altered without a harmful phenotype	243856	30.37%
Genetically altered with a harmful phenotype	46385	5.78%
Total	**802976**	**100.00%**

Sweden

Sweden: Narrative 2015

Adjustments in 2018

The European Commission noticed some irregularities in the Swedish statistic for 2015. After being in contact with four users, we have adjusted their reports. In total for 2015 (after the adjustments), 254,789 animal uses were reported, of which 235,961 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

1. General information on any changes in trends observed since the previous reporting period.

1.1 Number of animals

In 2015 SE 224,979 animals are reported in first time use, compared to 278,885 in 2014. The total figure encompassing reuse is 258,403 for 2015 and 284,170 for 2014.

The most used animal species are mice, followed by fish (mainly zebra fish) and rats. These categories topped the usage also in 2014. The figure for mice is lower compared to 2014, as is the figure for rats and other fish, while the use of zebra fish has increased.

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %).

1.2 More detailed data through the new statistics

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable '*Other*' group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of '*Other…*' for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as '*others*'. This is repeated in the 2015 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

i. Basic Research (first use and re-use); number of uses 200,580

Oncology 7 %
Cardiovascular Blood and Lymphatic System 14 %
Nervous System 22 %
Respiratory System 1 %
Gastrointestinal System including Liver 2 %
Musculoskeletal System 2 %

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Immune System 15 %
Urogenital/Reproductive System 1 %
Sensory Organs (skin, eyes and ears) 2 %
Endocrine System/Metabolism 9 %
Multisystemic 9 %
Ethology / Animal Behaviour /Animal Biology 10 %
Other 6 %

Thus, for 2015, 51 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* is 6 % in 2015 compared to 8 % in 2014.

ii. Translational and applied research (first use and re-use); number of uses 43,441

Human Cancer 27 %
Human Infectious Disorders 2%
Human Cardiovascular Disorders 17 %
Human Nervous and Mental Disorders 6 %
Human Respiratory Disorders 15 %
Human Gastrointestinal Disorders including Liver 1 %
Human Musculoskeletal Disorders 1 %
Human Immune Disorders 5 %
Human Urogenital/Reproductive Disorders <1 %
Human Sensory Organ Disorders (skin, eyes and ears) <1 %
Human Endocrine/Metabolism Disorders 7 %
Other Human Disorders 4 %
Animal Diseases and Disorders 10 %
Animal Welfare < 1%
Diagnosis of diseases 1 %
Plant diseases 0%
Non-regulatory toxicology and ecotoxicology 5 %

Thus, for 2015, only 4 % of the translational and applied research was specified into more detailed human disorders instead of ending up in *Other human disorders*, compared to 20 % in 2014. These have been identified as pharmacokinetic studies, pharmacological analysis of new formulations of already approved pharmaceuticals, pharmacological studies of candidate drugs, research on hemorrhagic chock, skin and transplantation research, hematology, skeleton and cartilage diseases, development of models for sepsis and treatment of severe infections affecting organs and circulation, and development of pharmaceuticals against preeclampsia.

iii. Genetic status

Results show that most uses are animals that are genetically altered without a harmful phenotype (49%), followed by not genetically altered (44 %), and finally genetically altered with a harmful phenotype (7 %). This is a slight shift from 2014, where the main use was not genetically altered (51 %), followed by genetically altered without a harmful phenotype (46%), and genetically altered with a harmful phenotype (3%).

iv. Creation of a genetically modified line

The amount of uses in the creation of genetically modified line has increased from 1 % in 2014 to 10 % in 2015.

v. Regulatory use and routine production; number of uses 2,188

SE has a low figure in regulatory use during 2015, in line with previous reports. Most of the animals have been used in *toxicity and other safety testing including pharmacology* (93 %), mainly used in *ecotoxicity* (62 %) followed by *pharmaco-dynamics* (26 %), *kinetics* (7 %), *repeated dose toxicity* (4 %) and *other toxicity/safety testing* (1 %). The remaining 7% under regulatory use and routine production falls under *Other efficacy and tolerance testing*.

There is a drop in the figures from 2014; from 12,175 uses to 2,188 uses in 2015. This is due to an erroneous reporting in 2014 of regulatory use of roosters (9,664 uses), for more details see 2.ii. These uses were wrongly reported as EU statistics, when they should have been reported in the national statistics only. The error was detected in time for this report, and is thus not repeated for 2015.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

i. Total number of uses

There is a decrease in the total number of uses. There is, however, no clear reason for the decrease which can be due to normal fluctuations in research efforts and/or financing.

ii. Species

We see a slight decrease in the percentage of mice being used; 175,962 compared to 197,491 in 2014. During the last years the figure has been approximately the same although slightly decreasing compared to earlier years.

The use of rats decreased from 26,762 in 2014 to 21,907 in 2015. This is in line with the last years where the use has been decreasing.

The use of zebrafish more than doubled from 8,171 in 2014 to 20,519 in 2015. A major reason for this was a significant increase in the use of zebrafish in *Basic Research/Multisystemic* between the years, from 3,174 uses in 2014 to 16,233 uses in 2015.

The use of other fish has decreased by a third from 21,697 in 2014 to 14,355 in 2015. This is partly explained by a large feeding regime study constituting ca 25 % of the total uses in 2014, as well as one

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user having a significant decrease in use in 2015. However, there are many users and many different projects, especially during 2014, and the analysis is complex.

The use of domestic fowl decreased from 10,899 in 2014 to 5,266 in 2015. However, what seems like a decrease is in fact an increase – in 2014, SE reported 9,664 domestic fowl, more specifically roosters, used for the production and harvesting of hyaluronic acid from their combs, as EU statistics. In 2015 roosters have been used for the same purpose, however, after due consideration this use has been categorized as non-EU purpose. The roosters used in 2014 were thus erroneously reported as EU statistics. The use in 2015 is now mostly derived from two major studies at one user; one on welfare indicators and one on ecologically produced chicken.

There was a rise in the use of cattle, from 129 in 2014 to 2,097 in 2015. The major part was under 2015 used in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* – but there was also a specific project on raw milk during the year causing the figures to increase.

Other rodents decreased slightly from 5,296 in 2014 to 3,323 in 2015. The decrease was almost in total due to a lower use by the same user and at least in part due a misreporting of insectivores under Other rodents, instead of reporting these under Other mammals. This was corrected in the 2015 report leading to a higher amount in this area; Other mammals doubled from 1,128 in 2014 to 2,104 in 2015.

Under 2015 57 uses of ferrets were reported whereas none was reported for 2014. The ferrets were used in a study under *Basic research/Nervous system*.

The use of horses, donkeys and cross-breads increased from 58 in 2014 to 275 in 2015. The increase is to the major part due to a large study on *Translational and applied research/Animal Diseases and Disorders.*

The use of pigs has increased from 585 in 2014 to 1,625 in 2015.This change is in part due to studies performed by users who did not use pigs in 2014, and also partly to an increase in the use of pigs for *Higher education or training for the acquisition, maintenance or improvement of vocational skills* by 420 uses.

The use of reptiles increased from 9 uses in 2014 to 50 in 2015. Both years the use took place in individual studies under *Basic Research/ Ethology/Animal Behaviour/Animal Biology*; one on European grass snake (*Natrix natrix*) (2014) and the other on the common European adder (*Vipera berus*) (2015).

Under 2015 600 uses of *Rana* were reported whereas none was reported for 2014. The *Rana* were used in a study for *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

The use of *Xenopus* decreased from 1,598 in 2014 to 574 in 2015. In 2014 more users performed studies on *Xenopus*, and there were also larger studies in *Translational and applied research/ Non-regulatory*

toxicology and ecotoxicology as well as studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other.*

The use of Other amphibians decreased from 2,857 uses in 2014 to 1,894 in 2015. In 2014 there was a large study of pH-changes in aquaria under *Basic Research/Ethology/Animal Behaviour /Animal Biology* with 2,080 uses, but the smaller decrease in 2015 does not reflect this entirely. A further explanation is that more animals were used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other* in 2015 compared to 2014.

iii. Use in specific areas

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2 %), *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (1 %), *Regulatory use and Routine production* (1 %), *Preservation of species* (<1 %), and finally *Maintenance of colonies of established genetically altered animals, not used in other procedures* (<1 %). This is in close correlation with figures from 2014, with the exception of *Preservation of species* which had decreased from 3 % to less than 1 % in 2015.The figures concerning *Regulatory use and Routine production* show a decrease from 4 % to 1 % in 2015, however, the 2014 figure is too high due to an erroneous report (for explanation see 1.2.v. and 2.ii.), therefore it is not a true decrease.

A comparison of specific areas under *Basic research* 2015 and 2014 shows many areas exhibit close correlation between the two years. There is a slight decrease in *Cardiovascular Blood and Lymphatic System* (14 % vs 19 %), Nervous System (22 % vs 30 %), *Urogenital/Reproductive System* (1 % vs 2 %) and *Other basic research* (6 % vs 8%). There is a slight increase in *Gastrointestinal System including Liver* (2 % vs 1 %), *Immune System* (15 % vs 12%), *Sensory Organs (skin, eyes and ears)* (2 % vs 1%) *Multisystemic* (9 % vs 7%), and *Ethology/Animal Behaviour/Animal Biology* (10 % vs 4 %). However, it is too early to tell if these changes are trends or simply normal fluctuations in research.

Furthermore, a comparison of specific areas under *Translational and applied research* 2015 and 2014 also shows close correlation between the two years. There is a slight decrease in *Human Nervous and Mental Disorders* (6 % vs 7 %), *Human Respiratory Disorders* (15 % vs 16 %), *Other Human Disorders* (4 % vs 20 %), *Animal Diseases and Disorders* (10 % vs 11 %), *Diagnosis of diseases* (1 % vs 2 %), and *Non-regulatory toxicology and ecotoxicology* (5 % vs 8 %). There is a slight increase in *Human Cancer* (27 % vs 19 %), *Human Infectious Disorders* (2 % vs 1 %), *Human Cardiovascular Disorders* (17 % vs 12 %), *Human Immune Disorders* (5 % vs 3 %), and *Human Endocrine/Metabolism Disorders* (7 % vs 0 %). As for *Basic research* it is too early to tell if these changes are trends or simply normal fluctuations in research.

iv. Reuse

Reuse is 13 % in 2015 compared to 2 % in 2014. The higher figure could indeed to some extent be due to a higher reuse, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of reuse with some users, leading to animals erroneously being recorded as reuse when

they should not have been. Where it has been possible to correct the figures this has been done, but this was not possible in all cases. Information work has been initiated to clear this misunderstanding in future reporting.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The results for 2015 show that (51 %) procedures are moderate followed by mild [up to and including] (36 %), non-recovery (6 %) and finally severe (7 %). It follows rather closely the figures from 2014, where (56 %) procedures were moderate followed by mild [up to and including] (28 %), non-recovery (9 %) and finally severe (7 %). No conclusions can be drawn from the material at this stage.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Swedish Board of Agriculture is since 2015 building a competence centre for the 3Rs. The Swedish National Committee will act as the steering group for the centre, which will be in place late 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2016, the Swedish National Committee for the protection of animals used for scientific purposes held two courses for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

5.1 Other animals

i. Fish

41 % of the reported fish constitutes of *Other fish*. Many different species are used, e.g. three-spined stickleback (*Gasterosteus aculeatus*), perch (*Perca fluviatilis*), eel (*Anguilla anguilla*), brown trout (*Salmo trutta*), rainbow trout (*Oncorhynchus mykiss*), *Cyclostomata*, salmon (*Salmo salar*), pike (*Esox lucius*) and burbot (*Lota lota*).

These were used mainly for *Basic research/Ethology/Animal behaviour/animal biology*, but also in f e *Protection of the natural environment in the interests of the health or welfare of human beings or*

animals and Preservation of species. In translational and applied research fish were used in *Non-regulatory toxicology and ecotoxicology*.

ii. Amphibians

More than half, 62 %, of the amphibians are registered as *Other amphibians*. These are Iberian ribbed newt (*Pleurodeles waltl*), eastern newt (*Notophthalmus viridescens*), European green toad (*Bufotes viridis*) and natterjack toad (*Epidalea calamita*).

Iberian ribbed newt and eastern newt have been used in *Other basic research*, more specifically studies of the ability of the nervous system and the locomotion to heal themselves and gene function. European green toad and natterjack toad have been used in *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

iii. Birds

A large percentage, 55 %, among the birds constitutes of *Other birds.* These are Old World flycatchers (*Muscicapidae*), collared flycatcher (*Ficedula albicollis*), Eurasian blue tit (*Cyanistes caeruleus*), great tit (*Parus major*), mallard (*Anas platyrhyncos*), northern wheatear (*Oenanthe oenanthe*), Eurasian teal (*Anas crecca*), bean goose (*Anser fabalis),* willow warbler (*Phylloscopus trochilus*), golden eagle (*Aquila chrysaetos*), Eurasian wryneck (*Jynx torquilla*), Eurasian skylark (*Alauda arvensis*), carrion crow (*Corvus [corone] corone*), hooded crow (*Corvus [corone] cornix)*, common crane (*Grus grus*), Eurasian wigeon (*Anas penelope*), tufted duck (*Aythya fuligula*), common pochard (*Aythya ferina*), and northern pintail (*Anas acuta*).

Approximately half of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses and prevalence of malaria, infections in wild animals, or behavioural studies without restraining equipment. The remaining half has been used in *Basic Research/ Ethology / Animal Behaviour /Animal Biology*.

iv. Carnivores

Among the carnivores SE had a large percentage (38 %) of *Other carnivores*. These are raccoon dog (*Nyctereutes procyonoides*), fox (*Vulpes vulpes*), American mink (*Neovison vison*), Eurasian lynx (*Lynx lynx*), wolf (*Canis lupus*) and wolverine (*Gulo gulo*).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the racoon dogs, which have been used in *Translational and applied research/Animal Welfare.*

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Sweden: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	175904	69.04%
Rats	21907	8.6%
Guinea-Pigs	482	0.19%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	446	0.18%
Cats	23	0.01%
Dogs	115	0.05%
Ferrets	57	0.02%
Other carnivores	118	0.05%
Horses, donkeys and cross-breeds	275	0.11%
Pigs	1625	0.64%
Goats		
Sheep	52	0.02%
Cattle	2097	0.82%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	7	0%
Rhesus monkey	1	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1871	0.73%
Domestic fowl	5266	2.07%
Other birds	6551	2.57%
Reptiles	50	0.02%
Rana	600	0.24%
Xenopus	574	0.23%
Other Amphibians	1894	0.74%
Zebra fish	20519	8.05%
Other Fish	14355	5.63%
Cephalopods		
Total	**254789**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	190472	80.72%
Animals born in the EU but not at a registered breeder	39960	16.94%
Animals born in rest of Europe	249	0.11%
Animals born in rest of world	5277	2.24%
Total	**235958**	**100.00%**

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Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	3	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**3**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	3	100%
Self-sustaining colony		
Total	**3**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	202450	79.46%
Translational and applied research	39885	15.65%
Regulatory use and Routine production	2188	0.86%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6280	2.46%
Preservation of species	500	0.2%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3331	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	155	0.06%
Total	**254789**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	13825	6.83%
Cardiovascular Blood and Lymphatic System	28833	14.24%
Nervous System	44616	22.04%
Respiratory System	1652	0.82%
Gastrointestinal System including Liver	3971	1.96%
Musculoskeletal System	4597	2.27%
Immune System	29358	14.5%
Urogenital/Reproductive System	2892	1.43%
Sensory Organs (skin, eyes and ears)	3495	1.73%
Endocrine System/Metabolism	18578	9.18%
Multisystemic	18073	8.93%
Ethology / Animal Behaviour /Animal Biology	19510	9.64%
Other basic research	13050	6.45%
Total	**202450**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	11929	29.91%
Human Infectious Disorders	883	2.21%
Human Cardiovascular Disorders	7234	18.14%
Human Nervous and Mental Disorders	2777	6.96%
Human Respiratory Disorders	6436	16.14%
Human Gastrointestinal Disorders including Liver	386	0.97%
Human Musculoskeletal Disorders	263	0.66%
Human Immune Disorders	2053	5.15%
Human Urogenital/Reproductive Disorders	117	0.29%
Human Sensory Organ Disorders (skin, eyes and ears)	109	0.27%
Human Endocrine/Metabolism Disorders	2914	7.31%
Other Human Disorders	1636	4.1%
Animal Diseases and Disorders	728	1.83%
Animal Welfare	18	0.05%
Diagnosis of diseases	239	0.6%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	2163	5.42%
Total	**39885**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)		
Routine production		
Other efficacy and tolerance testing	144	6.58%
Toxicity and other safety testing including pharmacology	2044	93.42%
Total	**2188**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	80	3.91%
Kinetics	145	7.09%

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Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	535	26.17%
Ecotoxicity	1260	61.64%
Other toxicity/safety testing	24	1.17%
Total	**2044**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days	80	100%
Total	**80**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity	1260	100%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1260**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	928	42.41%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	1260	57.59%
Cosmetics legislation		
Other legislation		
Total	**2188**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	928	42.41%
Legislation satisfying national requirements only [within EU]	1260	57.59%
Legislation satisfying Non-EU requirements only		
Total	**2188**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235961	92.61%
Yes	18828	7.39%
Total	**254789**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	11034	4.33%
Mild [up to and including]	92991	36.5%
Moderate	132628	52.05%
Severe	18136	7.12%
Total	**254789**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	228629	89.73%
Yes	26160	10.27%
Total	**254789**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	109855	43.12%
Genetically altered without a harmful phenotype	126664	49.71%
Genetically altered with a harmful phenotype	18270	7.17%
Total	**254789**	**100.00%**

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Sweden: Narrative 2016

Adjustments in 2018

The European Commission noticed some irregularities in the Swedish statistic for 2016. After being in contact with four users, we have adjusted their reports. In total for 2016 (after the adjustments), 345,433 animal uses were reported, of which 339,299 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

1. General information on any changes in trends observed since the previous reporting period

1.1 Number of animals

For 2016, 344,255 uses were reported as first time use, compared to 224,979 in 2015. The total figure encompassing re-use was 258,403 for 2015 and 350,664 for 2016. The large part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

Re-Use	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
No	*224,979*	*87*	*344,255*	*98*
Yes	*33,424*	*13*	*6,409*	*2*
Totally	***258,403***	***100***	***350,664***	***100***

The most used animal species were mice, followed by zebra fish, rats and other fish. These four categories topped the usage also in 2015. The uses of mice, zebra fish and other fish increased numerically compared to 2015 (mice: 175,962 vs 261,847, zebrafish: 20,519 vs 24,607, and other fish: 14,355 vs 18,024). The use of rats was similar in 2015 and 2016 (21,907 vs 21,218). For the first time more uses of zebra fish than rats were reported (24,607 compared to 21,218). The major part of animals are used within *Basic Research* (81 %), followed by *Translational and applied research* (14 %).

1.2 More detailed data through the new statistics

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable '*Other'* group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of '*Other…*' for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as '*others*'. This pattern is repeated in the 2015 as well as the 2016 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

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vi. Basic Research (first use and re-use)

Basic research	2015		2016	
	Number of	*%*	*Number of*	*%*
Oncology	13,825	*7*	28,930	*10*
Cardiovascular Blood and Lymphatic System	28,833	*14*	39,229	*14*
Nervous System	44,616	*22*	51,837	*18*
Respiratory System	1,652	*1*	2,732	*1*
Gastrointestinal System including Liver	3,971	*2*	6,256	*2*
Musculoskeletal System	4,597	*2*	7,120	*3*
Immune System	29,358	*15*	42,537	*15*
Urogenital/Reproductive System	2,892	*1*	2,658	*1*
Sensory Organs (skin, eyes and ears)	3,495	*2*	4,523	*2*
Endocrine System/Metabolism	18,578	*9*	25,651	*9*
Multisystemic	18,073	*9*	31,111	*11*
Ethology / Animal Behaviour /Animal Biology	19,510	*10*	16,487	*6*
Other basic research	13,050	*6*	24,836	*9*
Totally	***202,450***	***100***	***283,907***	***100***

Thus, for 2016, 49 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* was 9 % in 2016 compared to 6 % in 2015.

vii. Translational and applied research (first use and re-use)

Translational and applied research	2015		2016	
	Number of	*%*	*Number of*	*%*
Human Cancer	11,929	*27*	14,014	*28*
Human Infectious Disorders	883	*2*	973	*2*
Human Cardiovascular Disorders	7,234	*17*	5,606	*11*
Human Nervous and Mental Disorders	2,777	*6*	4,523	*9*
Human Respiratory Disorders	6,436	*15*	5,806	*11*
Human Gastrointestinal Disorders including Liver	386	*1*	279	*1*
Human Musculoskeletal Disorders	263	*1*	246	*<1*
Human Immune Disorders	2,053	*5*	1,441	*3*
Human Urogenital/Reproductive Disorders	117	*<1*	75	*<1*
Human Sensory Organ Disorders (skin, eyes and ears)	109	*<1*	292	*1*
Human Endocrine/Metabolism Disorders	2,914	*7*	3,288	*7*
Other Human Disorders	1,636	*4*	3,802	*8*
Animal Diseases and Disorders	4,284	*10*	1,160	*2*
Animal Welfare	18	*<1*	6,578	*13*
Diagnosis of diseases	239	*1*	530	*1*
Plant diseases	0	*0*	0	*0*
Non-regulatory toxicology and ecotoxicology	2,163	*5*	1,955	*4*
Totally	***43, 441***	***100***	***50,568***	***100***

For 2016, 38 % of the translational and applied research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. For 2016, 8% were classified as *Other human disorders*, compared to 4% in 2015.

These have been identified among others as the following: Studies on anti-bacterial therapies against wound infections, research and development of products or devices in human medicine, understanding of growth mechanisms to treat children with growth abnormalities, creation of cartilage and skin in animal models, skeleton and cartilage diseases, studies on pharmaceuticals for patients with disturbed skin barriers e.g. psoriasis and eczema, research on haematology, recreation of human organs using tissue therapy for transplantation, creating individually designed blood vessels using tissue therapy for transplantation, test of substances to prevent rejection of transplanted organs, and pharmacokinetic studies of new formulations of registered pharmaceuticals.

viii. Genetic status

For 2016 most uses were of animals that were genetically altered without a harmful phenotype (52%), followed by not genetically altered (42 %), and finally genetically altered with a harmful phenotype (6 %). The figures are similar to the distribution in 2015.

Genetic Status	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Not genetically altered	113,411	*44*	146,110	*42*
Genetically altered without a harmful phenotype	126,722	*49*	182,261	*52*
Genetically altered with a harmful phenotype	18,270	*7*	22,293	*6*
Totally	**258,403**	***100***	**350,664**	***100***

ix. Creation of a genetically modified line

The amount of uses for the creation of genetically modified lines were 7 % for 2016 compared to 10 % in 2015.

x. Regulatory use and routine production

SE had a low figure in regulatory use during 2016 as in 2015. Most of the animals have been used in *Toxicity and other safety testing including pharmacology* (55 %), and *Quality control (incl batch safety and potency testing)* (40 %).

Regulatory use and routine production	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Quality control (incl batch safety and potency testing)	0	*0*	1,048	*40*
Other efficacy and tolerance testing	144	*7*	120	*5*
Toxicity and other safety testing including pharmacology	2,044	*93*	1,426	*55*
Routine production	0	*0*	5	*<1*
Totally	**2,188**	***100***	**2,599**	***100***

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

i. Total number of uses

There is an increase in the total number of uses reported, 350,664 uses in 2016 compared to 258,403

uses in 2015. The absolutely largest part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

ii. Species

There are increases as well as decreases in the number of uses in many of the species, however some of the species remain on the same level as the previous year. It is, however, difficult in most cases to determine the reasons behind the changes and also too early into the new reporting in accordance with Commission decision 2012/707/EU to tell if either increases or decreases are true significant differences that will prevail over time. We present data from 2014 to 2016 to illustrate the fluctuations over the past three year.

As discussed above, there was a large increase in number of mice uses being reported for 2016 (261,847 uses, 75 %) compared to 2015 (175,962 uses, 68 %). Much of this increase is due to a few users reporting considerably higher numbers for 2016 compared to 2015. In one case there is an increase of approximately 30,000 uses, and in another around 25,000 uses. The reason for this is unknown, but could be due to increased research funding, but also a mere consequence of the continuously rising use of mice in research that has been observed for the last decades.

Other rodents decreased from 3,323 uses in 2015 to 63 in 2016. All uses in 2016 were reported as *Basic Research* while all uses in 2015 was reported from one single user as *Translational and Applied Research*, more specifically as *Animal Diseases and Disorders*.

Cats increased from 23 uses in 2015 (all in *Basic Research/Musculoskeletal System*) to 94 uses in 2016 (54 uses in *Basic Research/Musculoskeletal System* and 40 uses in *Translational and applied research/Animal Diseases and Disorders*).

Dogs increased from 115 uses in 2015 to 204 uses in 2016. For both years most uses were reported as *Translational and applied research*. More specifically, in 2015, *Human Endocrine/ Metabolism Disorders* (83 uses), *Human Respiratory Disorders* (7 uses), *Non-regulatory toxicology and ecotoxicology* (14 uses), *Human Cardiovascular Disorders* (5 uses), and *Diagnosis of diseases* (2 uses). More specifically, in 2016,*Animal Diseases and Disorders* (128 uses), *Diagnosis of diseases* (21 uses), *Human Infectious Disorders* (6 uses), *Human Cardiovascular Disorders* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). The remaining uses in 2015 were reported in *Basic Research/Cardiovascular Blood and Lymphatic System* (5 uses), and in 2016 in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (24 uses), *Basic Research/Other* (12 uses), and *Regulatory use and Routine production/Toxicity and other safety testing including pharmacology/Kinetics* (4 uses). The wide distribution between many different categories makes it difficult to find clear reasons for the increase.

Other mammals decreased from 2,104 uses in 2015 to 427 uses in 2016. The main difference depends on the 1,500 uses of reindeer in 2015, and none in 2016. *Ethology/Animal Behaviour/Animal Biology* was the most common purpose in both years; 1,871 uses in 2015 and 416 uses in 2016.

Rabbits increased from 446 uses in 2015 to 1,447 uses in 2016. Most uses of rabbits in 2016 concerned *Basic Research* (1,391 uses), more specifically *Other basic research* (885 uses) and *Respiratory System* (409 uses).

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Horses/donkeys increased from 275 uses in 2015 to 824 uses in 2016. Most uses of horses/donkeys 2016 was reported as *Translational and Applied Research* (741 uses), more specifically as *Animal Diseases and Disorders*.

Domestic fowls decreased from 5,266 in 2015 to 971 in 2016. In 2016 most uses were reported in *Translational and applied research* (586 uses), whereas 385 uses were reported in *Basic research*. The more specific areas were diverse. Under *Basic research*; *Sensory Organs (skin, eyes and ears)* (144 uses), *Ethology / Animal Behaviour /Animal Biology* (105 uses), *Cardiovascular Blood and Lymphatic System* (84 uses), *Other basic research* (polyclonal antibodies) (37 uses), and *Endocrine System/ Metabolism* (15 uses). Under *Translational*: *Human Gastrointestinal Disorders including Liver* (240 uses), *Non-regulatory toxicology and ecotoxicology* (105 uses), *Human Respiratory Disorders* (90 uses), *Animal Diseases and Disorders* (90 uses) and *Diagnosis of diseases* (61 uses). In 2015 most uses were reported under *Basic research*, more specifically *Ethology / Animal Behaviour /Animal Biology* (4,140 uses, of which 3,240 uses are reported in a study on welfare indicators and 600 uses on ecologically produced chicken) and *Nervous System* (120 uses). Remaining uses were reported under *Translational and applied research*; *Animal Diseases and Disorders* (475 uses), *Non-regulatory toxicology and ecotoxicology* (351 uses) and *Diagnosis of diseases* (180 uses).

Other birds increased from 6,551 in 2015 to 11,583 in 2016. Almost all uses were reported as *Basic research*. In 2015, 3,008 uses were reported in *Ethology/Animal Behaviour/Animal Biology,* and 3,543 uses in *Other Basic Research* (blood sampling for gene analyses and prevalence of malaria, 2,969 uses; infections on wild animals, 553 uses; behavioural studies, 21 uses). In 2016, 4,570 uses were reported in *Ethology/Animal Behaviour/Animal Biology.* The large increase for 2016 is found under *Other Basic Research* with 6,940 uses reported (blood sampling for genetical analyses, 3,486; blood sampling, 3,072 uses; infections on wild animals, 365 uses; and behavioural studies, 17 uses). Remaining uses were reported under *Musculoskeletal System* (8 uses), *Sensory organs* (4 uses) and *Translational and applied research, Animal Diseases and Disorders* (61 uses).

Reptiles increased from 50 in 2015 to 380 in 2016. All were used in *Basic research*, more specifically, in 2015 in *Ethology / Animal Behaviour /Animal Biology*, and in 2016 in the *Other* category; 300 uses in evolutionary biology and 80 uses for blood sampling and marking.

The use of Other amphibians increased from 1,894 in 2015 to 3,923 in 2016. All were reported under Basic research. In 2015, 1,236 uses were reported for studies of the ability of the nervous system and the locomotion to heal themselves and gene function compared to 1,624 in 2016. In 2016, 1,320 uses of moor frog (*Rana arvalis*) were reported in *Basic Research/Ethology/Animal Behaviour/Animal Biology*, and another study in 2016 reported 553 uses for how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. Remaining uses were reported in the *Other* category for 2016 (426 uses, 130 of these for marking) and in *Ethology/Animal Behaviour/Animal Biology* for 2015 (658 uses).

Animal group	**Animal species**	**2014**	**2015**	**2016**
Rodents	Mice	197,491	175,962	261,847
	Rats	26,762	21,907	21,218

	Guinea-Pigs	663	482	422
	Hamsters (Syrian)	0	0	0
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	5,296	3,323	63
Lagomorphs	Rabbits	571	446	1,447
Carnivores	Cats	28	23	94
	Dogs	111	115	204
	Ferrets	0	57	0
	Other carnivores	91	118	167
Ungulates	Horses, donkeys and cross-breeds	58	275	824
	Pigs	585	1,625	1,840
	Goats	0	0	58
	Sheep	51	52	27
	Cattle	129	2,097	1,436
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	3	7	10
	Rhesus monkey	0	1	28
	Vervets (Chlorocebus spp.)	0	0	0
	Baboons	0	0	0
	Squirrel monkey	0	0	0
	Other species of New World Monkeys (Ceboidea)	0	0	0
	Other species of Old World Monkeys (Cercopithecoidea)	0	0	0
	Other species of non-human primates	0	0	0

	Apes	0	0	0
Other mammals	Other mammals	1,128	2,104	427
Birds	Domestic fowl	10,899	5,266	971
	Other birds	5,972	6,551	11,583
Reptiles	Reptiles	9	50	380
Amphibians	Rana	0	600	623
	Xenopus	1,598	574	441
	Other amphibians	2,857	1,894	3,923
Fish	Zebra fish	8,171	20,519	24,607
	Other fish	21,697	14,355	18,024
Cephalopods	Cephalopods	0	0	0
	Total uses	**284,170**	**258,403**	**350,664**

iii. Use in specific areas

The uses in overall, in percentages, were similar in 2015 and 2016, but the percentages of two of the less frequent reported categories have changed between 2015 and 2016. The category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has dropped from 2.4 % (6,280 uses) to 0.7 % (2,759 uses). *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased from 0.1 % (213 uses) to 1.6 % (5,676 uses).

The percentages for the specific areas under both *Basic research* and *Translational and applied research* 2015 and 2016 are similar. The most notable differences are for *Animal Diseases and Disorders* which were reported for 10 % (4,284 uses) in 2015 and 2 % (1,160 uses) in 2016 and *Animal Welfare* which increased from <1 % (18 uses) in 2015 to 13 % (6,578 uses) in 2016.

It is too early to tell if these changes are trends or simply normal fluctuations in research.

iv. Re-use

Re-use were reported for 2 % of the uses in 2016. For 2015, that number was 13 %; that higher figure could indeed to some extent be due to a higher re-use, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of re-use with some users, leading to animals erroneously being recorded as re-used when they should not have been. Figures were corrected where it was possible, which was unfortunately not always the case. In order to improve the future quality of the reporting, information efforts were initiated, that are believed to have led to a more accurate reporting on re-use in the 2016 statistics.

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3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of moderate severity has increased from 51 % in 2015 to 58 % in 2016, while the proportions of *Mild* and *Non-recovery* have decreased. No conclusions can be drawn from the material at this stage.

Severity	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Non-recovery	14,648	*6*	6,427	*2*
Mild (up to and including)	92,991	*36*	112,034	*32*
Moderate	132,628	*51*	202,626	*58*
Severe	18,136	*7*	29,577	*8*
Totally	**258,403**	***100***	**350,664**	***100***

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Swedish parliament decided in late 2016 to finance a competence centre for the 3Rs, placed at the Swedish Board of Agriculture. The Swedish National Committee will act as the steering group for the centre. The centre will have its official opening on the 21th of November 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2017, the Swedish National Committee for the protection of animals used for scientific purposes held one course for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

5.1 Other animals

i. Fish

42 % of the reported fish constitutes of *Other fish*. Of the 18,024 uses of *Other fish* most are reported as three-spined stickleback (*Gasterosteus aculeatus*, 4,339 uses), brown trout (*Salmo trutta,* 3,983 uses), salmon (*Salmo salar,* 3,417 uses), perch (*Perca fluviatilis,* 1,443 uses) and common roach (*Rutilus rutilus*, 1,358 uses).

The fish in this category were used mainly for *Basic research/Ethology/Animal behaviour/animal biology (8,303 uses)* and in *Translational and applied research/Animal Welfare* (6,566 uses), but also in *Protection of the natural environment in the interests of the health or welfare of human beings or*

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animals (2,159 uses). Remaining uses are reported in *Basic research* (*Gastrointestinal System including Liver,* 294 uses*; Nervous system,* 66 uses*;* and *Cardiovascular Blood and Lymphatic System*, 29 uses); *Translational and applied research (Diagnosis of disease,* 154 uses; and *Non-regulatory toxicology and ecotoxicology*, 70 uses) and *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (13 uses).

ii. Amphibians

79 %, of the amphibians are registered as *Other amphibians*. The category (3,923 uses) consists mostly of moor frog (*Rana arvalis*, 1,614 uses), Iberian ribbed newt (*Pleurodeles waltl,* 1,570 uses), but also common toad (*Bufo bufo*, 500 uses), natterjack toad (*Epidalea calamita,* 143 uses), eastern newt (*Notophthalmus viridescens*, 54 uses), European green toad (*Bufotes virides*, 36 uses) and edible frog (*Pelophylax kl esculentus*, 6 uses).

Most other amphibians have been used in *Other basic research*. Iberian ribbed newt and eastern newt have been used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function. Furthermore, the common toad, moor frog, European green toad, natterjack toad and edible frog have been used to understand how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. 1,320 uses of moor frog were categorised as *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

iii. Birds

A large percentage, 92 %, among the birds constitutes of *Other birds.* These (11,583 uses) consist mostly of Old World flycatchers (*Muscicapidae,* 3,486 uses), followed by collared flycatcher (*Ficedula albicollis*, 1,750 uses), Eurasian blue tit (*Cyanistes caeruleus*, 1,962 uses), European pied flycatcher (*Ficedula hypoleuca*, 766 uses) and marsh tit (*Poecile palustris*, 641 uses).

60 % of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses, infections in wild animals, or behavioural studies without restraining equipment. The remaining birds have been used in *Basic Research: Ethology / Animal Behaviour /Animal Biology* (4,570 uses), *Musculoskeletal System* (8 uses) and *Sensory Organs* (4 uses); and in *Translational and applied research/Animal Diseases and Disorders* (61 uses).

iv. Carnivores

Among the carnivores SE had a large percentage (36 %) of *Other carnivores*. These (167 uses) are mainly brown bear (*Ursus arctos*, 68 uses) and raccoon dog (*Nyctereutes procyonoides*, 60 uses), but also fox (*Vulpes vulpes*, 17 uses), American mink (*Neovison vison*, 12 uses), wolf (*Canis lupus,* 6 uses), and wolverine (*Gulo gulo*, 4 uses).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the American mink, used in *Translational and applied research/Animal Welfare.*

5.2 Other legislation

14 % of the uses in *Testing by legislation* are reported under *Other legislation*. These constitute 320 uses of rainbow trout (*Oncorhyncus mykiss*) and 50 uses of three-spined stickleback (*Gasterosteus aculeatus*) in *Regulatory use and Routine production /Toxicity and other safety testing including pharmacology/Acute and sub-acute/Non lethal methods, Legislation satisfying EU requirements.* The user has identified this legislation as concerning biotoxicity.

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6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Sweden: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	255949	74.24%
Rats	21218	6.15%
Guinea-Pigs	422	0.12%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	63	0.02%
Rabbits	1447	0.42%
Cats	94	0.03%
Dogs	204	0.06%
Ferrets		
Other carnivores	167	0.05%
Horses, donkeys and cross-breeds	824	0.24%
Pigs	1840	0.53%
Goats	58	0.02%
Sheep	27	0.01%
Cattle	1436	0.42%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	10	0%
Rhesus monkey	28	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	427	0.12%
Domestic fowl	971	0.28%
Other birds	11583	3.36%
Reptiles	380	0.11%
Rana	623	0.18%
Xenopus	441	0.13%
Other Amphibians	3923	1.14%
Zebra fish	24607	7.14%
Other Fish	18024	5.23%
Cephalopods		
Total	**344766**	**100.00%**

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Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	261665	77.28%
Animals born in the EU but not at a registered breeder	67459	19.92%
Animals born in rest of Europe	5884	1.74%
Animals born in rest of world	3586	1.06%
Total	**338594**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	38	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**38**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	38	100%
Self-sustaining colony		
Total	**38**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	283240	82.15%
Translational and applied research	50568	14.67%
Regulatory use and Routine production	2599	0.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2759	0.8%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5155	1.5%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	445	0.13%
Total	**344766**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	28930	10.21%
Cardiovascular Blood and Lymphatic System	39229	13.85%
Nervous System	51837	18.3%
Respiratory System	2732	0.96%
Gastrointestinal System including Liver	6256	2.21%
Musculoskeletal System	7120	2.51%
Immune System	41870	14.78%
Urogenital/Reproductive System	2658	0.94%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	4523	1.6%
Endocrine System/Metabolism	25651	9.06%
Multisystemic	31111	10.98%
Ethology / Animal Behaviour /Animal Biology	16487	5.82%
Other basic research	24836	8.77%
Total	**283240**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14014	27.71%
Human Infectious Disorders	973	1.92%
Human Cardiovascular Disorders	5606	11.09%
Human Nervous and Mental Disorders	4523	8.94%
Human Respiratory Disorders	5806	11.48%
Human Gastrointestinal Disorders including Liver	279	0.55%
Human Musculoskeletal Disorders	246	0.49%
Human Immune Disorders	1441	2.85%
Human Urogenital/Reproductive Disorders	75	0.15%
Human Sensory Organ Disorders (skin, eyes and ears)	292	0.58%
Human Endocrine/Metabolism Disorders	3288	6.5%
Other Human Disorders	3802	7.52%
Animal Diseases and Disorders	1160	2.29%
Animal Welfare	6578	13.01%
Diagnosis of diseases	530	1.05%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1955	3.87%
Total	**50568**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1048	40.32%
Other efficacy and tolerance testing	120	4.62%
Toxicity and other safety testing including pharmacology	1426	54.87%
Routine production	5	0.19%
Total	**2599**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	36	3.44%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	1012	96.56%
Total	**1048**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	370	25.95%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Neurotoxicity	119	8.35%
Kinetics	937	65.71%
Total	**1426**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	370	100%
Total	**370**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	5	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**5**	**100.00%**

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Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1093	42.05%
Legislation on medicinal products for veterinary use and their residues	1136	43.71%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	370	14.24%
Total	**2599**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2594	99.81%
Legislation satisfying national requirements only [within EU]	5	0.19%
Legislation satisfying Non-EU requirements only		
Total	**2599**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	338632	98.22%
Yes	6134	1.78%
Total	**344766**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	6427	1.86%
Mild [up to and including]	111460	32.33%
Moderate	197302	57.23%
Severe	29577	8.58%
Total	**344766**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	318807	92.47%
Yes	25959	7.53%
Total	**344766**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	145476	42.2%
Genetically altered without a harmful phenotype	176997	51.34%
Genetically altered with a harmful phenotype	22293	6.47%
Total	**344766**	**100.00%**

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Sweden: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

Total number of uses
There was a decrease in the total number of uses reported for 2017 (325,838 uses) compared to 2016 (345,433 uses), but more were used than in 2015 (254,789 uses).

Genetic status
The use of genetically altered animals with a harmful phenotype has gradually increased since 2015; with twice as many uses reported in 2017 (36,929 uses, 11%) compared to 2015 (18,270 uses, 7%).

Place of birth
A minority of the animal uses in 2017 were with animals born in rest of the world (2,714 uses, 1%), and the numbers have decreased compared to 2016 (3,586 uses, 1%) and 2015 (5,277 uses, 2%).

Non-human Primate Source
Most uses of non-human primates in 2017 (19 uses, 76%) were of primates born in America. This is in contrast to both 2016 and 2015 were all were born in Asia (2016: 38 uses, 2015: 3 uses).

Species
Hamsters (Syrian) increased to 34 uses in 2017, while none was reported for 2016 and 2015. Most (31 uses) of the uses in 2017 were reported as *Translational and Applied Research*, mainly *Human Endocrine/Metobolism Studies* (26 uses). Other rodents decreased to 5 uses in 2017 compared to 63 uses in 2016; none was reported for 2015. All uses in 2017 of other rodents were reported as *Preservation of species.*

Dogs had 386 uses in 2017, which is an increase compared to 2016 (204 uses) and 2015 (115 uses). For all three years, most uses were reported as *Translational and applied research* (for 2017 it was 330 uses, 85%). More specifically in 2017: *Animal Diseases and Disorders* (251 uses), *Human Cardiovascular Disorders* (45 uses), *Human Respiratory Disorders* (15 uses), *Diagnosis of diseases* (10 uses), *Human Endocrine/Metobolism Studies* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). Also for 2016 *Animal Diseases and Disorders* were the most reported category in *Translational and applied research* (785 in 2016, 765 in 2017).

Horses, donkeys and cross-breeds had 41 uses in 2017 which is a large decrease compared to 2016 (824 uses) and 2015 (275 uses). The uses in 2017 was reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (26 uses) and *Basic research* (15 uses, of which 8 were for *Other basic research* and 7 for *Respiratory System*). A main difference from 2016 is that one user in 2016 reported 741 uses (90%) as *Translational and Applied Research* (more specifically as *Animal Diseases and Disorders*).

Goats had 30 uses in 2017, which is about half as many as in 2016 (58 uses); none was reported for 2015. In 2017 most uses were reported in *Translational and applied research,* more precisely *Diagnosis of diseases* (20 uses), whereas 10 uses were reported in *Basic research*. The uses was similar in 2016 except that 24 uses were reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* in 2016.

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Domestic fowls had 1,452 uses in 2017, which is an increase compared to 2016 (971 uses), but a decrease compared to 2015 (5,266 uses). In 2017 most uses were reported in *Translational and applied research* (1,125 uses), more specifically *Non-regulatory toxicology and ecotoxicology* (653 uses), followed by *Animal Diseases and Disorders* (130 uses), *Human Infectious Disorders* (128 uses), and *Human Respiratory Disorders* (118 uses). Of the reported domestic fowls 327 uses were reported in *Basic research*, mainly in *Cardiovascular Blood and Lymphatic System* (200 uses) and *Oncology* (76 uses). Also in 2016 most fowl uses were reported as *Translational and applied research* (586 uses), followed by *Basic research* (385 uses). The more specific areas were diverse in 2016 as well.

No reptiles was reported for 2017, which is a decrease compared to 2016 (380 uses) and 2015 (50 uses). In 2016 all uses were reported as *Other basic research*, more specifically: evolutionary biology (300 uses) and blood sampling and marking (80 uses).

Rana (a genus of frogs) had 308 uses in 2017, which is about half as many compared to 2016 (623 uses) and 2015 (600 uses). In 2017, the uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (200 uses), and *Translational and applied research,* more specifically *Non-regulatory toxicology and ecotoxicology* (108 uses). For 2015 and 2016 all or almost all (100% respectively 96%) uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

Xenopus (a genus of frogs) had 261 uses in 2017, and has had a gradual decrease from 2015 to 2017 (2016: 441 uses and 2015: 574 uses). For 2017 the uses were reported as *Basic research* (145 uses, all under *Nervous System*) and *Translational and applied research* (116 uses, all under *Non-regulatory toxicology and ecotoxicology*). Both these categories had uses reported in 2015 and 2016 as well.

Other amphibians had 2,694 uses in 2017, which is a decrease compared to 2016 (3,923 uses), but an increase compared to 2015 (1,894 uses). For 2017 most uses were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses; all to study how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians). For 2017 an additional 60 uses were reported as *Preservation of species* and 60 uses as *Translational and applied research*, more specifically *Non-regulatory toxicology and ecotoxicology*. For both 2015 and 2016 all uses were reported under Basic research (*Ethology/Animal Behaviour/Animal Biology* and *Other basic research*).

Zebra fish has gradually increased since 2015. For 2017 was 29,158 uses reported, compared to 24,607 uses in 2016 and 20,519 uses in 2015. The uses in 2017 were reported as *Basic Research* (19,057 uses, mainly *Cardiovascular Blood and Lymphatic System* [7,282 uses] and *Multisystemic* [7,399 uses]) and *Translational and applied research* (10,101 uses, mainly
Human Nervous and Mental Disorders [7,000 uses] and *Human Endocrine/Metabolism Disorders* [300 uses]).

Other fish has gradually increased since 2015. For 2017 was 33,940 uses reported, compared to 18,024 uses in 2016 and 14,355 uses in 2015. For 2017 most uses was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in the category *Ethology/Animal Behaviour/Animal Biology*).

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The uses in overall are similar 2015-2017. A change is that the category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has increased to 27,916 in 2017 compared to 2,759 uses in 2016 and 6,280 uses in 2015. In 2017, 98% of these uses were other fish. Another change is that *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased to 1,679 uses in 2017 compared to 445 uses in 2016 and 155 uses in 2015. In 2017, 99% of these uses were mice and all were classified as mild severity.

The number of uses for many of the categories under *Basic research* are either similar to 2016 or to 2015. A change is that *Respiratory System* increased to 7,362 uses in 2017 compared to 2,732 uses in 2016 and 1,652 uses in 2015. *Gastrointestinal System including Liver* has decreased to 1,531 uses from 6,256 uses in 2016 and 3,971 uses in 2015. In addition, the *Immune System* has decreased; 23,611 uses in 2017 compared to 42,537 uses in 2016.

The number of uses for many of the categories under *Translational and applied research* are either similar to 2016 or to 2015. A change is that *Human Nervous and Mental Disorders* increased to 9,737 uses in 2017 compared to 4,523 uses in 2016 and 2,777 uses in 2015. In addition, *Human Immune Disorders* increased to 9,271 uses in 2017 compared to 1,441 uses in 2016 and 2,053 uses in 2015; and *Human Endocrine/Metabolism Disorders* increased to 5,687 uses in 2017 compared to 3,288 uses in 2016 and 2,914 uses in 2015.

It is unclear what the changes depends on.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The uses with severe severity has gradually increased since 2015, reaching 41,475 uses (13%) in 2017, which is more than twice as many as in 2015 (18,136 uses, 7%). Most uses classified as severe in 2017 were reported as *Basic research* (79%). Of those, *Oncology*, *Nervous system*, *Respiratory system* and *Musculoskeletal System* are purpose categories that has increased 2015-2017. *Oncology* increased from 516 uses in 2015 to 4,854 uses in 2017, *Nervous system* from 8,375 uses in 2015 to 12,466 uses in 2017, *Respiratory system* from 0 uses in 2015 to 979 uses in 2017, and *Musculoskeletal System* from 732 uses in 2015 to 1,895 uses in 2017.

Of the uses classified as severe in 2017 under *Translational and applied research* (21%), *Human Immune disorders* increased most (2015: 50 uses; 2017: 7,191 uses) and *Human Cancer* decreased most (2015: 853 uses; 2017: 33 uses).

25% of the uses reported as severe in 2017 comes from two purposes in two user reports. One of the report has 6,869 uses within *Human Immune disorders* and the other has 3,316 uses within *Nervous System* (*Basic research*).

It is unclear what the changes depends on.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Sweden established a 3Rs center for the promotion of the 3Rs. The Swedish 3Rs Center had its official opening on the 21st of November 2017. The 3Rs Center is the executive body of the Swedish National Committee for the Protection of Animals Used for Scientific Purposes. As such, the 3Rs Center assists the Committee in carrying out its tasks by e.g. developing advice on alternative methods, disseminating information on the 3Rs, and supporting the local animal welfare bodies, the regional ethics committees and authorities concerned with animal experiments.

During 2017, two working groups were appointed by the National Committee to develop advice for marking and tagging of fish, and group housing of male mice. While the fish project is entirely based on existing literature, the mice project also includes workshops and a questionnaire targeting animal technicians and researchers.

On 14 June 2017, the Swedish 3Rs Center together with the Users' Committee and the Ethics and Education Committee held a meeting with Sweden's animal welfare bodies.
The purpose of the meeting was to establish contact and develop efficient cooperation methods between the animal welfare bodies and the 3Rs Center as the committee's executive body. The meeting provided an opportunity for the participants to make new contacts, gather new knowledge and acquire new tools to carry out their assignments effectively.

On 17–19 October 2017, the Committee on ethics and education of the National Committee together with the Swedish Centre for Animal Welfare (SCAW) arranged the annual education in ethical evaluation for members of the regional ethics committees. The Swedish 3Rs Center participated with a lecture.

In November 2017, the 3Rs Centre used a quantitative questionnaire to learn more about researchers´ thoughts and implementation of the 3Rs, but also to increase their awareness of the 3Rs and the Swedish 3Rs Centre. The results from the survey shall serve as base for the development of further strategies to promote the 3Rs. The results were presented at the scientific conference Scand-LAS in 2018, and will be published in a report.

The Swedish Government has suggested that the Swedish 3Rs Center support six authorities in their 3Rs work by, for example, compiling and reviewing the authorities' 3R-related activities and the establishing of 3R-strategies. During 2017, the centre begun working on compiling and analysing these authorities' 3R-strategies.

The Swedish 3Rs Center created a website during 2017. This is an important channel for disseminating information on the 3Rs. It is accessible via the Swedish Board of Agriculture's website with its home page: www.jordbruksverket.se/3R. During the development of the website, the focus was on putting together pages with information on what the 3Rs are and why it is important to work with the 3Rs. The website also contains information on the centre's history, vision, mission and objectives as well as the National Committees and 3Rs centers organisational structure. During 2017 the 3Rs Center started also working on developing more specialised pages with information on, for example, animal welfare bodies, how to apply for research funding for projects linked to the 3Rs as well as links to other organisations

that work with animal welfare and 3R-related issues. Those pages were published early in 2018. The 3Rs Center also publishes news and information on its website regarding courses and conferences related to the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other fish
54% of the reported fish constitutes of other fish. Of the 33,940 uses of other fish most are reported as goldsinny wrasse (*Ctenolabrus rupestris*, 8,518 uses), corkwing wrasse (S*ymphodus melops*, 6,127 uses), and Atlantic cod (*Gadus morhua,* 5,224 uses). As mentioned above (section 1), most uses of other fish was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in *Ethology/Animal Behaviour/Animal Biology*).

Other amphibians
83% of the amphibians are registered as other amphibians. This category (2,787 uses) consists mostly of moor frog (*Rana arvalis*, 1,132 uses), Iberian ribbed newt (*Pleurodeles waltl,* 956 uses) and common toad (*Bufo bufo*, 388 uses). As mentioned above (section 1), most uses of other amphibians were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses).

Other birds
89% of the birds are reported as other birds. These 11,269 uses consist mostly of European pied flycatcher (*Ficedula hypoleuca,* 3,511 uses), followed by Eurasian blue tit (*Cyanistes caeruleus*, 1,882 uses), collared flycatcher (*Ficedula albicollis*, 1,800 uses), great tit (*Parus major*, 978 uses), mallard (*anas platyrhynchos*, 663 uses), and marsh tit (*Poecile palustris*, 558 uses). Most uses of other birds was reported as *Basic research* (10,744 uses, of which 10,072 was specified as *Ethology/Animal Behaviour/Animal Biology*).

Other carnivores
22% of the carnivores was recorded as other carnivores. These 140 uses consist of *Arctic fox* (*Vulpes lagopus*, 66 uses), raccoon dog (*Nyctereutes procyonoides*, 39 uses), red fox (*Vulpes vulpes*, 22 uses), wolverine (*Gulo gulo*, 7 uses) and wolf (*Canis lupus,* 6 uses). The uses of other carnivores was reported as *Preservation of species* (73 uses), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (369 uses), and *Basic research* (28 uses).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Appendix

The European Commission noticed some irregularities in the Swedish statistic for 2015 and 2016. After being in contact with those users, we have adjusted their reports. We have used the updated numbers for 2015 and 2016 in the present narrative.

Animal group	**Animal species**	**2015**	**2016**	**2017**
Rodents	Mice	175,904	256,616	221,232
	Rats	21,907	21,218	19,437
	Guinea-Pigs	482	422	409
	Hamsters (Syrian)	0	0	34
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	0	63	5
Lagomorphs	Rabbits	446	1,447	1,574
Carnivores	Cats	23	94	104
	Dogs	115	204	386
	Ferrets	57	0	0
	Other carnivores	118	167	140
Ungulates	Horses, donkeys and cross-breeds	275	824	41
	Pigs	1,625	1,840	1,557
	Goats	0	58	30
	Sheep	52	27	35
	Cattle	2,097	1,436	1,420
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	7	10	2
	Rhesus monkey	1	28	23
	Vervets (Chlorocebus spp.)	0	0	0
	Baboons	0	0	0
	Squirrel monkey	0	0	0
	Other species of New World Monkeys (Ceboidea)	0	0	0
	Other species of Old World Monkeys (Cercopithecoidea)	0	0	0
	Other species of non-human primates	0	0	0
	Apes	0	0	0
Other mammals	Other mammals	1,871	427	327
Birds	Domestic fowl	5,266	971	1,452
	Other birds	6,551	11,583	11,269

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Reptiles	Reptiles	50	380	0
Amphibians	Rana	600	623	308
	Xenopus	574	441	261
	Other amphibians	1,894	3,923	2,694
Fish	Zebra fish	20,519	24,607	29,158
	Other fish	14,355	18,024	33,940
Cephalopods	Cephalopods	0	0	0
	Total uses	**254,789**	**345,433**	**325,838**

Severity	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Non-recovery	11,034	*4*	6,427	*2*	*9,324*	*3*
Mild (up to and including)	92,991	*37*	112,034	*32*	*109,950*	*34*
Moderate	132,628	*52*	197,395	*57*	*165,089*	*51*
Severe	18,136	*7*	29,577	*9*	*41,475*	*13*
Totally	**258,345**	***100***	**345,433**	***100***	***325,838***	***100***

Genetic Status	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Not genetically altered	109,855	*43*	146,110	*42*	*150,383*	*46*
Genetically altered without a harmful phenotype	126,664	*50*	177,030	*51*	*138,526*	*43*
Genetically altered with a harmful phenotype	18,270	*7*	22,293	*6*	*36,929*	*11*
Totally	**254,789**	***100***	**345,433**	***100***	***325,838***	***100***

Regulatory use and routine production	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Quality control (incl batch safety and potency testing)	0	*0*	1,048	*40*	*773*	*32*
Other efficacy and tolerance testing	144	*7*	120	*5*	*235*	*10*
Toxicity and other safety testing including pharmacology	2,044	*93*	1,426	*55*	*1,416*	*58*
Routine production	0	*0*	5	*<1*	*0*	*0*
Totally	**2,188**	***100***	**2,599**	***100***	***2,424***	***100***

Re-use	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
No	235,961	*93*	339,299	*98*	319,236	*98*
Yes	18,828	*7*	6,134	*2*	6,602	*2*
Totally	**254,789**	***100***	**345,433**	***100***	**325,838**	***100***

Basic research (first use and re-use)	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Oncology	13,825	*7*	28,930	*10*	*22,557*	*10*
Cardiovascular Blood and Lymphatic System	28,833	*14*	39,229	*14*	*44,731*	*19*
Nervous System	44,616	*22*	51,837	*18*	*53,838*	*23*
Respiratory System	1,652	*1*	2,732	*1*	*7,362*	*3*
Gastrointestinal System including Liver	3,971	*2*	6,256	*2*	*1,531*	*1*
Musculoskeletal System	4,597	*2*	7,120	*3*	*4,220*	*2*
Immune System	29,358	*15*	42,537	*15*	*23,611*	*10*
Urogenital/Reproductive System	2,892	*1*	2,658	*1*	*6,543*	*3*
Sensory Organs (skin, eyes and ears)	3,495	*2*	4,523	*2*	*3,150*	*1*
Endocrine System/Metabolism	18,578	*9*	25,651	*9*	*28,055*	*12*
Multisystemic	18,073	*9*	31,111	*11*	*10,201*	*4*
Ethology / Animal Behaviour /Animal Biology	19,510	*10*	16,487	*6*	*16,914*	*7*
Other basic research	13,050	*6*	24,836	*9*	*10,528*	*5*
Totally	***202,450***	***100***	***283,907***	***100***	***233,241***	***100***

Translational and applied research (first use and re-use)	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Human Cancer	11,929	*30*	14,014	*28*	10,841	*19*
Human Infectious Disorders	883	*2*	973	*2*	1,328	*2*
Human Cardiovascular Disorders	7,234	*18*	5,606	*11*	6,483	*12*
Human Nervous and Mental Disorders	2,777	*7*	4,523	*9*	9,737	*17*
Human Respiratory Disorders	6,436	*16*	5,806	*11*	5,077	*9*
Human Gastrointestinal Disorders including Liver	386	*1*	279	*1*	0	*0*
Human Musculoskeletal Disorders	263	*1*	246	*<1*	862	*2*
Human Immune Disorders	2,053	*5*	1,441	*3*	9,271	*17*
Human Urogenital/Reproductive Disorders	117	*<1*	75	*<1*	255	*<1*
Human Sensory Organ Disorders (skin, eyes and ears)	109	*<1*	292	*1*	500	*1*
Human Endocrine/Metabolism Disorders	2,914	*7*	3,288	*7*	5,687	*10*
Other Human Disorders	1,636	*4*	3,802	*8*	2,323	*4*
Animal Diseases and Disorders	728	*2*	1,160	*2*	704	*1*
Animal Welfare	18	*<1*	6,578	*13*	105	*<1*
Diagnosis of diseases	239	*1*	530	*1*	542	*1*
Plant diseases	0	*0*	0	*0*	0	*0*
Non-regulatory toxicology and ecotoxicology	2,163	*5*	1,955	*4*	1,998	*4*
Totally	***39,885***	***100***	***50,568***	***100***	***55,713***	***100***

Sweden: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	220281	67.83%
Rats	19321	5.95%
Guinea-Pigs	409	0.13%
Hamsters (Syrian)	34	0.01%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	5	0%
Rabbits	1574	0.48%
Cats	104	0.03%
Dogs	386	0.12%
Ferrets		
Other carnivores	140	0.04%
Horses, donkeys and cross-breeds	41	0.01%
Pigs	1557	0.48%
Goats	30	0.01%
Sheep	35	0.01%
Cattle	1420	0.44%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	2	0%
Rhesus monkey	23	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	327	0.1%
Domestic fowl	1452	0.45%
Other birds	11269	3.47%
Reptiles		
Rana	308	0.09%
Xenopus	261	0.08%
Other Amphibians	2694	0.83%
Zebra fish	29158	8.98%
Other Fish	33940	10.45%
Cephalopods		
Total	**324771**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	249147	78.31%
Animals born in the EU but not at a registered breeder	64675	20.33%
Animals born in rest of Europe	1608	0.51%
Animals born in rest of world	2714	0.85%
Total	**318144**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	6	24%
Animals born in America	19	76%
Animals born in Africa		
Animals born elsewhere		
Total	**25**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	25	100%
Self-sustaining colony		
Total	**25**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	232174	71.49%
Translational and applied research	55713	17.15%
Regulatory use and Routine production	2424	0.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	27916	8.6%
Preservation of species	617	0.19%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4248	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	1679	0.52%
Total	**324771**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	22549	9.71%
Cardiovascular Blood and Lymphatic System	44502	19.17%
Nervous System	53425	23.01%
Respiratory System	7362	3.17%
Gastrointestinal System including Liver	1531	0.66%
Musculoskeletal System	4220	1.82%
Immune System	23194	9.99%
Urogenital/Reproductive System	6543	2.82%
Sensory Organs (skin, eyes and ears)	3150	1.36%
Endocrine System/Metabolism	28055	12.08%
Multisystemic	10201	4.39%
Ethology / Animal Behaviour /Animal Biology	16914	7.29%
Other basic research	10528	4.53%
Total	**232174**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	10841	19.46%
Human Infectious Disorders	1328	2.38%
Human Cardiovascular Disorders	6483	11.64%
Human Nervous and Mental Disorders	9737	17.48%
Human Respiratory Disorders	5077	9.11%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	862	1.55%
Human Immune Disorders	9271	16.64%
Human Urogenital/Reproductive Disorders	255	0.46%
Human Sensory Organ Disorders (skin, eyes and ears)	500	0.9%
Human Endocrine/Metabolism Disorders	5687	10.21%
Other Human Disorders	2323	4.17%
Animal Diseases and Disorders	704	1.26%
Animal Welfare	105	0.19%
Diagnosis of diseases	542	0.97%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1998	3.59%
Total	**55713**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	773	31.89%
Other efficacy and tolerance testing	235	9.69%
Toxicity and other safety testing including pharmacology	1416	58.42%
Routine production		
Total	**2424**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	773	100%
Total	**773**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	113	7.98%
Kinetics	1303	92.02%
Total	**1416**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	113	100%
29 - 90 days		
> 90 days		
Total	**113**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1651	68.11%
Legislation on medicinal products for veterinary use and their residues	773	31.89%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		

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Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total	**2424**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2424	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2424**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	318169	97.97%
Yes	6602	2.03%
Total	**324771**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9324	2.87%
Mild [up to and including]	109850	33.82%
Moderate	164539	50.66%
Severe	41058	12.64%
Total	**324771**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	291525	89.76%
Yes	33246	10.24%
Total	**324771**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	149970	46.18%
Genetically altered without a harmful phenotype	137872	42.45%
Genetically altered with a harmful phenotype	36929	11.37%
Total	**324771**	**100.00%**

United Kingdom

United Kingdom: Narrative 2015

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2015 data for Great Britain on the 20 July 2016 and the statistical release can be accessed online here:

https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2015.

The Northern Ireland Department for Health data is available here:
https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the Department for Health. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures' whereas this information is not provided to the EU. The UK releases additionally include, for all other purposes of procedure, procedures assessed as having sub-threshold or mild severity but such procedures are submitted to the EU in the "Mild [up to and including]" category. Additional breakdowns are also collected for the source of animals (distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (birds, dogs). These breakdowns are aggregated to form the EU categories prior to submission to the EU.

Comparison between the 2015 and 2014 data should be exercised with caution due to some under-reporting and misclassification in 2014. See introductory section, data quality section (page 7) of 'Annual Statistics of Scientific Procedures on Living Animals Great Britain 2015' for further information. The report can be accessed online at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/537708/scientific-procedures-living-animals-2015.pdf.

1. General information on any changes in trends observed since the previous reporting period.

In 2015, a total of 3.17 million procedures were completed. This represents an increase of 3% (92 thousand) compared with the 3.08 million procedures completed in 2014.

Of the 3.17 million procedures, 2.10 million (66%) were experimental procedures and 1.07 million (34%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2014, experimental procedures have increased by 8% (155 thousand) and creation/breeding procedures have decreased by 6% (63 thousand).

There were 3.10 million animals used for the first time in completed procedures in 2015, representing an increase of 3% (89 thousand) compared with 2014.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 2.10 million experimental procedures completed in 2015, the majority involved the use of mice (61%), fish (14%), and rats (12%). Comparing with 2014, there were notable changes[2] to the number of procedures involving:

- mice, which increased by 107 thousand (9%) to 1.28 million procedures in 2015;
- fish[3], which increased by 29 thousand (11%) to 294 thousand procedures in 2015;
- rats, which increased by 24 thousand (10%) to 258 thousand procedures in 2015;
- pigs, which increased by 1,900 (45%) to 6,100 procedures in 2015;
- hamsters[4], which decreased by 1,300 (-46%) to 1,500 procedures in 2015;
- goats, which decreased by 240 (-69%) to 110 procedures in 2015.

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (87%), fish (12%), and amphibians (0.7%). Comparing with 2014, there were notable changes[5] to the number of procedures involving:

- fish[6], which increased by 47 thousand (61%) to 124 thousand procedures in 2015;
- amphibians[7], which increased by 6,000 thousand (414%) to 7,400 procedures in 2015;
- mice, which decreased by 105 thousand (-10%) to 932 thousand procedures in 2015;
- rats, which decreased by 11 thousand (-60%) to 6,900 procedures in 2015;
- sheep, which decreased by 80 (-71%) to 30 procedures in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 2.10 million experimental procedures completed in 2015:

- 6% (123 thousand) were assessed as non-recovery (compared with 7% in 2014);
- 64% (1.34 million) were assessed as (up to and including) mild (compared with 60% in 2014);
- 24% (509 thousand) were assessed as moderate (compared with 25% in 2014);
- 6% (124 thousand) were assessed as severe (compared with 8% in 2014).

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.2% (2,100) were assessed as non-recovery (compared with 0.2% in 2014);
- 88% (940 thousand) were assessed as (up to and including) mild (compared with 90% in 2014);
- 6% (67 thousand) were assessed as moderate (compared with 7% in 2014);
- 6% (62 thousand) were assessed as severe (compared with 3% in 2014).

The changes in severity from 2014 to 2015 are compared as proportions only due to the suspected under-reporting of procedures that occurred in 2014. Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather

[2] Covers the three largest numeric and the three largest percentage changes between 2014 and 2015.
[3] Specifically, Zebrafish and other fish species.
[4] Specifically, Syrian Hamsters.
[5] Covers the three largest numeric and the three largest percentage changes between 2014 and 2015. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed.
[6] Specifically, Zebrafish and other fish species.
[7] Specifically, Xenopus (Laevis and Tropicalis).

than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death. Further guidance is required in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other member states, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals and work is ongoing to improve guidance for users on this matter.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research through the project licence evaluation process, advice given by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research “other category” included:

- Embryology and molecular biology;
- Parasitology;
- Some probable erroneous entries caused by confusion, e.g. research on renal system which could have been returned under urogenital/reproduction. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation.

Applied research “other” category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial disease;
- Haematology.

Regulatory use, routine production “other”:

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);
- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose “other”:

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2208377	69.7%
Rats	264697	8.35%
Guinea-Pigs	21831	0.69%
Hamsters (Syrian)	1500	0.05%
Hamsters (Chinese)		
Mongolian gerbil	278	0.01%
Other Rodents	1763	0.06%
Rabbits	14224	0.45%
Cats	322	0.01%
Dogs	4753	0.15%
Ferrets	626	0.02%
Other carnivores	496	0.02%
Horses, donkeys and cross-breeds	8356	0.26%
Pigs	6350	0.2%
Goats	105	0%
Sheep	47237	1.49%
Cattle	4629	0.15%
Prosimians		
Marmoset and tamarins	131	0%
Cynomolgus monkey	3333	0.11%
Rhesus monkey	148	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	720	0.02%
Domestic fowl	128718	4.06%
Other birds	14061	0.44%
Reptiles		

Animal Species	Number of animals	Percentage
Rana	378	0.01%
Xenopus	15577	0.49%
Other Amphibians	1840	0.06%
Zebra fish	271773	8.58%
Other Fish	146257	4.62%
Cephalopods		
Total	**3168480**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2830494	91.43%
Animals born in the EU but not at a registered breeder	239430	7.73%
Animals born in rest of Europe	8705	0.28%
Animals born in rest of world	17316	0.56%
Total	**3095945**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	221	9.89%
Animals born in rest of Europe		
Animals born in Asia	596	26.68%
Animals born in America		
Animals born in Africa	1417	63.43%
Animals born elsewhere		
Total	**2234**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	598	26.77%
Self-sustaining colony	1636	73.23%
Total	**2234**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1408901	44.47%
Translational and applied research	417992	13.19%
Regulatory use and Routine production	556113	17.55%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	18200	0.57%
Preservation of species	757	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1845	0.06%
Forensic enquiries	121	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	764551	24.13%
Total	**3168480**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	161953	11.49%
Cardiovascular Blood and Lymphatic System	95627	6.79%
Nervous System	256944	18.24%
Respiratory System	30767	2.18%
Gastrointestinal System including Liver	27312	1.94%
Musculoskeletal System	31016	2.2%
Immune System	247072	17.54%
Urogenital/Reproductive System	50092	3.56%
Sensory Organs (skin, eyes and ears)	29681	2.11%
Endocrine System/Metabolism	34373	2.44%
Multisystemic	274443	19.48%
Ethology / Animal Behaviour /Animal Biology	90950	6.46%
Other basic research	78671	5.58%
Total	**1408901**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	84909	20.31%
Human Infectious Disorders	62048	14.84%
Human Cardiovascular Disorders	8285	1.98%
Human Nervous and Mental Disorders	55650	13.31%
Human Respiratory Disorders	9648	2.31%
Human Gastrointestinal Disorders including Liver	6115	1.46%
Human Musculoskeletal Disorders	2637	0.63%
Human Immune Disorders	19467	4.66%
Human Urogenital/Reproductive Disorders	3666	0.88%
Human Sensory Organ Disorders (skin, eyes and ears)	11059	2.65%
Human Endocrine/Metabolism Disorders	5416	1.3%
Other Human Disorders	84111	20.12%
Animal Diseases and Disorders	28285	6.77%
Animal Welfare	5283	1.26%
Diagnosis of diseases	3182	0.76%
Plant diseases	9	0%
Non-regulatory toxicology and ecotoxicology	28222	6.75%
Total	**417992**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	185742	33.4%
Other efficacy and tolerance testing	18374	3.3%
Toxicity and other safety testing including pharmacology	211600	38.05%
Routine production	140397	25.25%
Total	**556113**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	16803	9.05%
Pyrogenicity testing	2609	1.4%
Batch potency testing	154450	83.15%
Other quality controls	11880	6.4%
Total	**185742**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16115	7.62%
Skin irritation/corrosion	340	0.16%
Skin sensitisation	5304	2.51%
Eye irritation/corrosion	173	0.08%
Repeated dose toxicity	44153	20.87%
Carcinogenicity	15365	7.26%
Genotoxicity	5335	2.52%
Reproductive toxicity	26842	12.69%
Developmental toxicity	64814	30.63%
Neurotoxicity	395	0.19%
Kinetics	4792	2.26%
Pharmaco-dynamics (incl safety pharmacology)	4240	2%
Phototoxicity		
Ecotoxicity	12433	5.88%
Safety testing in food and feed area	681	0.32%
Target animal safety	7004	3.31%
Other toxicity/safety testing	3614	1.71%
Total	**211600**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	8898	55.22%
Other lethal methods	285	1.77%
Non lethal methods	6932	43.02%
Total	**16115**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	24189	54.78%
29 - 90 days	12736	28.85%
> 90 days	7228	16.37%
Total	**44153**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	4152	33.39%
Chronic toxicity	6816	54.82%
Reproductive ecotoxicity		
Endocrine activity	932	7.5%

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Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	265	2.13%
Other ecotoxicity	268	2.16%
Total	**12433**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	48690	34.68%
Monoclonal antibody by mouse ascites method		
Other product types	91707	65.32%
Total	**140397**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	269750	48.51%
Legislation on medicinal products for veterinary use and their residues	128586	23.12%
Medical devices legislation	8308	1.49%
Industrial chemicals legislation	75640	13.6%
Plant protection product legislation	22056	3.97%
Biocides legislation	1550	0.28%
Food legislation including food contact material	1934	0.35%
Feed legislation including legislation for the safety of target animals, workers and environment	5971	1.07%
Cosmetics legislation		
Other legislation	42318	7.61%
Total	**556113**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	536912	96.55%
Legislation satisfying national requirements only [within EU]	161	0.03%
Legislation satisfying Non-EU requirements only	19040	3.42%
Total	**556113**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	3098179	97.78%
Yes	70301	2.22%
Total	**3168480**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	125003	3.95%
Mild [up to and including]	2281252	72%
Moderate	576163	18.18%
Severe	186062	5.87%
Total	**3168480**	**100.00%**

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Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2861245	90.3%
Yes	307235	9.7%
Total	**3168480**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1485634	46.89%
Genetically altered without a harmful phenotype	1220639	38.52%
Genetically altered with a harmful phenotype	462207	14.59%
Total	**3168480**	**100.00%**

United Kingdom: Narrative 2016

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2016 data for Great Britain on the 13 July 2017 and the statistical release can be accessed online here: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2016.

The Northern Ireland Department for Health data is available here: https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures', whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold or mild severity, whereas all such procedures are combined into the "Mild [up to and including]" category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

1. General information on any changes in trends observed since the previous reporting period.

In 2016, a total of 2.79 million procedures were completed. This represents a decrease of 12% (378,000) compared with the 3.17 million procedures completed in 2015.

Of the 2.79 million procedures, 2.04 million (73%) were experimental procedures and 751,000 (27%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2015, experimental procedures have decreased by 3% (57,000) and creation/breeding procedures have decreased by 30% (321,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to occur because licensees are more accurately recording actual severity, rather than returning procedures according to the prospective severity category. As such, in 2016, a substantially greater proportion of breeding procedures prospectively accorded mild severity were returned as sub-threshold and therefore not included in this dataset.

There were 2.72 million animals used for the first time in completed procedures in 2016, representing a decrease of 12% (378,000) compared with 2015. This difference from the previous year may be explained, at least in part, by an improvement in the accuracy of recording the procedural severity. Licensees are increasingly correctly returning the actual severity suffered by the animal rather than the prospective severity of the procedure as described in their licence, as explained above. Other reasons why the number of animals has dropped sharply may also include an actual reduction in the number in experimental animals required and the reported improved efficiencies in the creation of new strains, in particular by the use of CRISPR/Cas9 technology.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 2.04 million experimental procedures completed in 2016, the majority involved the use of mice (60%), fish (14%), and rats (12%). Comparing with 2015, there were notable changes[8] to the number of procedures involving:

- mice, which decreased by 47,000 (-4%) to 1.23 million procedures in 2016;
- rats, which decreased by 19,000 (-7%) to 239,000 procedures in 2016;
- birds[9], which increased by 8,100 (6%) to 150,000 procedures in 2016;
- guinea pigs, which increased by 4,400 (20%) to 26,000 procedures in 2016;
- ferrets, which decreased by 150 (-24%) to 480 procedures in 2016;
- goats, which increased by 110 (104%) to 210 procedures in 2016.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (83%), fish (16%), and rats (1%). Comparing with 2015, there were notable changes[10] to the number of procedures involving:

- mice, which decreased by 309,000 (-33%) to 623,000 procedures in 2016;
- amphibians[11], which decreased by 6,200 (-83%) to 1,300 procedures in 2016;
- fish[12], which decreased by 5,300 (-4%) to 119,000 procedures in 2016;
- birds[13], which increased by 500 (83%) to 1,100 procedures in 2016;
- sheep, which increased by 160 (516%) to 190 procedures in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 2.04 million experimental procedures completed in 2016:

- 8% (155,000) were assessed as non-recovery, compared with 6% (123,000) in 2015;
- 58% (1.18 million) were assessed as (up to and including) mild, compared with 64% (1.34 million) in 2015;
- 29% (589,000) were assessed as moderate, compared with 24% (509,000) in 2015;
- 6% (115,000) were assessed as severe, compared with 6% (124,000) in 2015.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.2% (1,500) were assessed as non-recovery, compared with 0.2% (2,100) in 2015;
- 88% (659,000) were assessed as (up to and including) mild, compared with 88% (940,000) in 2015;
- 7% (51,000) were assessed as moderate, compared with 6% (67,000) in 2015;
- 5% (40,000) were assessed as severe, compared with 6% (62,000) in 2015).

[8] Covers the three largest numeric and the three largest percentage changes between 2015 and 2016.
[9] Specifically, domestic fowl and other bird species.
[10] Covers the three largest numeric and the three largest percentage changes between 2015 and 2016. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed.
[11] Specifically, Xenopus (Laevis and Tropicalis).
[12] Specifically, Zebrafish and other fish species.
[13] Specifically domestic fowl.

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as 'severe'. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2016 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research "other category" included:

- Embryology and molecular biology;
- Parasitology;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation.
- Some probable erroneous entries caused by confusion. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;

Applied research "other" category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial diseases;
- Haematology.

Regulatory use, routine production "other":

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);

- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose “other”:

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1852305	66.38%
Rats	244904	8.78%
Guinea-Pigs	26192	0.94%
Hamsters (Syrian)	1239	0.04%
Hamsters (Chinese)	230	0.01%
Mongolian gerbil	236	0.01%
Other Rodents	1521	0.05%
Rabbits	15568	0.56%
Cats	345	0.01%
Dogs	5005	0.18%
Ferrets	476	0.02%
Other carnivores	236	0.01%
Horses, donkeys and cross-breeds	8948	0.32%
Pigs	6361	0.23%
Goats	214	0.01%
Sheep	48596	1.74%
Cattle	4996	0.18%
Prosimians		
Marmoset and tamarins	197	0.01%
Cynomolgus monkey	3240	0.12%
Rhesus monkey	132	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	860	0.03%
Domestic fowl	139789	5.01%
Other birds	11543	0.41%
Reptiles		

Animal Species	Number of animals	Percentage
Rana	225	0.01%
Xenopus	10123	0.36%
Other Amphibians	893	0.03%
Zebra fish	308108	11.04%
Other Fish	97910	3.51%
Cephalopods		
Total	**2790392**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2593408	95.42%
Animals born in the EU but not at a registered breeder	108530	3.99%
Animals born in rest of Europe	4803	0.18%
Animals born in rest of world	11057	0.41%
Total	**2717798**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	263	10.78%
Animals born in rest of Europe		
Animals born in Asia	652	26.72%
Animals born in America		
Animals born in Africa	1525	62.5%
Animals born elsewhere		
Total	**2440**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	701	28.73%
Self-sustaining colony	1739	71.27%
Total	**2440**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1350177	48.39%
Translational and applied research	354145	12.69%
Regulatory use and Routine production	539454	19.33%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	18800	0.67%
Preservation of species	1789	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1675	0.06%
Forensic enquiries	92	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	524260	18.79%
Total	**2790392**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	173650	12.86%
Cardiovascular Blood and Lymphatic System	89072	6.6%
Nervous System	271513	20.11%
Respiratory System	16937	1.25%
Gastrointestinal System including Liver	28417	2.1%
Musculoskeletal System	23767	1.76%
Immune System	243534	18.04%
Urogenital/Reproductive System	41652	3.08%
Sensory Organs (skin, eyes and ears)	31810	2.36%
Endocrine System/Metabolism	32237	2.39%
Multisystemic	181829	13.47%
Ethology / Animal Behaviour /Animal Biology	55479	4.11%
Other basic research	160280	11.87%
Total	**1350177**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	86416	24.4%
Human Infectious Disorders	86702	24.48%
Human Cardiovascular Disorders	6491	1.83%
Human Nervous and Mental Disorders	37303	10.53%
Human Respiratory Disorders	15171	4.28%
Human Gastrointestinal Disorders including Liver	6347	1.79%
Human Musculoskeletal Disorders	5447	1.54%
Human Immune Disorders	10463	2.95%
Human Urogenital/Reproductive Disorders	2464	0.7%
Human Sensory Organ Disorders (skin, eyes and ears)	9052	2.56%
Human Endocrine/Metabolism Disorders	6651	1.88%
Other Human Disorders	8292	2.34%
Animal Diseases and Disorders	29218	8.25%
Animal Welfare	2908	0.82%
Diagnosis of diseases	1434	0.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	39786	11.23%
Total	**354145**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	181199	33.59%
Other efficacy and tolerance testing	26707	4.95%
Toxicity and other safety testing including pharmacology	189460	35.12%
Routine production	142088	26.34%
Total	**539454**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	7239	4%
Pyrogenicity testing	2472	1.36%
Batch potency testing	145190	80.13%
Other quality controls	26298	14.51%
Total	**181199**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	18993	10.02%
Skin irritation/corrosion	266	0.14%
Skin sensitisation	4586	2.42%
Eye irritation/corrosion	128	0.07%
Repeated dose toxicity	43054	22.72%
Carcinogenicity	3742	1.98%
Genotoxicity	3746	1.98%
Reproductive toxicity	39078	20.63%
Developmental toxicity	44812	23.65%
Neurotoxicity	280	0.15%
Kinetics	4197	2.22%
Pharmaco-dynamics (incl safety pharmacology)	4472	2.36%
Phototoxicity		
Ecotoxicity	15038	7.94%
Safety testing in food and feed area	346	0.18%
Target animal safety	2265	1.2%
Other toxicity/safety testing	4457	2.35%
Total	**189460**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	11204	58.99%
Other lethal methods	326	1.72%
Non lethal methods	7463	39.29%
Total	**18993**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	20143	46.79%
29 - 90 days	14889	34.58%
> 90 days	8022	18.63%
Total	**43054**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3786	25.18%
Chronic toxicity	8066	53.64%
Reproductive ecotoxicity	2370	15.76%
Endocrine activity	389	2.59%
Bioaccumulation	427	2.84%
Other ecotoxicity		
Total	**15038**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	52732	37.11%
Monoclonal antibody by mouse ascites method		
Other product types	89356	62.89%
Total	**142088**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	250469	46.43%
Legislation on medicinal products for veterinary use and their residues	127249	23.59%
Medical devices legislation	9641	1.79%
Industrial chemicals legislation	71086	13.18%
Plant protection product legislation	17480	3.24%
Biocides legislation	3149	0.58%
Food legislation including food contact material	1904	0.35%
Feed legislation including legislation for the safety of target animals, workers and environment	12988	2.41%
Cosmetics legislation		
Other legislation	45488	8.43%
Total	**539454**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	517132	95.86%
Legislation satisfying national requirements only [within EU]	96	0.02%
Legislation satisfying Non-EU requirements only	22226	4.12%
Total	**539454**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2720238	97.49%
Yes	70154	2.51%
Total	**2790392**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	156086	5.59%
Mild [up to and including]	1839922	65.94%
Moderate	640064	22.94%
Severe	154320	5.53%
Total	**2790392**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2564079	91.89%
Yes	226313	8.11%
Total	**2790392**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1380447	49.47%
Genetically altered without a harmful phenotype	1041325	37.32%
Genetically altered with a harmful phenotype	368620	13.21%
Total	**2790392**	**100.00%**

United Kingdom: Narrative 2017

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2017 data for Great Britain on the 19 July 2018 and the statistical release can be accessed online here: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2017.

The Northern Ireland Department for Health (NIDH) published their 2017 data here: https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures', whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold from those of mild severity, whereas all such procedures (i.e. all procedures other than PG43) are combined into the "Mild [up to and including]" category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

1. General information on any changes in trends observed since the previous reporting period.

In 2017, a total of 2.57 million procedures were completed. This represents a decrease of 8% (216,000) compared with the 2.79 million procedures completed in 2016.

Of the 2.57 million procedures, 1.91 million (74%) were experimental procedures and 669,000 (26%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2016, experimental procedures have decreased by 7% (134,000) and creation/breeding procedures have decreased by 11% (82,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to be due largely for two reasons: i) a decrease in the number of zebra fish bred but not used compared to 2016 and ii) more accurate recording of actual severity (a greater proportion of animals reported to be subthreshold instead of mild and hence omitted from the UK return).

There were 2.51 million animals used for the first time in completed procedures in 2017, representing a decrease of 8% (214,000) compared with 2016. The reason for this is not clear but appears to reflect a reduction in research activity across several sectors and is not confined to any particular purpose.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 1.91 million experimental procedures completed in 2017, the majority involved the use of mice (58%), fish (16%) and rats (12%). Comparing with 2016, there were notable changes[14] to the number of procedures involving:

- mice, which decreased by 124,000 (-10%) to 1.10 million procedures in 2017;
- birds[15], which decreased by 19,000 (-13%) to 131,000 procedures in 2017;
- Rana, which decreased by 120 (-52%) to 110 procedures in 2017.
- other rodents, which increased by 810 (+53%) to 2,300 procedures in 2017;
- cattle, which increased by 4,100 (+82%) to 9,100 procedures in 2017;
- fish[16], which increased by 22,000(+8%) to 309,000 procedures in 2017;

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (84%), fish (15%), and rats (0.5%). Comparing with 2016, there were notable changes[17] to the number of procedures involving:

- mice, which decreased by 63,000 (-10%) to 560,000 procedures in 2017;
- fish[18], which decreased by 16,000 (-13%) to 104,000 procedures in 2017;
- rats, which decreased by 2,400 (-45%) to 3,100 procedures in 2017;
- sheep, which decreased by 170 (-91%) to 20 procedures in 2017;
- pigs, which decreased by 120 (-49%) to 120 procedures in 2017;
- amphibians[19], which decreased by 620 (-49%) to 640 procedures in 2017;

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 1.91 million experimental procedures completed in 2017:

- 7% (135,000) were assessed as non-recovery, compared with 8% (155,000) in 2016;
- 61% (1.17 million) were assessed as (up to and including) mild, compared with 58% (1.18 million) in 2016;
- 26% (504,000) were assessed as moderate, compared with 29% (589,000) in 2016;
- 5% (95,000) were assessed as severe, compared with 6% (115,000) in 2016.

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.07% (470) were assessed as non-recovery, compared with 0.2% (1,500) in 2016;
- 85% (570,000) were assessed as (up to and including) mild, compared with 88% (658,000) in 2016;
- 8% (55,000) were assessed as moderate, compared with 7% (51,000) in 2016;
- 6% (43,000) were assessed as severe, compared with 5% (40,000) in 2016.

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

[14] Covers the three largest numeric and the three largest percentage changes between 2016 and 2017.
[15] Specifically, domestic fowl and other bird species.
[16] Specifically, Zebrafish and other fish species.
[17] Covers the three largest numeric and the three largest percentage changes between 2016 and 2017.
[18] Specifically, Zebrafish and other fish species.
[19] Specifically, Xenopus (Laevis and Tropicalis).

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as 'severe'. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2017 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research "other category" included:

- Embryology, cell and molecular biology;
- Genetics;
- Parasitology;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation;
- Some probable erroneous entries eg. renal disease, caused by confusion as to which category to use. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future.

Applied research "other" category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial diseases;
- Haematology;
- Wound healing;
- Pain disorders;
- Sleep.

Regulatory use, routine production "other":

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);

- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.
- Rodenticide evaluation (not field trials).

Regulatory use, legislative purpose “other”:

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, toxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species;
- Metabolism.

Regulatory Use: Other legislative requirements

- Mainly production to meet industry specifications.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1665386	64.68%
Rats	237831	9.24%
Guinea-Pigs	22560	0.88%
Hamsters (Syrian)	1126	0.04%
Hamsters (Chinese)		
Mongolian gerbil	311	0.01%
Other Rodents	2327	0.09%
Rabbits	10444	0.41%
Cats	288	0.01%
Dogs	3949	0.15%
Ferrets	405	0.02%
Other carnivores	244	0.01%
Horses, donkeys and cross-breeds	10600	0.41%
Pigs	4742	0.18%
Goats	304	0.01%
Sheep	47946	1.86%
Cattle	9085	0.35%
Prosimians		
Marmoset and tamarins	166	0.01%
Cynomolgus monkey	2662	0.1%
Rhesus monkey	132	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		

Animal Species	Number of animals	Percentage
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	804	0.03%
Domestic fowl	125670	4.88%
Other birds	6729	0.26%
Reptiles	92	0%
Rana	108	0%
Xenopus	8095	0.31%
Other Amphibians	533	0.02%
Zebra fish	320146	12.43%
Other Fish	92190	3.58%
Cephalopods		
Total	**2574875**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2377256	94.92%
Animals born in the EU but not at a registered breeder	112655	4.5%
Animals born in rest of Europe	3240	0.13%
Animals born in rest of world	11315	0.45%
Total	**2504466**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	253	11.42%
Animals born in rest of Europe		
Animals born in Asia	616	27.81%
Animals born in America		
Animals born in Africa	1346	60.77%
Animals born elsewhere		
Total	**2215**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	1	0.05%
F2 or greater	587	26.5%
Self-sustaining colony	1627	73.45%
Total	**2215**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1314541	51.05%
Translational and applied research	335968	13.05%
Regulatory use and Routine production	505504	19.63%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	11901	0.46%
Preservation of species	1925	0.07%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1235	0.05%
Forensic enquiries	88	0%

Purpose Category	Number of uses	Percentage
Maintenance of colonies of established genetically altered animals, not used in other procedures	403713	15.68%
Total	**2574875**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	176024	13.39%
Cardiovascular Blood and Lymphatic System	78397	5.96%
Nervous System	273172	20.78%
Respiratory System	11654	0.89%
Gastrointestinal System including Liver	26197	1.99%
Musculoskeletal System	28423	2.16%
Immune System	246232	18.73%
Urogenital/Reproductive System	34838	2.65%
Sensory Organs (skin, eyes and ears)	23477	1.79%
Endocrine System/Metabolism	29411	2.24%
Multisystemic	173366	13.19%
Ethology / Animal Behaviour /Animal Biology	67223	5.11%
Other basic research	146127	11.12%
Total	**1314541**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	90879	27.05%
Human Infectious Disorders	70203	20.9%
Human Cardiovascular Disorders	4374	1.3%
Human Nervous and Mental Disorders	42354	12.61%
Human Respiratory Disorders	12633	3.76%
Human Gastrointestinal Disorders including Liver	3943	1.17%
Human Musculoskeletal Disorders	6113	1.82%
Human Immune Disorders	7354	2.19%
Human Urogenital/Reproductive Disorders	3541	1.05%
Human Sensory Organ Disorders (skin, eyes and ears)	10854	3.23%
Human Endocrine/Metabolism Disorders	7815	2.33%
Other Human Disorders	10850	3.23%
Animal Diseases and Disorders	23507	7%
Animal Welfare	2843	0.85%
Diagnosis of diseases	3476	1.03%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	35229	10.49%
Total	**335968**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	145113	28.71%
Other efficacy and tolerance testing	24606	4.87%
Toxicity and other safety testing including pharmacology	196061	38.79%
Routine production	139724	27.64%
Total	**505504**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	18401	12.68%
Pyrogenicity testing	1125	0.78%
Batch potency testing	114151	78.66%
Other quality controls	11436	7.88%
Total	**145113**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16580	8.46%
Skin irritation/corrosion	112	0.06%
Skin sensitisation	2942	1.5%
Eye irritation/corrosion	63	0.03%
Repeated dose toxicity	40429	20.62%
Carcinogenicity	8067	4.11%
Genotoxicity	5314	2.71%
Reproductive toxicity	61241	31.24%
Developmental toxicity	34779	17.74%
Neurotoxicity	314	0.16%
Kinetics	3124	1.59%
Pharmaco-dynamics (incl safety pharmacology)	5309	2.71%
Phototoxicity		
Ecotoxicity	11444	5.84%
Safety testing in food and feed area	183	0.09%
Target animal safety	1360	0.69%
Other toxicity/safety testing	4800	2.45%
Total	**196061**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10622	64.07%
Other lethal methods	98	0.59%
Non lethal methods	5860	35.34%
Total	**16580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	21572	53.36%
29 - 90 days	11727	29.01%
> 90 days	7130	17.64%
Total	**40429**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3653	31.92%
Chronic toxicity	6320	55.23%
Reproductive ecotoxicity	514	4.49%
Endocrine activity	84	0.73%
Bioaccumulation	873	7.63%
Other ecotoxicity		
Total	**11444**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	55197	39.5%
Monoclonal antibody by mouse ascites method		
Other product types	84527	60.5%
Total	**139724**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	208938	41.33%
Legislation on medicinal products for veterinary use and their residues	118458	23.43%
Medical devices legislation	7285	1.44%
Industrial chemicals legislation	86337	17.08%
Plant protection product legislation	18417	3.64%
Biocides legislation	292	0.06%
Food legislation including food contact material	1688	0.33%
Feed legislation including legislation for the safety of target animals, workers and environment	14831	2.93%
Cosmetics legislation		
Other legislation	49258	9.74%
Total	**505504**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	478397	94.64%
Legislation satisfying national requirements only [within EU]	1670	0.33%
Legislation satisfying Non-EU requirements only	25437	5.03%
Total	**505504**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2506681	97.35%
Yes	68194	2.65%
Total	**2574875**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	135780	5.27%
Mild [up to and including]	1741624	67.64%
Moderate	559401	21.73%
Severe	138070	5.36%
Total	**2574875**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2309701	89.7%
Yes	265174	10.3%
Total	**2574875**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1263597	49.07%
Genetically altered without a harmful phenotype	1102809	42.83%
Genetically altered with a harmful phenotype	208469	8.1%
Total	**2574875**	**100.00%**

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PART 4/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

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V.3. Recalculated presentation of Member State data for 2017

Introduction

Member States submitted statistical data to the Commission grouped by the main categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU (Section C, V.1.-2. of this Staff Working Document). However, the presentation of data at EU level was restructured to allow for an improved understanding of when and how animals are still used in science today: animals (and uses) in relation to research, testing, routine production and education/training separated from animals (and uses) for the creation and maintenance of genetically altered animals.

To allow for a similar presentation and correlation with the EU data for the year 2017, the Member State annual submissions for the year 2017 were recalculated.

The recalculation was made on the basis of the three Parts of this Staff Working Document:

- **Numbers of animals** used for purposes of research, testing, routine production and education (including training) – Part 1 (III.1)
- **Details of all uses** (first and any subsequent reuse) of animals for the purposes of research, testing, routine production and education (including training) - Part 2 (III.2)
- Numbers and uses of animals for the **creation and maintenance of genetically altered animals** in the EU – Part 3 (III.3)

The main recalculation rules are explained below. As a result, some of the numbers may differ between the original Member Submission for the year 2017 compared to the corresponding table found in the recalculated report.

- **Part 1 – Numbers of animals used in research and testing**
  - Excludes records that were indicated as being carried out for the creation of a new genetically altered animal line;
  - Excludes records for the purposes of maintenance of established genetically altered animal lines;
  - Excludes reuses.

- **Part 2 – All animal uses for research and testing**
  - Excludes records that were indicated as being carried out for the creation of a new genetically altered animal line;
  - Excludes records for the purposes of maintenance of established genetically altered animal lines;
  - Includes both the first use and any subsequent reuse;
  - Excludes legislative information (type and origin of legislative requirement) that is not related to regulatory use. For example, entries for the purposes of "Routine

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production" have been submitted with legislative information as this requirement is included in the Commission Implementing Decision 2012/707/EU. However, since the adoption of the Decision, it has become clear that this link between routine production and legislative information is an error and the erroneous legislative data have been removed from purpose category "Routine production". This provides for a more accurate presentation of the type and origin of legislation that results in regulatory testing.

N.B. When products (produced by using of animals such as blood based products) are placed on the market, there may be requirements for testing their purity, efficacy etc. These are reported separately under regulatory use, and therefore linked correctly with the respective legislative information.

- **Part 3 – Animals (numbers and uses) used for the creation and maintenance of genetically altered animal lines**
    - Includes records that were indicated as being carried out for the creation of a new genetically altered animal line;
    - Includes records for the purposes of maintenance of established genetically altered animal lines – other purposes excluded unless carried out for the creation of a new genetically altered animal line;
    - Includes both first and any subsequent reuse.

To reduce the length of the document, only those lines in which data were reported are included in the tables below.

Member State: Austria, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	169345	80.19%
Rats	5309	2.51%
Guinea-Pigs	1127	0.53%
Other Rodents	998	0.47%
Rabbits	10367	4.91%
Cats	61	0.03%
Dogs	149	0.07%
Horses, donkeys and cross-breeds	349	0.17%
Pigs	2040	0.97%
Goats	20	0.01%
Sheep	139	0.07%
Cattle	904	0.43%
Other Mammals	102	0.05%
Domestic fowl	3895	1.84%
Other birds	1810	0.86%
Xenopus	941	0.45%
Other Amphibians	912	0.43%
Zebra fish	8112	3.84%
Other Fish	4596	2.18%
Total	**211176**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	195266	92.47%
Animals born in the EU but not at a registered breeder	11909	5.64%
Animals born in rest of Europe	99	0.05%
Animals born in rest of world	3902	1.85%
Total	**211176**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	169345	563	169908
Rats	5309		5309
Guinea-Pigs	1127	27	1154
Hamsters (Syrian)		8	8
Mongolian gerbil		41	41
Other Rodents	998		998
Rabbits	10367	21	10388
Cats	61		61
Dogs	149	54	203
Horses, donkeys and cross-breeds	349	172	521
Pigs	2040		2040
Goats	20	2	22
Sheep	139	10	149
Cattle	904	4	908
Other Mammals	102		102
Domestic fowl	3895		3895
Other birds	1810	9	1819
Xenopus	941	31	972
Other Amphibians	912		912
Zebra fish	8112		8112
Other Fish	4596	34	4630
Total	**211176**	**976**	**212152**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	105109	49.54%
Translational and applied research	77138	36.36%
Regulatory use and Routine production	26569	12.52%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	198	0.09%
Preservation of species	30	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3108	1.46%
Total	**212152**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	21077	20.05%
Cardiovascular Blood and Lymphatic System	8833	8.4%
Nervous System	12522	11.91%
Respiratory System	316	0.3%
Gastrointestinal System including Liver	1997	1.9%
Musculoskeletal System	4947	4.71%
Immune System	25168	23.94%
Urogenital/Reproductive System	1128	1.07%
Sensory Organs (skin, eyes and ears)	1208	1.15%
Endocrine System/Metabolism	1304	1.24%
Multisystemic	7835	7.45%
Ethology / Animal Behaviour /Animal Biology	5799	5.52%
Other basic research	12975	12.34%
Total	**105109**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	14506	18.81%
Human Infectious Disorders	42202	54.71%
Human Cardiovascular Disorders	5109	6.62%
Human Nervous and Mental Disorders	5487	7.11%
Human Respiratory Disorders	285	0.37%
Human Gastrointestinal Disorders including Liver	151	0.2%
Human Musculoskeletal Disorders	260	0.34%
Human Immune Disorders	785	1.02%
Human Urogenital/Reproductive Disorders	201	0.26%
Human Sensory Organ Disorders (skin, eyes and ears)	300	0.39%
Human Endocrine/Metabolism Disorders	1138	1.48%
Other Human Disorders	576	0.75%
Animal Diseases and Disorders	4816	6.24%
Animal Welfare	542	0.7%
Diagnosis of diseases	715	0.93%
Non-regulatory toxicology and ecotoxicology	65	0.08%
Total	**77138**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25823	97.19%
Toxicity and other safety testing including pharmacology	740	2.79%
Routine production	6	0.02%
Total	**26569**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2700	10.46%
Pyrogenicity testing	9125	35.34%
Batch potency testing	13554	52.49%
Other quality controls	444	1.72%
Total	**25823**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	43	5.81%
Neurotoxicity	32	4.32%
Target animal safety	665	89.86%
Total	**740**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
29 - 90 days	43	100%
Total	**43**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25864	97.37%
Medical devices legislation	2	0.01%
Plant protection product legislation	665	2.5%
Other legislation	32	0.12%
Total	**26563**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23031	86.7%
Legislation satisfying Non-EU requirements only	3532	13.3%
Total	**26563**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	6	100%
Total	**6**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	211176	99.54%
Yes	976	0.46%
Total	**212152**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	5087	2.4%
Mild [up to and including]	125863	59.33%
Moderate	60095	28.33%
Severe	21107	9.95%
Total	**212152**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	135474	63.86%
Genetically altered without a harmful phenotype	56923	26.83%
Genetically altered with a harmful phenotype	19755	9.31%
Total	**212152**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	14373		14373
Zebra fish	8185		8185
Total	**22558**		**22558**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	20298	89.98%
Moderate	2040	9.04%
Severe	220	0.98%
Total	**22558**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	2545	11.28%
Genetically altered without a harmful phenotype	7059	31.29%
Genetically altered with a harmful phenotype	12954	57.43%
Total	**22558**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	4329	19.19%
Cardiovascular Blood and Lymphatic System	1439	6.38%
Nervous System	4069	18.04%
Gastrointestinal System including Liver	232	1.03%
Immune System	115	0.51%
Endocrine System/Metabolism	390	1.73%
Multisystemic	4970	22.03%
Other basic research	7014	31.09%
Total	**22558**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	28632		28632
Rats	729		729
Total	**29361**		**29361**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	66	0.22%
Mild [up to and including]	28861	98.3%
Moderate	381	1.3%
Severe	53	0.18%
Total	**29361**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	7912	26.95%
Genetically altered without a harmful phenotype	18527	63.1%
Genetically altered with a harmful phenotype	2922	9.95%
Total	**29361**	**100.00%**

Member State: Belgium, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	306605	60.46%
Rats	23207	4.58%
Guinea-Pigs	15539	3.06%
Hamsters (Syrian)	1147	0.23%
Mongolian gerbil	174	0.03%
Other Rodents	115	0.02%
Rabbits	57849	11.41%
Cats	53	0.01%
Dogs	334	0.07%
Ferrets	26	0.01%
Horses, donkeys and cross-breeds	135	0.03%
Pigs	4847	0.96%
Goats	77	0.02%
Sheep	628	0.12%
Cattle	1354	0.27%
Rhesus monkey	9	0%
Other Mammals	77	0.02%
Domestic fowl	39661	7.82%
Other birds	6887	1.36%
Reptiles	42	0.01%
Xenopus	866	0.17%
Other Amphibians	71	0.01%
Zebra fish	23912	4.71%
Other Fish	23538	4.64%
Total	**507153**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	483302	95.3%
Animals born in the EU but not at a registered breeder	19519	3.85%
Animals born in rest of Europe	903	0.18%
Animals born in rest of world	3420	0.67%
Total	**507144**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	9	100%
Total	**9**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	9	100%
Total	**9**	**100.00%**

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	306605	314	306919
Rats	23207	397	23604
Guinea-Pigs	15539	2	15541
Hamsters (Syrian)	1147		1147
Mongolian gerbil	174		174
Other Rodents	115		115
Rabbits	57849	39	57888
Cats	53	8	61
Dogs	334	1522	1856
Ferrets	26		26
Horses, donkeys and cross-breeds	135	99	234
Pigs	4847	123	4970
Goats	77	1	78
Sheep	628	38	666
Cattle	1354	204	1558
Rhesus monkey	9	35	44
Other Mammals	77	63	140
Domestic fowl	39661	13	39674
Other birds	6887	251	7138
Reptiles	42	139	181
Xenopus	866	52	918
Other Amphibians	71	252	323
Zebra fish	23912		23912
Other Fish	23538	489	24027
Total	**507153**	**4041**	**511194**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	243476	47.63%
Translational and applied research	116957	22.88%
Regulatory use and Routine production	141853	27.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	706	0.14%
Preservation of species	151	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8051	1.57%
Total	**511194**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	49489	20.33%
Cardiovascular Blood and Lymphatic System	10890	4.47%
Nervous System	37566	15.43%
Respiratory System	3403	1.4%
Gastrointestinal System including Liver	14181	5.82%
Musculoskeletal System	4058	1.67%
Immune System	68939	28.31%
Urogenital/Reproductive System	5450	2.24%
Sensory Organs (skin, eyes and ears)	4674	1.92%
Endocrine System/Metabolism	10658	4.38%
Multisystemic	2599	1.07%
Ethology / Animal Behaviour /Animal Biology	14701	6.04%
Other basic research	16868	6.93%
Total	**243476**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	12720	10.88%
Human Infectious Disorders	15691	13.42%
Human Cardiovascular Disorders	1573	1.34%
Human Nervous and Mental Disorders	28677	24.52%
Human Respiratory Disorders	5945	5.08%
Human Gastrointestinal Disorders including Liver	977	0.84%
Human Musculoskeletal Disorders	783	0.67%
Human Immune Disorders	2039	1.74%
Human Urogenital/Reproductive Disorders	503	0.43%
Human Sensory Organ Disorders (skin, eyes and ears)	5441	4.65%
Human Endocrine/Metabolism Disorders	3722	3.18%
Other Human Disorders	40	0.03%
Animal Diseases and Disorders	17918	15.32%
Animal Welfare	3525	3.01%
Diagnosis of diseases	4292	3.67%
Non-regulatory toxicology and ecotoxicology	13111	11.21%
Total	**116957**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68615	48.37%
Other efficacy and tolerance testing	17201	12.13%
Toxicity and other safety testing including pharmacology	4133	2.91%
Routine production	51904	36.59%
Total	**141853**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	8016	11.68%
Batch potency testing	57716	84.12%
Other quality controls	2883	4.2%
Total	**68615**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1037	25.09%
Repeated dose toxicity	672	16.26%
Reproductive toxicity	290	7.02%
Developmental toxicity	11	0.27%
Neurotoxicity	20	0.48%
Kinetics	399	9.65%
Ecotoxicity	1418	34.31%
Safety testing in food and feed area	150	3.63%
Target animal safety	136	3.29%
Total	**4133**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	4.82%
Non lethal methods	987	95.18%
Total	**1037**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	505	75.15%
29 - 90 days	42	6.25%
> 90 days	125	18.6%
Total	**672**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1202	84.77%
Chronic toxicity	216	15.23%
Total	**1418**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	62092	69.03%
Legislation on medicinal products for veterinary use and their residues	25534	28.39%
Medical devices legislation	779	0.87%
Industrial chemicals legislation	216	0.24%
Plant protection product legislation	52	0.06%
Food legislation including food contact material	74	0.08%
Other legislation	1202	1.34%
Total	**89949**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	76304	84.83%
Legislation satisfying national requirements only [within EU]	50	0.06%
Legislation satisfying Non-EU requirements only	13595	15.11%
Total	**89949**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	51804	99.81%
Other product types	100	0.19%
Total	**51904**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	507153	99.21%
Yes	4041	0.79%
Total	**511194**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	25003	4.89%
Mild [up to and including]	275109	53.82%
Moderate	128546	25.15%
Severe	82536	16.15%
Total	**511194**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	395188	77.31%
Genetically altered without a harmful phenotype	100218	19.6%
Genetically altered with a harmful phenotype	15788	3.09%
Total	**511194**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	24875		24875
Rats	222		222
Zebra fish	3544	979	4523
Total	**28641**	**979**	**29620**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	1543	5.21%
Mild [up to and including]	20452	69.05%
Moderate	5403	18.24%
Severe	2222	7.5%
Total	**29620**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	7096	23.96%
Genetically altered without a harmful phenotype	16407	55.39%
Genetically altered with a harmful phenotype	6117	20.65%
Total	**29620**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	8598	29.33%
Cardiovascular Blood and Lymphatic System	2572	8.77%
Nervous System	5408	18.45%
Respiratory System	180	0.61%
Gastrointestinal System including Liver	2594	8.85%
Musculoskeletal System	909	3.1%
Immune System	1166	3.98%
Urogenital/Reproductive System	402	1.37%
Sensory Organs (skin, eyes and ears)	111	0.38%
Endocrine System/Metabolism	4203	14.34%
Multisystemic	3001	10.24%
Other basic research	175	0.6%
Total	**29319**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	259	86.05%
Animal Diseases and Disorders	42	13.95%
Total	**301**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	2249	11	2260
Total	**2249**	**11**	**2260**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	1628	72.04%
Moderate	628	27.79%
Severe	4	0.18%
Total	**2260**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	5	0.22%
Genetically altered without a harmful phenotype	1701	75.27%
Genetically altered with a harmful phenotype	554	24.51%
Total	**2260**	**100.00%**

Member State: Bulgaria, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	989	11.39%
Rats	1892	21.79%
Guinea-Pigs	1841	21.21%
Rabbits	568	6.54%
Cats	30	0.35%
Pigs	20	0.23%
Sheep	340	3.92%
Cattle	15	0.17%
Domestic fowl	680	7.83%
Rana	2306	26.56%
Total	**8681**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	8651	99.65%
Animals born in the EU but not at a registered breeder	30	0.35%
Total	**8681**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	989		989
Rats	1892		1892
Guinea-Pigs	1841		1841
Rabbits	568		568
Cats	30		30
Pigs	20		20
Sheep	340		340
Cattle	15		15
Domestic fowl	680		680
Rana	2306		2306
Total	**8681**		**8681**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	2246	25.87%
Translational and applied research	19	0.22%
Regulatory use and Routine production	4126	47.53%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2290	26.38%
Total	**8681**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Nervous System	1651	73.51%
Gastrointestinal System including Liver	11	0.49%
Musculoskeletal System	74	3.29%
Immune System	42	1.87%
Urogenital/Reproductive System	45	2%
Endocrine System/Metabolism	56	2.49%
Multisystemic	62	2.76%
Ethology / Animal Behaviour /Animal Biology	235	10.46%
Other basic research	70	3.12%
Total	**2246**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	19	100%
Total	**19**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2843	68.9%

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	238	5.77%
Routine production	1045	25.33%
Total	**4126**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2843	100%
Total	**2843**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	38	15.97%
Pharmaco-dynamics (incl safety pharmacology)	150	63.03%
Ecotoxicity	50	21.01%
Total	**238**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	38	100%
Total	**38**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Chronic toxicity	50	100%
Total	**50**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3081	100%
Total	**3081**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3081	100%
Total	**3081**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	1045	100%
Total	**1045**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	8681	100%
Total	**8681**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Mild [up to and including]	4547	52.38%
Moderate	3869	44.57%
Severe	265	3.05%
Total	**8681**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	8681	100%
Total	**8681**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Croatia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	19710	70.13%
Rats	7638	27.18%
Guinea-Pigs	16	0.06%
Rabbits	426	1.52%
Pigs	2	0.01%
Sheep	28	0.1%
Cattle	30	0.11%
Domestic fowl	255	0.91%
Total	**28105**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	27966	99.51%
Animals born in the EU but not at a registered breeder	60	0.21%
Animals born in rest of world	79	0.28%
Total	**28105**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	19710		19710
Rats	7638	62	7700
Guinea-Pigs	16	5	21
Rabbits	426		426
Horses, donkeys and cross-breeds		25	25
Pigs	2		2
Sheep	28	11	39
Cattle	30		30
Domestic fowl	255		255
Total	**28105**	**103**	**28208**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	22067	78.23%
Translational and applied research	2531	8.97%
Regulatory use and Routine production	2182	7.74%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1428	5.06%
Total	**28208**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1345	6.1%
Cardiovascular Blood and Lymphatic System	378	1.71%
Nervous System	1428	6.47%
Respiratory System	5721	25.93%
Gastrointestinal System including Liver	2069	9.38%
Musculoskeletal System	30	0.14%
Immune System	3764	17.06%
Urogenital/Reproductive System	234	1.06%
Sensory Organs (skin, eyes and ears)	688	3.12%
Endocrine System/Metabolism	384	1.74%
Multisystemic	4582	20.76%
Ethology / Animal Behaviour /Animal Biology	122	0.55%
Other basic research	1322	5.99%
Total	**22067**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	230	9.09%
Human Infectious Disorders	1394	55.08%
Human Cardiovascular Disorders	510	20.15%
Human Nervous and Mental Disorders	214	8.46%
Human Musculoskeletal Disorders	28	1.11%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	60	2.37%
Animal Diseases and Disorders	30	1.19%
Non-regulatory toxicology and ecotoxicology	65	2.57%
Total	**2531**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1585	72.64%
Toxicity and other safety testing including pharmacology	556	25.48%
Routine production	41	1.88%
Total	**2182**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	262	16.53%
Batch potency testing	128	8.08%
Other quality controls	1195	75.39%
Total	**1585**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	556	100%
Total	**556**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	556	100%
Total	**556**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1758	82.11%
Legislation on medicinal products for veterinary use and their residues	383	17.89%
Total	**2141**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2141	100%

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Origin of legislative requirement	Number of uses	Percentage
Total	**2141**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	41	100%
Total	**41**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	28105	99.63%
Yes	103	0.37%
Total	**28208**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2965	10.51%
Mild [up to and including]	8242	29.22%
Moderate	11403	40.42%
Severe	5598	19.85%
Total	**28208**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	25797	91.45%
Genetically altered without a harmful phenotype	2356	8.35%
Genetically altered with a harmful phenotype	55	0.19%
Total	**28208**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Zebra fish	230		230
Total	**230**		**230**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	40	17.39%
Moderate	190	82.61%
Total	**230**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	230	100%
Total	**230**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Non-regulatory toxicology and ecotoxicology	230	100%
Total	**230**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	96		96
Total	**96**		**96**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	96	100%
Total	**96**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	96	100%
Total	**96**	**100.00%**

Member State: Cyprus, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1209	100%
Total	**1209**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1209	100%
Total	**1209**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1209		1209
Total	**1209**		**1209**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	839	69.4%
Translational and applied research	370	30.6%
Total	**1209**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	129	15.38%
Cardiovascular Blood and Lymphatic System	17	2.03%
Nervous System	368	43.86%
Musculoskeletal System	275	32.78%
Sensory Organs (skin, eyes and ears)	50	5.96%
Total	**839**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	370	100%
Total	**370**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1209	100%
Total	**1209**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Mild [up to and including]	1197	99.01%
Moderate	12	0.99%
Total	**1209**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	623	51.53%
Genetically altered without a harmful phenotype	586	48.47%
Total	**1209**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Czechia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	71954	33.92%
Rats	24809	11.69%
Guinea-Pigs	1377	0.65%
Hamsters (Syrian)	15	0.01%
Mongolian gerbil	46	0.02%
Other Rodents	635	0.3%
Rabbits	2031	0.96%
Cats	121	0.06%
Dogs	437	0.21%
Ferrets	1	0%
Other carnivores	1	0%
Horses, donkeys and cross-breeds	90	0.04%
Pigs	1893	0.89%
Goats	91	0.04%
Sheep	524	0.25%
Cattle	1413	0.67%
Domestic fowl	21166	9.98%
Other birds	4234	2%
Reptiles	558	0.26%
Xenopus	50	0.02%
Other Amphibians	531	0.25%
Zebra fish	5414	2.55%
Other Fish	74753	35.24%
Total	**212144**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	202387	95.4%
Animals born in the EU but not at a registered breeder	9222	4.35%
Animals born in rest of world	535	0.25%
Total	**212144**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	71954	1042	72996
Rats	24809	46	24855
Guinea-Pigs	1377	6	1383
Hamsters (Syrian)	15		15
Mongolian gerbil	46		46
Other Rodents	635		635
Rabbits	2031	102	2133
Cats	121	11	132
Dogs	437	200	637
Ferrets	1		1
Other carnivores	1		1
Horses, donkeys and cross-breeds	90	15	105
Pigs	1893	554	2447
Goats	91	6	97
Sheep	524	394	918
Cattle	1413	1321	2734
Domestic fowl	21166	51	21217
Other birds	4234	26	4260
Reptiles	558		558
Xenopus	50		50
Other Amphibians	531		531
Zebra fish	5414		5414
Other Fish	74753	108	74861
Total	**212144**	**3882**	**216026**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	74438	34.46%
Translational and applied research	27640	12.79%
Regulatory use and Routine production	54133	25.06%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	47646	22.06%
Preservation of species	6437	2.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5732	2.65%
Total	**216026**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	7593	10.2%
Cardiovascular Blood and Lymphatic System	6413	8.62%
Nervous System	8951	12.02%
Respiratory System	503	0.68%
Gastrointestinal System including Liver	1727	2.32%
Musculoskeletal System	484	0.65%
Immune System	11401	15.32%
Urogenital/Reproductive System	6488	8.72%
Sensory Organs (skin, eyes and ears)	525	0.71%
Endocrine System/Metabolism	3777	5.07%
Multisystemic	6311	8.48%
Ethology / Animal Behaviour /Animal Biology	7542	10.13%
Other basic research	12723	17.09%
Total	**74438**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3761	13.61%
Human Infectious Disorders	1309	4.74%
Human Cardiovascular Disorders	1308	4.73%
Human Nervous and Mental Disorders	2009	7.27%
Human Gastrointestinal Disorders including Liver	861	3.12%
Human Musculoskeletal Disorders	114	0.41%
Human Immune Disorders	303	1.1%
Human Urogenital/Reproductive Disorders	496	1.79%
Human Sensory Organ Disorders (skin, eyes and ears)	112	0.41%
Human Endocrine/Metabolism Disorders	2066	7.47%
Other Human Disorders	379	1.37%
Animal Diseases and Disorders	3643	13.18%
Animal Welfare	3897	14.1%
Diagnosis of diseases	7373	26.68%
Non-regulatory toxicology and ecotoxicology	9	0.03%
Total	**27640**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	12209	22.55%
Other efficacy and tolerance testing	326	0.6%
Toxicity and other safety testing including pharmacology	25293	46.72%
Routine production	16305	30.12%
Total	**54133**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	523	4.28%
Pyrogenicity testing	81	0.66%
Batch potency testing	11397	93.35%
Other quality controls	208	1.7%
Total	**12209**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	4646	18.37%
Skin sensitisation	637	2.52%
Eye irritation/corrosion	18	0.07%
Repeated dose toxicity	1440	5.69%
Reproductive toxicity	3136	12.4%
Developmental toxicity	274	1.08%
Kinetics	144	0.57%
Pharmaco-dynamics (incl safety pharmacology)	24	0.09%
Ecotoxicity	14374	56.83%
Safety testing in food and feed area	438	1.73%
Target animal safety	50	0.2%
Other toxicity/safety testing	112	0.44%
Total	**25293**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	994	21.39%
Other lethal methods	3652	78.61%
Total	**4646**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	482	33.47%
29 - 90 days	552	38.33%
> 90 days	406	28.19%
Total	**1440**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	12714	88.45%
Other ecotoxicity	1660	11.55%
Total	**14374**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2682	7.09%
Legislation on medicinal products for veterinary use and their residues	12127	32.06%
Medical devices legislation	719	1.9%
Industrial chemicals legislation	4345	11.49%
Food legislation including food contact material	170	0.45%
Feed legislation including legislation for the safety of target animals, workers and environment	525	1.39%
Other legislation	17260	45.63%
Total	**37828**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	28179	74.49%
Legislation satisfying national requirements only [within EU]	9649	25.51%
Total	**37828**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	777	4.77%
Monoclonal antibody by mouse ascites method	230	1.41%
Other product types	15298	93.82%
Total	**16305**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	212144	98.2%
Yes	3882	1.8%
Total	**216026**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	13419	6.21%
Mild [up to and including]	93112	43.1%
Moderate	93344	43.21%
Severe	16151	7.48%
Total	**216026**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	199255	92.24%
Genetically altered without a harmful phenotype	13888	6.43%
Genetically altered with a harmful phenotype	2883	1.33%
Total	**216026**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	9007	216	9223
Rats	2112		2112
Zebra fish		14351	14351
Total	**11119**	**14567**	**25686**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	5695	22.17%
Mild [up to and including]	17018	66.25%
Moderate	2973	11.57%
Total	**25686**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	25686	100%
Total	**25686**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	1325	5.16%
Cardiovascular Blood and Lymphatic System	16566	64.54%
Nervous System	155	0.6%
Immune System	1726	6.72%
Urogenital/Reproductive System	5617	21.88%
Other basic research	280	1.09%
Total	**25669**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Animal Welfare	17	100%
Total	**17**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Denmark, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	159566	68.84%
Rats	37955	16.37%
Guinea-Pigs	2932	1.26%
Hamsters (Syrian)	282	0.12%
Other Rodents	3	0%
Rabbits	2439	1.05%
Dogs	69	0.03%
Ferrets	4	0%
Other carnivores	935	0.4%
Horses, donkeys and cross-breeds	55	0.02%
Pigs	5481	2.36%
Goats	1	0%
Sheep	56	0.02%
Cattle	3663	1.58%
Other Mammals	28	0.01%
Domestic fowl	402	0.17%
Other birds	408	0.18%
Reptiles	269	0.12%
Xenopus	75	0.03%
Other Amphibians	47	0.02%
Zebra fish	1587	0.68%
Other Fish	15538	6.7%
Total	**231795**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	201515	86.94%
Animals born in the EU but not at a registered breeder	24528	10.58%
Animals born in rest of Europe	537	0.23%
Animals born in rest of world	5215	2.25%
Total	**231795**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	159566	856	160422
Rats	37955	543	38498
Guinea-Pigs	2932	15	2947
Hamsters (Syrian)	282		282
Other Rodents	3		3
Rabbits	2439	4	2443
Dogs	69	145	214
Ferrets	4		4
Other carnivores	935	100	1035
Horses, donkeys and cross-breeds	55	64	119
Pigs	5481	320	5801
Goats	1		1
Sheep	56	10	66
Cattle	3663	14	3677
Other Mammals	28		28
Domestic fowl	402	64	466
Other birds	408		408
Reptiles	269	20	289
Rana		4	4
Xenopus	75	210	285
Other Amphibians	47		47
Zebra fish	1587		1587
Other Fish	15538	68	15606
Total	**231795**	**2437**	**234232**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	79399	33.9%
Translational and applied research	121977	52.08%
Regulatory use and Routine production	19865	8.48%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2875	1.23%
Preservation of species	5637	2.41%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4463	1.91%
Forensic enquiries	16	0.01%
Total	**234232**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6469	8.15%
Cardiovascular Blood and Lymphatic System	4268	5.38%
Nervous System	18149	22.86%
Respiratory System	2444	3.08%
Gastrointestinal System including Liver	2478	3.12%
Musculoskeletal System	2462	3.1%
Immune System	22727	28.62%
Urogenital/Reproductive System	2220	2.8%
Sensory Organs (skin, eyes and ears)	77	0.1%
Endocrine System/Metabolism	12359	15.57%
Multisystemic	485	0.61%
Ethology / Animal Behaviour /Animal Biology	2363	2.98%
Other basic research	2898	3.65%
Total	**79399**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18429	15.11%
Human Infectious Disorders	7665	6.28%
Human Cardiovascular Disorders	2016	1.65%
Human Nervous and Mental Disorders	31340	25.69%
Human Respiratory Disorders	176	0.14%
Human Gastrointestinal Disorders including Liver	762	0.62%
Human Musculoskeletal Disorders	378	0.31%
Human Immune Disorders	4959	4.07%
Human Urogenital/Reproductive Disorders	647	0.53%
Human Sensory Organ Disorders (skin, eyes and ears)	336	0.28%
Human Endocrine/Metabolism Disorders	37015	30.35%
Other Human Disorders	9168	7.52%
Animal Diseases and Disorders	5708	4.68%
Animal Welfare	1568	1.29%
Diagnosis of diseases	1023	0.84%
Non-regulatory toxicology and ecotoxicology	787	0.65%
Total	**121977**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	8139	40.97%
Other efficacy and tolerance testing	725	3.65%
Toxicity and other safety testing including pharmacology	10257	51.63%
Routine production	744	3.75%
Total	**19865**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2504	30.77%
Batch potency testing	5601	68.82%
Other quality controls	34	0.42%
Total	**8139**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3968	38.69%
Skin irritation/corrosion	28	0.27%
Skin sensitisation	177	1.73%
Repeated dose toxicity	2205	21.5%
Reproductive toxicity	935	9.12%
Kinetics	818	7.98%
Pharmaco-dynamics (incl safety pharmacology)	26	0.25%
Ecotoxicity	2100	20.47%
Total	**10257**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	3968	100%
Total	**3968**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1382	62.68%
29 - 90 days	586	26.58%
> 90 days	237	10.75%
Total	**2205**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	120	5.71%
Chronic toxicity	1800	85.71%
Bioaccumulation	180	8.57%
Total	**2100**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16100	84.2%
Industrial chemicals legislation	2987	15.62%
Other legislation	34	0.18%
Total	**19121**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19021	99.48%
Legislation satisfying national requirements only [within EU]	100	0.52%
Total	**19121**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	288	38.71%
Other product types	456	61.29%
Total	**744**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	231795	98.96%
Yes	2437	1.04%
Total	**234232**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	22792	9.73%
Mild [up to and including]	123841	52.87%
Moderate	85837	36.65%
Severe	1762	0.75%
Total	**234232**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	195240	83.35%
Genetically altered without a harmful phenotype	27228	11.62%
Genetically altered with a harmful phenotype	11764	5.02%
Total	**234232**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	3686		3686
Pigs	2		2
Total	**3688**		**3688**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	79	2.14%
Mild [up to and including]	3143	85.22%
Moderate	466	12.64%
Total	**3688**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	2803	76%
Genetically altered without a harmful phenotype	679	18.41%
Genetically altered with a harmful phenotype	206	5.59%
Total	**3688**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	258	7.33%
Cardiovascular Blood and Lymphatic System	2	0.06%
Nervous System	92	2.61%
Musculoskeletal System	818	23.25%
Endocrine System/Metabolism	273	7.76%
Ethology / Animal Behaviour /Animal Biology	91	2.59%
Other basic research	1985	56.41%
Total	**3519**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	169	100%
Total	**169**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	29		29
Total	**29**		**29**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	29	100%
Total	**29**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	29	100%
Total	**29**	**100.00%**

Member State: Estonia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	2168	81.38%
Rats	296	11.11%
Pigs	4	0.15%
Cattle	16	0.6%
Other birds	180	6.76%
Total	**2664**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2484	93.24%
Animals born in the EU but not at a registered breeder	180	6.76%
Total	**2664**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	2168		2168
Rats	296		296
Pigs	4		4
Cattle	16		16
Other birds	180		180
Total	**2664**		**2664**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	2304	86.49%
Translational and applied research	210	7.88%
Regulatory use and Routine production	112	4.2%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	38	1.43%
Total	**2664**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	985	42.75%
Cardiovascular Blood and Lymphatic System	93	4.04%
Nervous System	407	17.66%
Gastrointestinal System including Liver	32	1.39%
Musculoskeletal System	88	3.82%
Immune System	99	4.3%
Sensory Organs (skin, eyes and ears)	32	1.39%
Endocrine System/Metabolism	219	9.51%
Multisystemic	153	6.64%
Ethology / Animal Behaviour /Animal Biology	180	7.81%
Other basic research	16	0.69%
Total	**2304**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Respiratory Disorders	210	100%
Total	**210**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	112	100%
Total	**112**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	38	33.93%
Carcinogenicity	74	66.07%
Total	**112**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	38	100%
Total	**38**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	112	100%
Total	**112**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	112	100%
Total	**112**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	2664	100%
Total	**2664**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	122	4.58%
Mild [up to and including]	955	35.85%
Moderate	1312	49.25%
Severe	275	10.32%
Total	**2664**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1940	72.82%
Genetically altered without a harmful phenotype	724	27.18%
Total	**2664**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	16		16
Rats	72		72
Total	**88**		**88**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	10	11.36%
Mild [up to and including]	36	40.91%
Moderate	42	47.73%
Total	**88**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	16	18.18%
Genetically altered without a harmful phenotype	72	81.82%
Total	**88**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Nervous System	88	100%
Total	**88**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	394		394
Total	**394**		**394**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	394	100%
Total	**394**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	394	100%
Total	**394**	**100.00%**

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Member State: Finland, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	48580	49.9%
Rats	13467	13.83%
Guinea-Pigs	9	0.01%
Hamsters (Syrian)	149	0.15%
Other Rodents	690	0.71%
Rabbits	223	0.23%
Cats	311	0.32%
Dogs	3035	3.12%
Other carnivores	107	0.11%
Horses, donkeys and cross-breeds	30	0.03%
Pigs	632	0.65%
Sheep	1319	1.35%
Cattle	207	0.21%
Other Mammals	1521	1.56%
Domestic fowl	8485	8.72%
Other birds	404	0.41%
Zebra fish	6454	6.63%
Other Fish	11729	12.05%
Total	**97352**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	71217	73.15%
Animals born in the EU but not at a registered breeder	23562	24.2%
Animals born in rest of Europe	5	0.01%
Animals born in rest of world	2568	2.64%
Total	**97352**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	48580	51	48631
Rats	13467		13467
Guinea-Pigs	9		9
Hamsters (Syrian)	149		149
Other Rodents	690		690
Rabbits	223	4	227
Cats	311		311
Dogs	3035	26	3061
Other carnivores	107		107
Horses, donkeys and cross-breeds	30	47	77
Pigs	632		632
Sheep	1319		1319
Cattle	207	9	216
Other Mammals	1521	12	1533
Domestic fowl	8485		8485
Other birds	404		404
Zebra fish	6454		6454
Other Fish	11729		11729
Total	**97352**	**149**	**97501**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	54625	56.03%
Translational and applied research	33315	34.17%
Regulatory use and Routine production	7895	8.1%
Preservation of species	60	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1606	1.65%
Total	**97501**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6529	11.95%
Cardiovascular Blood and Lymphatic System	5098	9.33%
Nervous System	10383	19.01%
Respiratory System	80	0.15%
Gastrointestinal System including Liver	545	1%
Musculoskeletal System	337	0.62%
Immune System	10325	18.9%
Urogenital/Reproductive System	181	0.33%
Sensory Organs (skin, eyes and ears)	268	0.49%
Endocrine System/Metabolism	900	1.65%
Multisystemic	6005	10.99%
Ethology / Animal Behaviour /Animal Biology	7546	13.81%
Other basic research	6428	11.77%
Total	**54625**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	5016	15.06%
Human Infectious Disorders	860	2.58%
Human Cardiovascular Disorders	662	1.99%
Human Nervous and Mental Disorders	19579	58.77%
Human Gastrointestinal Disorders including Liver	117	0.35%
Human Musculoskeletal Disorders	605	1.82%
Human Immune Disorders	71	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	470	1.41%
Human Endocrine/Metabolism Disorders	371	1.11%
Other Human Disorders	755	2.27%
Animal Diseases and Disorders	4384	13.16%
Animal Welfare	226	0.68%
Diagnosis of diseases	123	0.37%
Non-regulatory toxicology and ecotoxicology	68	0.2%
Total	**33315**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	3395	43%
Other efficacy and tolerance testing	156	1.98%
Toxicity and other safety testing including pharmacology	2868	36.33%
Routine production	1476	18.7%
Total	**7895**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch potency testing	3395	100%
Total	**3395**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	134	4.67%
Kinetics	1171	40.83%
Pharmaco-dynamics (incl safety pharmacology)	1556	54.25%
Other toxicity/safety testing	7	0.24%
Total	**2868**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	134	100%
Total	**134**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2992	46.61%
Legislation on medicinal products for veterinary use and their residues	3395	52.89%
Feed legislation including legislation for the safety of target animals, workers and environment	32	0.5%
Total	**6419**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6419	100%
Total	**6419**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	296	20.05%
Other product types	1180	79.95%
Total	**1476**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	97352	99.85%
Yes	149	0.15%
Total	**97501**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	8735	8.96%
Mild [up to and including]	46758	47.96%
Moderate	33282	34.14%
Severe	8726	8.95%
Total	**97501**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	71470	73.3%
Genetically altered without a harmful phenotype	17743	18.2%
Genetically altered with a harmful phenotype	8288	8.5%
Total	**97501**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	4155		4155
Rats	5		5
Zebra fish	699		699
Total	**4859**		**4859**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	347	7.14%
Mild [up to and including]	2805	57.73%
Moderate	1694	34.86%
Severe	13	0.27%
Total	**4859**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1607	33.07%
Genetically altered without a harmful phenotype	2756	56.72%
Genetically altered with a harmful phenotype	496	10.21%
Total	**4859**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	262	5.63%
Cardiovascular Blood and Lymphatic System	47	1.01%
Nervous System	1522	32.71%
Immune System	699	15.02%
Endocrine System/Metabolism	487	10.47%
Multisystemic	1582	34%
Other basic research	54	1.16%
Total	**4653**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	124	60.19%
Human Sensory Organ Disorders (skin, eyes and ears)	7	3.4%
Human Endocrine/Metabolism Disorders	71	34.47%
Other Human Disorders	4	1.94%
Total	**206**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	215		215
Total	**215**		**215**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	207	96.28%
Moderate	8	3.72%
Total	**215**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	3	1.4%
Genetically altered without a harmful phenotype	179	83.26%
Genetically altered with a harmful phenotype	33	15.35%
Total	**215**	**100.00%**

Member State: France, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1011925	57.57%
Rats	173535	9.87%
Guinea-Pigs	44976	2.56%
Hamsters (Syrian)	6529	0.37%
Hamsters (Chinese)	167	0.01%
Mongolian gerbil	429	0.02%
Other Rodents	857	0.05%
Rabbits	124544	7.09%
Cats	315	0.02%
Dogs	2752	0.16%
Ferrets	148	0.01%
Other carnivores	24	0%
Horses, donkeys and cross-breeds	109	0.01%
Pigs	9261	0.53%
Goats	311	0.02%
Sheep	2633	0.15%
Cattle	956	0.05%
Prosimians	86	0%
Marmoset and tamarins	131	0.01%
Cynomolgus monkey	2001	0.11%
Rhesus monkey	26	0%
Vervets (Chlorocebus spp.)	33	0%
Baboons	11	0%
Squirrel monkey	7	0%
Other species of Old World Monkeys (Cercopithecoidea)	9	0%
Other Mammals	18125	1.03%
Domestic fowl	42582	2.42%
Other birds	26997	1.54%
Reptiles	14	0%
Rana	118	0.01%
Xenopus	3570	0.2%
Other Amphibians	742	0.04%
Zebra fish	16199	0.92%
Other Fish	267714	15.23%
Cephalopods	1	0%
Total	**1757837**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1501087	85.51%
Animals born in the EU but not at a registered breeder	152224	8.67%
Animals born in rest of Europe	48610	2.77%
Animals born in rest of world	53612	3.05%
Total	**1755533**	**100.00%**

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Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	236	10.24%
Animals born in rest of Europe	5	0.22%
Animals born in Asia	130	5.64%
Animals born in America	35	1.52%
Animals born in Africa	1729	75.04%
Animals born elsewhere	169	7.34%
Total	**2304**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	885	38.41%
F2 or greater	1285	55.77%
Self-sustaining colony	134	5.82%
Total	**2304**	**100.00%**

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1011925	16158	1028083
Rats	173535	6078	179613
Guinea-Pigs	44976	58	45034
Hamsters (Syrian)	6529		6529
Hamsters (Chinese)	167		167
Mongolian gerbil	429		429
Other Rodents	857	100	957
Rabbits	124544	2354	126898
Cats	315	552	867
Dogs	2752	1344	4096
Ferrets	148		148
Other carnivores	24	3	27
Horses, donkeys and cross-breeds	109	196	305
Pigs	9261	1085	10346
Goats	311	527	838
Sheep	2633	2763	5396
Cattle	956	821	1777
Prosimians	86		86
Marmoset and tamarins	131	93	224
Cynomolgus monkey	2001	1278	3279
Rhesus monkey	26	45	71
Vervets (Chlorocebus spp.)	33	5	38
Baboons	11	21	32
Squirrel monkey	7		7
Other species of Old World Monkeys (Cercopithecoidea)	9		9
Other Mammals	18125	400	18525
Domestic fowl	42582	562	43144
Other birds	26997	228	27225
Reptiles	14	3448	3462
Rana	118		118
Xenopus	3570	1327	4897
Other Amphibians	742		742
Zebra fish	16199	600	16799
Other Fish	267714	360	268074
Cephalopods	1		1
Total	**1757837**	**40406**	**1798243**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	687105	38.21%
Translational and applied research	477884	26.58%
Regulatory use and Routine production	574030	31.92%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4918	0.27%
Preservation of species	18786	1.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	35512	1.97%
Forensic enquiries	8	0%
Total	**1798243**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	92211	13.42%
Cardiovascular Blood and Lymphatic System	32298	4.7%
Nervous System	123850	18.02%
Respiratory System	12314	1.79%
Gastrointestinal System including Liver	27363	3.98%
Musculoskeletal System	17391	2.53%
Immune System	90438	13.16%
Urogenital/Reproductive System	18745	2.73%
Sensory Organs (skin, eyes and ears)	5415	0.79%
Endocrine System/Metabolism	40474	5.89%
Multisystemic	7270	1.06%
Ethology / Animal Behaviour /Animal Biology	161945	23.57%
Other basic research	57391	8.35%
Total	**687105**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	120252	25.16%
Human Infectious Disorders	52555	11%
Human Cardiovascular Disorders	14990	3.14%
Human Nervous and Mental Disorders	46285	9.69%
Human Respiratory Disorders	6669	1.4%
Human Gastrointestinal Disorders including Liver	12366	2.59%
Human Musculoskeletal Disorders	13833	2.89%
Human Immune Disorders	19048	3.99%
Human Urogenital/Reproductive Disorders	2240	0.47%
Human Sensory Organ Disorders (skin, eyes and ears)	7750	1.62%
Human Endocrine/Metabolism Disorders	12181	2.55%
Other Human Disorders	9642	2.02%
Animal Diseases and Disorders	37908	7.93%
Animal Welfare	216	0.05%
Diagnosis of diseases	97413	20.38%
Plant diseases	89	0.02%
Non-regulatory toxicology and ecotoxicology	24447	5.12%
Total	**477884**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	201610	35.12%
Other efficacy and tolerance testing	83928	14.62%
Toxicity and other safety testing including pharmacology	113238	19.73%
Routine production	175254	30.53%
Total	**574030**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	20294	10.07%
Pyrogenicity testing	6191	3.07%
Batch potency testing	138017	68.46%
Other quality controls	37108	18.41%
Total	**201610**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3294	2.91%
Skin irritation/corrosion	1754	1.55%
Skin sensitisation	14019	12.38%
Eye irritation/corrosion	253	0.22%
Repeated dose toxicity	24250	21.42%
Carcinogenicity	2295	2.03%
Genotoxicity	486	0.43%
Reproductive toxicity	14165	12.51%
Developmental toxicity	7483	6.61%
Kinetics	18338	16.19%
Pharmaco-dynamics (incl safety pharmacology)	9821	8.67%
Phototoxicity	521	0.46%
Ecotoxicity	13533	11.95%
Safety testing in food and feed area	1570	1.39%
Target animal safety	171	0.15%
Other toxicity/safety testing	1285	1.13%
Total	**113238**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	702	21.31%
Other lethal methods	561	17.03%
Non lethal methods	2031	61.66%
Total	**3294**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	12892	53.16%
29 - 90 days	6543	26.98%
> 90 days	4815	19.86%
Total	**24250**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10955	80.95%
Chronic toxicity	1107	8.18%
Bioaccumulation	846	6.25%
Other ecotoxicity	625	4.62%
Total	**13533**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	226886	56.9%
Legislation on medicinal products for veterinary use and their residues	55686	13.96%
Medical devices legislation	25090	6.29%
Industrial chemicals legislation	12737	3.19%
Plant protection product legislation	4541	1.14%
Biocides legislation	757	0.19%
Food legislation including food contact material	698	0.18%
Feed legislation including legislation for the safety of target animals, workers and environment	72087	18.08%
Other legislation	294	0.07%
Total	**398776**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	392531	98.43%
Legislation satisfying national requirements only [within EU]	1470	0.37%
Legislation satisfying Non-EU requirements only	4775	1.2%
Total	**398776**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	74243	42.36%
Monoclonal antibody by mouse ascites method	44198	25.22%
Other product types	56813	32.42%
Total	**175254**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1757837	97.75%
Yes	40406	2.25%
Total	**1798243**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	99949	5.56%
Mild [up to and including]	636482	35.39%
Moderate	739008	41.1%
Severe	322804	17.95%
Total	**1798243**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1469131	81.7%
Genetically altered without a harmful phenotype	285514	15.88%
Genetically altered with a harmful phenotype	43598	2.42%
Total	**1798243**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	36512	180	36692
Rats	3346		3346
Rabbits	306		306
Zebra fish	5080		5080
Total	**45244**	**180**	**45424**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	3145	6.92%
Mild [up to and including]	18783	41.35%
Moderate	22237	48.95%
Severe	1259	2.77%
Total	**45424**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	16437	36.19%
Genetically altered without a harmful phenotype	23553	51.85%
Genetically altered with a harmful phenotype	5434	11.96%
Total	**45424**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	2002	4.56%
Cardiovascular Blood and Lymphatic System	279	0.64%
Nervous System	17558	39.96%
Gastrointestinal System including Liver	713	1.62%
Musculoskeletal System	110	0.25%
Immune System	1755	3.99%
Urogenital/Reproductive System	1161	2.64%
Sensory Organs (skin, eyes and ears)	20	0.05%
Endocrine System/Metabolism	234	0.53%
Multisystemic	13626	31.01%
Ethology / Animal Behaviour /Animal Biology	2511	5.72%
Other basic research	3967	9.03%
Total	**43936**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	91	6.12%
Human Cardiovascular Disorders	213	14.31%
Human Nervous and Mental Disorders	63	4.23%
Human Gastrointestinal Disorders including Liver	7	0.47%
Human Musculoskeletal Disorders	648	43.55%
Human Sensory Organ Disorders (skin, eyes and ears)	10	0.67%
Human Endocrine/Metabolism Disorders	321	21.57%
Other Human Disorders	100	6.72%
Animal Diseases and Disorders	35	2.35%
Total	**1488**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	69742		69742
Rats	755		755
Dogs	10		10
Total	**70507**		**70507**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	48518	68.81%
Moderate	19608	27.81%
Severe	2381	3.38%
Total	**70507**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	66463	94.26%
Genetically altered with a harmful phenotype	4044	5.74%
Total	**70507**	**100.00%**

Member State: Germany, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1171550	65.33%
Rats	245998	13.72%
Guinea-Pigs	14349	0.8%
Hamsters (Syrian)	1217	0.07%
Hamsters (Chinese)	8	0%
Mongolian gerbil	4154	0.23%
Other Rodents	9950	0.55%
Rabbits	89147	4.97%
Cats	431	0.02%
Dogs	1720	0.1%
Ferrets	172	0.01%
Other carnivores	535	0.03%
Horses, donkeys and cross-breeds	1013	0.06%
Pigs	16069	0.9%
Goats	195	0.01%
Sheep	2832	0.16%
Cattle	5842	0.33%
Prosimians	12	0%
Marmoset and tamarins	197	0.01%
Cynomolgus monkey	2387	0.13%
Rhesus monkey	67	0%
Baboons	14	0%
Squirrel monkey	1	0%
Other Mammals	1259	0.07%
Domestic fowl	24463	1.36%
Other birds	11339	0.63%
Reptiles	351	0.02%
Rana	377	0.02%
Xenopus	3405	0.19%
Other Amphibians	2652	0.15%
Zebra fish	87413	4.87%
Other Fish	94180	5.25%
Total	**1793299**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1663522	92.9%
Animals born in the EU but not at a registered breeder	98960	5.53%
Animals born in rest of Europe	15127	0.84%
Animals born in rest of world	13012	0.73%
Total	**1790621**	**100.00%**

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Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	350	13.07%
Animals born in Asia	1699	63.44%
Animals born in Africa	628	23.45%
Animals born elsewhere	1	0.04%
Total	**2678**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	338	12.62%
F2 or greater	1786	66.69%
Self-sustaining colony	554	20.69%
Total	**2678**	**100.00%**

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1171550	17159	1188709
Rats	245998	4481	250479
Guinea-Pigs	14349	502	14851
Hamsters (Syrian)	1217	5	1222
Hamsters (Chinese)	8		8
Mongolian gerbil	4154	101	4255
Other Rodents	9950		9950
Rabbits	89147	3497	92644
Cats	431	287	718
Dogs	1720	1610	3330
Ferrets	172	24	196
Other carnivores	535		535
Horses, donkeys and cross-breeds	1013	196	1209
Pigs	16069	1214	17283
Goats	195	17	212
Sheep	2832	221	3053
Cattle	5842	490	6332
Prosimians	12	75	87
Marmoset and tamarins	197	17	214
Cynomolgus monkey	2387	615	3002
Rhesus monkey	67	50	117
Vervets (Chlorocebus spp.)		15	15
Baboons	14		14
Squirrel monkey	1		1
Other species of Old World Monkeys (Cercopithecoidea)		12	12
Other Mammals	1259	93	1352
Domestic fowl	24463	457	24920
Other birds	11339	661	12000
Reptiles	351	18	369
Rana	377		377
Xenopus	3405	1141	4546
Other Amphibians	2652		2652
Zebra fish	87413		87413
Other Fish	94180	30	94210
Total	**1793299**	**32988**	**1826287**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	875421	47.93%
Translational and applied research	291152	15.94%
Regulatory use and Routine production	556946	30.5%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8491	0.46%
Preservation of species	41156	2.25%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	53121	2.91%
Total	**1826287**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	85330	9.75%
Cardiovascular Blood and Lymphatic System	84382	9.64%
Nervous System	194683	22.24%
Respiratory System	23256	2.66%
Gastrointestinal System including Liver	30152	3.44%
Musculoskeletal System	16529	1.89%
Immune System	183041	20.91%
Urogenital/Reproductive System	14651	1.67%
Sensory Organs (skin, eyes and ears)	20387	2.33%
Endocrine System/Metabolism	50807	5.8%
Multisystemic	42693	4.88%
Ethology / Animal Behaviour /Animal Biology	46171	5.27%
Other basic research	83339	9.52%
Total	**875421**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	124509	42.76%
Human Infectious Disorders	17913	6.15%
Human Cardiovascular Disorders	15246	5.24%
Human Nervous and Mental Disorders	36680	12.6%
Human Respiratory Disorders	13197	4.53%
Human Gastrointestinal Disorders including Liver	13424	4.61%
Human Musculoskeletal Disorders	3926	1.35%
Human Immune Disorders	11314	3.89%
Human Urogenital/Reproductive Disorders	4613	1.58%
Human Sensory Organ Disorders (skin, eyes and ears)	5491	1.89%
Human Endocrine/Metabolism Disorders	8031	2.76%
Other Human Disorders	1223	0.42%
Animal Diseases and Disorders	17368	5.97%
Animal Welfare	6271	2.15%
Diagnosis of diseases	2488	0.85%
Plant diseases	69	0.02%
Non-regulatory toxicology and ecotoxicology	9389	3.22%
Total	**291152**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	188089	33.77%
Other efficacy and tolerance testing	32991	5.92%
Toxicity and other safety testing including pharmacology	260473	46.77%
Routine production	75393	13.54%
Total	**556946**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	19382	10.3%
Pyrogenicity testing	5591	2.97%
Batch potency testing	161272	85.74%
Other quality controls	1844	0.98%
Total	**188089**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10357	3.98%
Skin irritation/corrosion	884	0.34%
Skin sensitisation	8711	3.34%
Eye irritation/corrosion	171	0.07%
Repeated dose toxicity	19136	7.35%
Carcinogenicity	1961	0.75%
Genotoxicity	3522	1.35%
Reproductive toxicity	21926	8.42%
Developmental toxicity	35887	13.78%
Neurotoxicity	86	0.03%
Kinetics	31782	12.2%
Pharmaco-dynamics (incl safety pharmacology)	79250	30.43%
Ecotoxicity	38843	14.91%
Safety testing in food and feed area	1721	0.66%
Target animal safety	3423	1.31%
Other toxicity/safety testing	2813	1.08%
Total	**260473**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4136	39.93%
Other lethal methods	182	1.76%
Non lethal methods	6039	58.31%
Total	**10357**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13183	68.89%
29 - 90 days	4136	21.61%
> 90 days	1817	9.5%
Total	**19136**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	6957	17.91%
Chronic toxicity	16704	43%
Reproductive ecotoxicity	904	2.33%
Endocrine activity	5840	15.03%
Bioaccumulation	1807	4.65%
Other ecotoxicity	6631	17.07%
Total	**38843**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	340657	70.74%
Legislation on medicinal products for veterinary use and their residues	23605	4.9%
Medical devices legislation	12591	2.61%
Industrial chemicals legislation	50430	10.47%
Plant protection product legislation	46143	9.58%
Biocides legislation	2284	0.47%
Food legislation including food contact material	14	0%
Feed legislation including legislation for the safety of target animals, workers and environment	3554	0.74%
Other legislation	2275	0.47%
Total	**481553**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	470469	97.7%
Legislation satisfying national requirements only [within EU]	2083	0.43%
Legislation satisfying Non-EU requirements only	9001	1.87%
Total	**481553**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	73520	97.52%
Monoclonal antibody by mouse ascites method	384	0.51%
Other product types	1489	1.97%
Total	**75393**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1793299	98.19%
Yes	32988	1.81%
Total	**1826287**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	166236	9.1%
Mild [up to and including]	1040646	56.98%
Moderate	507633	27.8%
Severe	111772	6.12%
Total	**1826287**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1241283	67.97%
Genetically altered without a harmful phenotype	465516	25.49%
Genetically altered with a harmful phenotype	119488	6.54%
Total	**1826287**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	117993	432	118425
Rats	3396		3396
Rabbits	17		17
Pigs	61	3	64
Marmoset and tamarins	10		10
Zebra fish	48540	3451	51991
Other Fish	3348		3348
Total	**173365**	**3886**	**177251**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	11592	6.54%
Mild [up to and including]	143868	81.17%
Moderate	21251	11.99%
Severe	540	0.3%
Total	**177251**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	159047	89.73%
Genetically altered with a harmful phenotype	18204	10.27%
Total	**177251**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	6057	3.7%
Cardiovascular Blood and Lymphatic System	24671	15.06%
Nervous System	21445	13.09%
Respiratory System	323	0.2%
Gastrointestinal System including Liver	2935	1.79%
Musculoskeletal System	9128	5.57%
Immune System	19540	11.93%
Urogenital/Reproductive System	8775	5.36%
Sensory Organs (skin, eyes and ears)	7414	4.53%
Endocrine System/Metabolism	7078	4.32%
Multisystemic	14782	9.02%
Ethology / Animal Behaviour /Animal Biology	135	0.08%
Other basic research	41521	25.35%
Total	**163804**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	1105	8.22%
Human Infectious Disorders	475	3.53%
Human Cardiovascular Disorders	1677	12.47%
Human Nervous and Mental Disorders	1893	14.08%
Human Respiratory Disorders	174	1.29%
Human Gastrointestinal Disorders including Liver	2474	18.4%
Human Musculoskeletal Disorders	13	0.1%
Human Immune Disorders	345	2.57%
Human Urogenital/Reproductive Disorders	171	1.27%
Human Sensory Organ Disorders (skin, eyes and ears)	1009	7.5%
Human Endocrine/Metabolism Disorders	4107	30.54%
Other Human Disorders	4	0.03%
Total	**13447**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	61184	129	61313
Rats	1574		1574
Zebra fish	2272		2272
Other Fish	116		116
Total	**65146**	**129**	**65275**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	267	0.41%
Mild [up to and including]	42476	65.07%
Moderate	19737	30.24%
Severe	2795	4.28%
Total	**65275**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	34238	52.45%
Genetically altered with a harmful phenotype	31037	47.55%
Total	**65275**	**100.00%**

Member State: Greece, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	21190	50.08%
Rats	2435	5.76%
Guinea-Pigs	6	0.01%
Rabbits	213	0.5%
Dogs	23	0.05%
Pigs	283	0.67%
Sheep	8	0.02%
Cattle	3	0.01%
Domestic fowl	6	0.01%
Zebra fish	1859	4.39%
Other Fish	16250	38.41%
Cephalopods	33	0.08%
Total	**42309**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	41636	98.41%
Animals born in the EU but not at a registered breeder	33	0.08%
Animals born in rest of world	640	1.51%
Total	**42309**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	21190	329	21519
Rats	2435	3	2438
Guinea-Pigs	6		6
Rabbits	213		213
Cats		8	8
Dogs	23	18	41
Pigs	283	6	289
Sheep	8		8
Cattle	3		3
Rhesus monkey		1	1
Domestic fowl	6		6
Zebra fish	1859		1859
Other Fish	16250	96	16346
Cephalopods	33		33
Total	**42309**	**461**	**42770**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	23613	55.21%
Translational and applied research	8058	18.84%
Regulatory use and Routine production	6887	16.1%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3093	7.23%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1119	2.62%
Total	**42770**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	923	3.91%
Cardiovascular Blood and Lymphatic System	1315	5.57%
Nervous System	1204	5.1%
Gastrointestinal System including Liver	428	1.81%
Musculoskeletal System	520	2.2%
Immune System	2225	9.42%
Urogenital/Reproductive System	242	1.02%
Sensory Organs (skin, eyes and ears)	988	4.18%
Endocrine System/Metabolism	843	3.57%
Multisystemic	99	0.42%
Ethology / Animal Behaviour /Animal Biology	14686	62.19%
Other basic research	140	0.59%
Total	**23613**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	2487	30.86%
Human Infectious Disorders	271	3.36%
Human Cardiovascular Disorders	967	12%
Human Nervous and Mental Disorders	1372	17.03%
Human Respiratory Disorders	291	3.61%
Human Gastrointestinal Disorders including Liver	363	4.5%
Human Musculoskeletal Disorders	710	8.81%
Human Immune Disorders	200	2.48%
Human Sensory Organ Disorders (skin, eyes and ears)	381	4.73%
Human Endocrine/Metabolism Disorders	34	0.42%
Other Human Disorders	648	8.04%
Animal Welfare	40	0.5%
Diagnosis of diseases	230	2.85%
Non-regulatory toxicology and ecotoxicology	64	0.79%
Total	**8058**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	6887	100%
Total	**6887**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	10	0.15%
Safety testing in food and feed area	6877	99.85%
Total	**6887**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

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Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	10	0.15%
Food legislation including food contact material	6877	99.85%
Total	**6887**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6887	100%
Total	**6887**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	42309	98.92%
Yes	461	1.08%
Total	**42770**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	3646	8.52%
Mild [up to and including]	25432	59.46%
Moderate	9198	21.51%
Severe	4494	10.51%
Total	**42770**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	31622	73.94%
Genetically altered without a harmful phenotype	9022	21.09%
Genetically altered with a harmful phenotype	2126	4.97%
Total	**42770**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	3960		3960
Total	**3960**		**3960**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	3960	100%
Total	**3960**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	3960	100%
Total	**3960**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Other basic research	3960	100%
Total	**3960**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

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Member State: Hungary, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	65368	49.18%
Rats	33255	25.02%
Guinea-Pigs	5731	4.31%
Rabbits	1343	1.01%
Cats	16	0.01%
Dogs	359	0.27%
Ferrets	4	0%
Pigs	2078	1.56%
Cattle	12	0.01%
Rhesus monkey	2	0%
Domestic fowl	20575	15.48%
Other birds	2084	1.57%
Zebra fish	928	0.7%
Other Fish	1174	0.88%
Total	**132929**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	126369	95.07%
Animals born in the EU but not at a registered breeder	5062	3.81%
Animals born in rest of Europe	1187	0.89%
Animals born in rest of world	309	0.23%
Total	**132927**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	2	100%
Total	**2**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	2	100%
Total	**2**	**100.00%**

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	65368	346	65714
Rats	33255	691	33946
Guinea-Pigs	5731	34	5765
Rabbits	1343	88	1431
Cats	16		16
Dogs	359	104	463
Ferrets	4		4
Pigs	2078	327	2405
Cattle	12	21	33
Rhesus monkey	2		2
Domestic fowl	20575	4594	25169
Other birds	2084		2084
Zebra fish	928	748	1676
Other Fish	1174		1174
Total	**132929**	**6953**	**139882**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	37658	26.92%
Translational and applied research	41847	29.92%
Regulatory use and Routine production	58007	41.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2370	1.69%
Total	**139882**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	3346	8.89%
Cardiovascular Blood and Lymphatic System	3342	8.87%
Nervous System	16376	43.49%
Respiratory System	718	1.91%
Gastrointestinal System including Liver	1865	4.95%
Musculoskeletal System	189	0.5%
Immune System	4412	11.72%
Urogenital/Reproductive System	1678	4.46%
Sensory Organs (skin, eyes and ears)	488	1.3%
Endocrine System/Metabolism	1417	3.76%
Multisystemic	1802	4.79%
Ethology / Animal Behaviour /Animal Biology	526	1.4%
Other basic research	1499	3.98%
Total	**37658**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	4919	11.75%
Human Infectious Disorders	581	1.39%
Human Cardiovascular Disorders	293	0.7%
Human Nervous and Mental Disorders	20172	48.2%
Human Gastrointestinal Disorders including Liver	211	0.5%
Human Musculoskeletal Disorders	79	0.19%
Human Immune Disorders	89	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	40	0.1%
Other Human Disorders	224	0.54%
Animal Diseases and Disorders	9410	22.49%
Animal Welfare	4573	10.93%
Diagnosis of diseases	788	1.88%
Non-regulatory toxicology and ecotoxicology	460	1.1%
Total	**41847**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	27156	46.82%
Other efficacy and tolerance testing	329	0.57%
Toxicity and other safety testing including pharmacology	29813	51.4%
Routine production	709	1.22%
Total	**58007**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	10102	37.2%
Pyrogenicity testing	29	0.11%
Batch potency testing	16682	61.43%
Other quality controls	343	1.26%
Total	**27156**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	17639	59.17%
Skin irritation/corrosion	293	0.98%
Skin sensitisation	4629	15.53%
Eye irritation/corrosion	137	0.46%
Repeated dose toxicity	1125	3.77%
Carcinogenicity	40	0.13%
Genotoxicity	562	1.89%
Reproductive toxicity	833	2.79%
Developmental toxicity	1286	4.31%
Kinetics	1207	4.05%
Pharmaco-dynamics (incl safety pharmacology)	569	1.91%
Ecotoxicity	1028	3.45%
Other toxicity/safety testing	465	1.56%
Total	**29813**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	14255	80.82%
Non lethal methods	3384	19.18%
Total	**17639**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	438	38.93%
29 - 90 days	75	6.67%
> 90 days	612	54.4%
Total	**1125**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1028	100%
Total	**1028**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	24550	42.85%
Legislation on medicinal products for veterinary use and their residues	28770	50.21%
Medical devices legislation	516	0.9%
Industrial chemicals legislation	834	1.46%
Plant protection product legislation	2167	3.78%
Food legislation including food contact material	461	0.8%
Total	**57298**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	56022	97.77%
Legislation satisfying Non-EU requirements only	1276	2.23%
Total	**57298**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	40	5.64%
Monoclonal antibody by mouse ascites method	157	22.14%
Other product types	512	72.21%
Total	**709**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	132929	95.03%
Yes	6953	4.97%
Total	**139882**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	12314	8.8%
Mild [up to and including]	69792	49.89%
Moderate	39760	28.42%
Severe	18016	12.88%
Total	**139882**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	131890	94.29%
Genetically altered without a harmful phenotype	7386	5.28%
Genetically altered with a harmful phenotype	606	0.43%
Total	**139882**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	162		162
Rabbits	152		152
Zebra fish		567	567
Total	**314**	**567**	**881**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	96	10.9%
Mild [up to and including]	591	67.08%
Moderate	194	22.02%
Total	**881**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	339	38.48%
Genetically altered without a harmful phenotype	512	58.12%
Genetically altered with a harmful phenotype	30	3.41%
Total	**881**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	64	7.26%
Nervous System	122	13.85%
Multisystemic	567	64.36%
Other basic research	128	14.53%
Total	**881**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Ireland, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	205849	85.57%
Rats	16858	7.01%
Guinea-Pigs	518	0.22%
Rabbits	400	0.17%
Dogs	46	0.02%
Ferrets	442	0.18%
Horses, donkeys and cross-breeds	59	0.02%
Pigs	1519	0.63%
Goats	11	0%
Sheep	1189	0.49%
Cattle	2805	1.17%
Domestic fowl	40	0.02%
Other birds	823	0.34%
Xenopus	18	0.01%
Zebra fish	236	0.1%
Other Fish	9755	4.05%
Total	**240568**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	226935	94.33%
Animals born in the EU but not at a registered breeder	13065	5.43%
Animals born in rest of Europe	121	0.05%
Animals born in rest of world	447	0.19%
Total	**240568**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	205849		205849
Rats	16858		16858
Guinea-Pigs	518		518
Rabbits	400		400
Dogs	46	43	89
Ferrets	442		442
Horses, donkeys and cross-breeds	59	1	60
Pigs	1519	28	1547
Goats	11		11
Sheep	1189	132	1321
Cattle	2805	439	3244
Domestic fowl	40		40
Other birds	823		823
Xenopus	18		18
Zebra fish	236		236
Other Fish	9755	32	9787
Total	**240568**	**675**	**241243**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	8492	3.52%
Translational and applied research	29295	12.14%
Regulatory use and Routine production	194816	80.76%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8366	3.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	274	0.11%
Total	**241243**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	391	4.6%
Cardiovascular Blood and Lymphatic System	5	0.06%
Nervous System	2068	24.35%
Respiratory System	658	7.75%
Gastrointestinal System including Liver	1111	13.08%
Musculoskeletal System	192	2.26%
Immune System	991	11.67%
Urogenital/Reproductive System	238	2.8%
Sensory Organs (skin, eyes and ears)	54	0.64%
Endocrine System/Metabolism	139	1.64%
Multisystemic	6	0.07%
Ethology / Animal Behaviour /Animal Biology	2635	31.03%
Other basic research	4	0.05%
Total	**8492**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	754	2.57%
Human Infectious Disorders	780	2.66%
Human Cardiovascular Disorders	1129	3.85%
Human Nervous and Mental Disorders	9381	32.02%
Human Respiratory Disorders	277	0.95%
Human Gastrointestinal Disorders including Liver	1114	3.8%
Human Musculoskeletal Disorders	734	2.51%
Human Immune Disorders	7789	26.59%
Human Urogenital/Reproductive Disorders	50	0.17%
Human Sensory Organ Disorders (skin, eyes and ears)	2057	7.02%
Human Endocrine/Metabolism Disorders	444	1.52%
Animal Diseases and Disorders	2115	7.22%
Animal Welfare	2553	8.71%
Diagnosis of diseases	118	0.4%
Total	**29295**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	194247	99.71%
Toxicity and other safety testing including pharmacology	540	0.28%
Routine production	29	0.01%
Total	**194816**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1920	0.99%
Pyrogenicity testing	312	0.16%
Batch potency testing	192015	98.85%
Total	**194247**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	500	92.59%
Target animal safety	40	7.41%
Total	**540**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	500	100%
Total	**500**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	185698	95.33%
Legislation on medicinal products for veterinary use and their residues	8589	4.41%
Other legislation	500	0.26%
Total	**194787**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	194755	99.98%
Legislation satisfying national requirements only [within EU]	32	0.02%
Total	**194787**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	29	100%
Total	**29**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	240568	99.72%
Yes	675	0.28%
Total	**241243**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2283	0.95%
Mild [up to and including]	113244	46.94%
Moderate	55158	22.86%
Severe	70558	29.25%
Total	**241243**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	234363	97.15%
Genetically altered without a harmful phenotype	5121	2.12%
Genetically altered with a harmful phenotype	1759	0.73%
Total	**241243**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	586		586
Total	**586**		**586**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	548	93.52%
Severe	38	6.48%
Total	**586**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	586	100%
Total	**586**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Respiratory System	66	100%
Total	**66**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	66	12.69%
Human Musculoskeletal Disorders	13	2.5%
Human Immune Disorders	441	84.81%
Total	**520**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	473		473
Total	**473**		**473**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	469	99.15%
Moderate	4	0.85%
Total	**473**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	443	93.66%
Genetically altered without a harmful phenotype	30	6.34%
Total	**473**	**100.00%**

Member State: Italy, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	347361	61.54%
Rats	117203	20.76%
Guinea-Pigs	14246	2.52%
Hamsters (Syrian)	277	0.05%
Other Rodents	647	0.11%
Rabbits	18146	3.21%
Dogs	373	0.07%
Ferrets	42	0.01%
Pigs	1559	0.28%
Sheep	120	0.02%
Cattle	270	0.05%
Cynomolgus monkey	545	0.1%
Rhesus monkey	3	0%
Other Mammals	24	0%
Domestic fowl	33358	5.91%
Other birds	420	0.07%
Xenopus	371	0.07%
Zebra fish	19415	3.44%
Other Fish	10079	1.79%
Cephalopods	10	0%
Total	**564469**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	497349	88.19%
Animals born in the EU but not at a registered breeder	64411	11.42%
Animals born in rest of Europe	840	0.15%
Animals born in rest of world	1321	0.23%
Total	**563921**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	0.18%
Animals born in Asia	57	10.4%
Animals born in Africa	490	89.42%
Total	**548**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	137	25%
F2 or greater	411	75%
Total	**548**	**100.00%**

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	347361	483	347844
Rats	117203	338	117541
Guinea-Pigs	14246	111	14357
Hamsters (Syrian)	277		277
Other Rodents	647		647
Rabbits	18146	1179	19325
Dogs	373	266	639
Ferrets	42		42
Horses, donkeys and cross-breeds		17	17
Pigs	1559	62	1621
Goats		23	23
Sheep	120	72	192
Cattle	270	9	279
Marmoset and tamarins		1	1
Cynomolgus monkey	545	24	569
Rhesus monkey	3	1	4
Other Mammals	24	6	30
Domestic fowl	33358	1357	34715
Other birds	420		420
Xenopus	371	30	401
Zebra fish	19415	93	19508
Other Fish	10079	636	10715
Cephalopods	10		10
Total	**564469**	**4708**	**569177**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	187054	32.86%
Translational and applied research	152986	26.88%
Regulatory use and Routine production	225842	39.68%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1697	0.3%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1598	0.28%
Total	**569177**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	57091	30.52%
Cardiovascular Blood and Lymphatic System	8534	4.56%
Nervous System	69030	36.9%
Respiratory System	1384	0.74%
Gastrointestinal System including Liver	5792	3.1%
Musculoskeletal System	6922	3.7%
Immune System	13588	7.26%
Urogenital/Reproductive System	2830	1.51%
Sensory Organs (skin, eyes and ears)	3892	2.08%
Endocrine System/Metabolism	4459	2.38%
Multisystemic	3513	1.88%
Ethology / Animal Behaviour /Animal Biology	5028	2.69%
Other basic research	4991	2.67%
Total	**187054**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	46470	30.38%
Human Infectious Disorders	21902	14.32%
Human Cardiovascular Disorders	1844	1.21%
Human Nervous and Mental Disorders	18352	12%
Human Respiratory Disorders	16658	10.89%
Human Gastrointestinal Disorders including Liver	2644	1.73%
Human Musculoskeletal Disorders	5955	3.89%
Human Immune Disorders	3734	2.44%
Human Urogenital/Reproductive Disorders	2989	1.95%
Human Sensory Organ Disorders (skin, eyes and ears)	2447	1.6%
Human Endocrine/Metabolism Disorders	3064	2%
Other Human Disorders	4953	3.24%
Animal Diseases and Disorders	7228	4.72%
Animal Welfare	918	0.6%
Diagnosis of diseases	13483	8.81%
Non-regulatory toxicology and ecotoxicology	345	0.23%
Total	**152986**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	111851	49.53%
Other efficacy and tolerance testing	45856	20.3%
Toxicity and other safety testing including pharmacology	63786	28.24%
Routine production	4349	1.93%
Total	**225842**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	21535	19.25%
Pyrogenicity testing	2717	2.43%
Batch potency testing	84520	75.56%
Other quality controls	3079	2.75%
Total	**111851**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10612	16.64%
Skin irritation/corrosion	820	1.29%
Skin sensitisation	11983	18.79%
Eye irritation/corrosion	93	0.15%
Repeated dose toxicity	8757	13.73%
Genotoxicity	291	0.46%
Reproductive toxicity	628	0.98%
Developmental toxicity	5554	8.71%
Neurotoxicity	300	0.47%
Kinetics	5976	9.37%
Pharmaco-dynamics (incl safety pharmacology)	1154	1.81%
Ecotoxicity	4224	6.62%
Safety testing in food and feed area	10807	16.94%
Target animal safety	1212	1.9%
Other toxicity/safety testing	1375	2.16%
Total	**63786**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1211	11.41%
Other lethal methods	755	7.11%
Non lethal methods	8646	81.47%
Total	**10612**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4157	47.47%
29 - 90 days	2782	31.77%
> 90 days	1818	20.76%
Total	**8757**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3930	93.04%
Other ecotoxicity	294	6.96%
Total	**4224**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	143853	64.95%
Legislation on medicinal products for veterinary use and their residues	35700	16.12%
Medical devices legislation	16869	7.62%
Industrial chemicals legislation	8715	3.93%
Plant protection product legislation	595	0.27%
Biocides legislation	624	0.28%
Food legislation including food contact material	11492	5.19%
Feed legislation including legislation for the safety of target animals, workers and environment	1074	0.48%
Other legislation	2571	1.16%
Total	**221493**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	204920	92.52%
Legislation satisfying national requirements only [within EU]	3268	1.48%
Legislation satisfying Non-EU requirements only	13305	6.01%
Total	**221493**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	2861	65.79%
Other product types	1488	34.21%
Total	**4349**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	564469	99.17%
Yes	4708	0.83%
Total	**569177**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	29618	5.2%
Mild [up to and including]	275143	48.34%
Moderate	175666	30.86%
Severe	88750	15.59%
Total	**569177**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	448298	78.76%
Genetically altered without a harmful phenotype	103778	18.23%
Genetically altered with a harmful phenotype	17101	3%
Total	**569177**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	7799		7799
Rats	510		510
Pigs	36		36
Total	**8345**		**8345**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	2257	27.05%
Mild [up to and including]	3751	44.95%
Moderate	1470	17.62%
Severe	867	10.39%
Total	**8345**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	399	4.78%
Genetically altered without a harmful phenotype	7598	91.05%
Genetically altered with a harmful phenotype	348	4.17%
Total	**8345**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	1422	18.74%
Cardiovascular Blood and Lymphatic System	101	1.33%
Nervous System	5313	70.02%
Musculoskeletal System	11	0.14%
Immune System	79	1.04%
Endocrine System/Metabolism	317	4.18%
Multisystemic	345	4.55%
Total	**7588**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	8	1.06%
Human Nervous and Mental Disorders	146	19.29%
Human Gastrointestinal Disorders including Liver	62	8.19%
Human Musculoskeletal Disorders	52	6.87%
Human Immune Disorders	141	18.63%
Human Urogenital/Reproductive Disorders	3	0.4%
Human Sensory Organ Disorders (skin, eyes and ears)	10	1.32%
Other Human Disorders	335	44.25%
Total	**757**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	2485		2485
Rats	53		53
Total	**2538**		**2538**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	2175	85.7%
Moderate	44	1.73%
Severe	319	12.57%
Total	**2538**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	1498	59.02%
Genetically altered with a harmful phenotype	1040	40.98%
Total	**2538**	**100.00%**

Member State: Latvia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	3332	63%
Rats	1795	33.94%
Pigs	22	0.42%
Other Mammals	140	2.65%
Total	**5289**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5127	96.94%
Animals born in the EU but not at a registered breeder	162	3.06%
Total	**5289**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	3332		3332
Rats	1795		1795
Pigs	22		22
Other Mammals	140		140
Total	**5289**		**5289**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1724	32.6%
Translational and applied research	3543	66.99%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	22	0.42%
Total	**5289**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	4	0.23%
Nervous System	1580	91.65%
Ethology / Animal Behaviour /Animal Biology	140	8.12%
Total	**1724**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	840	23.71%
Human Infectious Disorders	135	3.81%
Human Cardiovascular Disorders	1406	39.68%
Human Nervous and Mental Disorders	605	17.08%
Human Urogenital/Reproductive Disorders	70	1.98%
Human Endocrine/Metabolism Disorders	0	0%
Animal Diseases and Disorders	377	10.64%
Non-regulatory toxicology and ecotoxicology	110	3.1%
Total	**3543**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	5289	100%
Total	**5289**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	1372	25.94%
Mild [up to and including]	2050	38.76%
Moderate	1701	32.16%
Severe	166	3.14%
Total	**5289**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	5229	98.87%
Genetically altered without a harmful phenotype	60	1.13%
Total	**5289**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Lithuania, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1718	62.11%
Rats	391	14.14%
Guinea-Pigs	15	0.54%
Rabbits	13	0.47%
Pigs	68	2.46%
Sheep	15	0.54%
Other birds	26	0.94%
Other Fish	520	18.8%
Total	**2766**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2683	97%
Animals born in the EU but not at a registered breeder	83	3%
Total	**2766**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1718		1718
Rats	391		391
Guinea-Pigs	15		15
Rabbits	13		13
Pigs	68		68
Sheep	15		15
Other birds	26		26
Other Fish	520		520
Total	**2766**		**2766**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1659	59.98%
Translational and applied research	501	18.11%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	606	21.91%
Total	**2766**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	337	20.31%
Cardiovascular Blood and Lymphatic System	20	1.21%
Nervous System	284	17.12%
Respiratory System	103	6.21%
Musculoskeletal System	10	0.6%
Immune System	873	52.62%
Multisystemic	32	1.93%
Total	**1659**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	102	20.36%
Human Cardiovascular Disorders	8	1.6%
Human Nervous and Mental Disorders	107	21.36%
Human Sensory Organ Disorders (skin, eyes and ears)	17	3.39%
Non-regulatory toxicology and ecotoxicology	267	53.29%
Total	**501**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	2766	100%
Total	**2766**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	83	3%
Mild [up to and including]	2186	79.03%
Moderate	497	17.97%
Total	**2766**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	2766	100%
Total	**2766**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Luxembourg, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	5348	21.14%
Rats	96	0.38%
Zebra fish	19849	78.48%
Total	**25293**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	25293	100%
Total	**25293**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	5348	224	5572
Rats	96		96
Zebra fish	19849		19849
Total	**25293**	**224**	**25517**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	24485	95.96%
Translational and applied research	888	3.48%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	144	0.56%
Total	**25517**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1861	7.6%
Cardiovascular Blood and Lymphatic System	374	1.53%
Nervous System	20188	82.45%
Immune System	2062	8.42%
Total	**24485**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	526	59.23%
Human Infectious Disorders	326	36.71%
Human Immune Disorders	36	4.05%
Total	**888**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	25293	99.12%
Yes	224	0.88%
Total	**25517**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	519	2.03%
Mild [up to and including]	21614	84.7%
Moderate	3213	12.59%
Severe	171	0.67%
Total	**25517**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	22113	86.66%
Genetically altered without a harmful phenotype	3336	13.07%
Genetically altered with a harmful phenotype	68	0.27%
Total	**25517**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Zebra fish	77		77
Total	**77**		**77**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	77	100%
Total	**77**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	77	100%
Total	**77**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Nervous System	77	100%
Total	**77**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Zebra fish	247		247
Total	**247**		**247**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	247	100%
Total	**247**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	247	100%
Total	**247**	**100.00%**

Member State: Malta, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Other Fish	250	100%
Total	**250**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in rest of Europe	250	100%
Total	**250**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Other Fish	250		250
Total	**250**		**250**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Translational and applied research	250	100%
Total	**250**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage

No data reported

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	250	100%
Total	**250**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	250	100%
Total	**250**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Mild [up to and including]	250	100%
Total	**250**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	250	100%
Total	**250**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Netherlands, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	188238	41.48%
Rats	89294	19.68%
Guinea-Pigs	5702	1.26%
Hamsters (Syrian)	1025	0.23%
Hamsters (Chinese)	12	0%
Other Rodents	736	0.16%
Rabbits	9551	2.1%
Cats	174	0.04%
Dogs	549	0.12%
Ferrets	608	0.13%
Other carnivores	270	0.06%
Horses, donkeys and cross-breeds	173	0.04%
Pigs	9587	2.11%
Goats	176	0.04%
Sheep	531	0.12%
Cattle	2629	0.58%
Marmoset and tamarins	27	0.01%
Cynomolgus monkey	23	0.01%
Rhesus monkey	141	0.03%
Other Mammals	3305	0.73%
Domestic fowl	55152	12.15%
Other birds	17946	3.95%
Reptiles	294	0.06%
Xenopus	278	0.06%
Other Amphibians	60	0.01%
Zebra fish	51456	11.34%
Other Fish	15842	3.49%
Total	**453779**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	350508	77.27%
Animals born in the EU but not at a registered breeder	94773	20.89%
Animals born in rest of Europe	44	0.01%
Animals born in rest of world	8263	1.82%
Total	**453588**	**100.00%**

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Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	189	98.95%
Animals born in Asia	2	1.05%
Total	**191**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	2	1.05%
Self-sustaining colony	189	98.95%
Total	**191**	**100.00%**

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	188238	5906	194144
Rats	89294	1805	91099
Guinea-Pigs	5702	114	5816
Hamsters (Syrian)	1025	10	1035
Hamsters (Chinese)	12		12
Other Rodents	736		736
Rabbits	9551	213	9764
Cats	174	26	200
Dogs	549	360	909
Ferrets	608	72	680
Other carnivores	270		270
Horses, donkeys and cross-breeds	173		173
Pigs	9587	151	9738
Goats	176	83	259
Sheep	531	27	558
Cattle	2629	1204	3833
Marmoset and tamarins	27	14	41
Cynomolgus monkey	23	19	42
Rhesus monkey	141	93	234
Other Mammals	3305	10	3315
Domestic fowl	55152	219	55371
Other birds	17946	376	18322
Reptiles	294		294
Rana		9	9
Xenopus	278	160	438
Other Amphibians	60		60
Zebra fish	51456	220	51676
Other Fish	15842	45	15887
Total	**453779**	**11136**	**464915**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	188633	40.57%
Translational and applied research	127029	27.32%
Regulatory use and Routine production	122247	26.29%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	873	0.19%
Preservation of species	3698	0.8%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	22074	4.75%
Forensic enquiries	361	0.08%
Total	**464915**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	86830	46.03%
Cardiovascular Blood and Lymphatic System	6673	3.54%
Nervous System	17654	9.36%
Respiratory System	758	0.4%
Gastrointestinal System including Liver	2857	1.51%
Musculoskeletal System	692	0.37%
Immune System	16286	8.63%
Urogenital/Reproductive System	1129	0.6%
Sensory Organs (skin, eyes and ears)	1030	0.55%
Endocrine System/Metabolism	4351	2.31%
Multisystemic	4084	2.17%
Ethology / Animal Behaviour /Animal Biology	20617	10.93%
Other basic research	25672	13.61%
Total	**188633**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	13914	10.95%
Human Infectious Disorders	22898	18.03%
Human Cardiovascular Disorders	5882	4.63%
Human Nervous and Mental Disorders	9358	7.37%
Human Respiratory Disorders	2410	1.9%
Human Gastrointestinal Disorders including Liver	2554	2.01%
Human Musculoskeletal Disorders	1587	1.25%
Human Immune Disorders	4179	3.29%
Human Urogenital/Reproductive Disorders	814	0.64%
Human Sensory Organ Disorders (skin, eyes and ears)	575	0.45%
Human Endocrine/Metabolism Disorders	2423	1.91%
Other Human Disorders	235	0.18%
Animal Diseases and Disorders	31368	24.69%
Animal Welfare	22221	17.49%
Diagnosis of diseases	1115	0.88%
Plant diseases	8	0.01%
Non-regulatory toxicology and ecotoxicology	5488	4.32%
Total	**127029**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	50082	40.97%
Other efficacy and tolerance testing	3235	2.65%
Toxicity and other safety testing including pharmacology	68753	56.24%
Routine production	177	0.14%
Total	**122247**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1948	3.89%
Batch potency testing	47934	95.71%
Other quality controls	200	0.4%
Total	**50082**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1886	2.74%
Skin irritation/corrosion	47	0.07%
Skin sensitisation	2378	3.46%
Eye irritation/corrosion	59	0.09%
Repeated dose toxicity	8739	12.71%
Genotoxicity	106	0.15%
Reproductive toxicity	36568	53.19%
Developmental toxicity	9944	14.46%
Kinetics	1635	2.38%
Pharmaco-dynamics (incl safety pharmacology)	8	0.01%
Phototoxicity	4	0.01%
Ecotoxicity	4101	5.96%
Safety testing in food and feed area	2104	3.06%
Target animal safety	1174	1.71%
Total	**68753**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	1886	100%
Total	**1886**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3875	44.34%
29 - 90 days	4131	47.27%
> 90 days	733	8.39%
Total	**8739**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1368	33.36%
Chronic toxicity	2329	56.79%
Bioaccumulation	404	9.85%
Total	**4101**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	30050	24.62%
Legislation on medicinal products for veterinary use and their residues	31915	26.14%
Industrial chemicals legislation	57024	46.71%
Plant protection product legislation	312	0.26%
Biocides legislation	92	0.08%
Food legislation including food contact material	447	0.37%
Feed legislation including legislation for the safety of target animals, workers and environment	2164	1.77%
Other legislation	66	0.05%
Total	**122070**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	119368	97.79%
Legislation satisfying national requirements only [within EU]	8	0.01%
Legislation satisfying Non-EU requirements only	2694	2.21%
Total	**122070**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	6	3.39%
Other product types	171	96.61%
Total	**177**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	453779	97.6%
Yes	11136	2.4%
Total	**464915**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	31581	6.79%
Mild [up to and including]	298851	64.28%
Moderate	120316	25.88%
Severe	14167	3.05%
Total	**464915**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	335918	72.25%
Genetically altered without a harmful phenotype	121284	26.09%
Genetically altered with a harmful phenotype	7713	1.66%
Total	**464915**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	10790	2	10792
Rats	9		9
Zebra fish	167		167
Total	**10966**	**2**	**10968**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	30	0.27%
Mild [up to and including]	10045	91.58%
Moderate	879	8.01%
Severe	14	0.13%
Total	**10968**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	8267	75.37%
Genetically altered without a harmful phenotype	2655	24.21%
Genetically altered with a harmful phenotype	46	0.42%
Total	**10968**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	7630	71.9%
Cardiovascular Blood and Lymphatic System	195	1.84%
Nervous System	521	4.91%
Gastrointestinal System including Liver	346	3.26%
Immune System	296	2.79%
Urogenital/Reproductive System	70	0.66%
Multisystemic	31	0.29%
Other basic research	1523	14.35%
Total	**10612**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	6	1.69%
Human Infectious Disorders	15	4.21%
Human Nervous and Mental Disorders	334	93.82%
Human Gastrointestinal Disorders including Liver	1	0.28%
Total	**356**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	1057		1057
Rats	429		429
Zebra fish	181		181
Total	**1667**		**1667**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	1106	66.35%
Moderate	544	32.63%
Severe	17	1.02%
Total	**1667**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	1667	100%
Total	**1667**	**100.00%**

Member State: Poland, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	88894	57.51%
Rats	28865	18.67%
Guinea-Pigs	5232	3.38%
Hamsters (Syrian)	150	0.1%
Mongolian gerbil	120	0.08%
Other Rodents	7930	5.13%
Rabbits	718	0.46%
Other carnivores	130	0.08%
Horses, donkeys and cross-breeds	50	0.03%
Pigs	1513	0.98%
Goats	17	0.01%
Sheep	1231	0.8%
Cattle	403	0.26%
Other species of Old World Monkeys (Cercopithecoidea)	14	0.01%
Other species of New World Monkeys (Ceboidea)	3	0%
Other Mammals	639	0.41%
Domestic fowl	5067	3.28%
Other birds	6470	4.19%
Reptiles	314	0.2%
Rana	20	0.01%
Other Amphibians	456	0.3%
Zebra fish	950	0.61%
Other Fish	5381	3.48%
Total	**154567**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	135019	87.36%
Animals born in the EU but not at a registered breeder	18496	11.97%
Animals born in rest of Europe	361	0.23%
Animals born in rest of world	674	0.44%
Total	**154550**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	17	100%
Total	**17**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	17	100%
Total	**17**	**100.00%**

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	88894	297	89191
Rats	28865	8	28873
Guinea-Pigs	5232	3	5235
Hamsters (Syrian)	150		150
Mongolian gerbil	120		120
Other Rodents	7930	178	8108
Rabbits	718	102	820
Dogs		10	10
Other carnivores	130		130
Horses, donkeys and cross-breeds	50	23	73
Pigs	1513	4	1517
Goats	17	7	24
Sheep	1231	70	1301
Cattle	403	10	413
Other species of Old World Monkeys (Cercopithecoidea)	14		14
Other species of New World Monkeys (Ceboidea)	3		3
Other Mammals	639		639
Domestic fowl	5067		5067
Other birds	6470	96	6566
Reptiles	314		314
Rana	20		20
Other Amphibians	456		456
Zebra fish	950		950
Other Fish	5381		5381
Total	**154567**	**808**	**155375**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	113469	73.03%
Translational and applied research	15947	10.26%
Regulatory use and Routine production	24762	15.94%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	43	0.03%
Preservation of species	25	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1129	0.73%
Total	**155375**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	8173	7.2%
Cardiovascular Blood and Lymphatic System	6727	5.93%
Nervous System	52378	46.16%
Respiratory System	784	0.69%
Gastrointestinal System including Liver	3070	2.71%
Musculoskeletal System	673	0.59%
Immune System	7755	6.83%
Urogenital/Reproductive System	2929	2.58%
Sensory Organs (skin, eyes and ears)	225	0.2%
Endocrine System/Metabolism	5992	5.28%
Multisystemic	5956	5.25%
Ethology / Animal Behaviour /Animal Biology	10531	9.28%
Other basic research	8276	7.29%
Total	**113469**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3081	19.32%
Human Infectious Disorders	366	2.3%
Human Cardiovascular Disorders	815	5.11%
Human Nervous and Mental Disorders	1176	7.37%
Human Respiratory Disorders	943	5.91%
Human Musculoskeletal Disorders	64	0.4%
Human Immune Disorders	120	0.75%
Human Urogenital/Reproductive Disorders	44	0.28%
Human Sensory Organ Disorders (skin, eyes and ears)	20	0.13%
Human Endocrine/Metabolism Disorders	316	1.98%
Other Human Disorders	35	0.22%
Animal Diseases and Disorders	490	3.07%
Animal Welfare	3852	24.16%
Diagnosis of diseases	3088	19.36%
Non-regulatory toxicology and ecotoxicology	1537	9.64%
Total	**15947**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16493	66.61%
Other efficacy and tolerance testing	195	0.79%
Toxicity and other safety testing including pharmacology	7784	31.44%
Routine production	290	1.17%
Total	**24762**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3982	24.14%
Pyrogenicity testing	236	1.43%
Batch potency testing	11482	69.62%
Other quality controls	793	4.81%
Total	**16493**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1050	13.49%
Skin irritation/corrosion	139	1.79%
Skin sensitisation	707	9.08%
Eye irritation/corrosion	9	0.12%
Repeated dose toxicity	807	10.37%
Reproductive toxicity	669	8.59%
Developmental toxicity	1694	21.76%
Kinetics	30	0.39%
Ecotoxicity	2364	30.37%
Other toxicity/safety testing	315	4.05%
Total	**7784**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	180	17.14%
Non lethal methods	870	82.86%
Total	**1050**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	387	47.96%
29 - 90 days	420	52.04%
Total	**807**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2364	100%
Total	**2364**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16253	66.41%
Legislation on medicinal products for veterinary use and their residues	2251	9.2%
Medical devices legislation	896	3.66%
Industrial chemicals legislation	2652	10.84%
Plant protection product legislation	2276	9.3%
Biocides legislation	24	0.1%
Food legislation including food contact material	120	0.49%
Total	**24472**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23931	97.79%
Legislation satisfying national requirements only [within EU]	514	2.1%
Legislation satisfying Non-EU requirements only	27	0.11%
Total	**24472**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	290	100%
Total	**290**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	154567	99.48%
Yes	808	0.52%
Total	**155375**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	4757	3.06%
Mild [up to and including]	49725	32%
Moderate	49829	32.07%
Severe	51064	32.87%
Total	**155375**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	146889	94.54%
Genetically altered without a harmful phenotype	5547	3.57%
Genetically altered with a harmful phenotype	2939	1.89%
Total	**155375**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	188		188
Rats	109		109
Other Mammals	61		61
Total	**358**		**358**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	34	9.5%
Mild [up to and including]	34	9.5%
Moderate	184	51.4%
Severe	106	29.61%
Total	**358**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	358	100%
Total	**358**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Nervous System	170	100%
Total	**170**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	188	100%
Total	**188**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	501		501
Total	**501**		**501**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	501	100%
Total	**501**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	501	100%
Total	**501**	**100.00%**

Member State: Portugal, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	35221	85.91%
Rats	3133	7.64%
Other Rodents	140	0.34%
Rabbits	36	0.09%
Pigs	155	0.38%
Sheep	12	0.03%
Other Mammals	32	0.08%
Domestic fowl	120	0.29%
Zebra fish	906	2.21%
Other Fish	793	1.93%
Cephalopods	450	1.1%
Total	**40998**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	39214	95.65%
Animals born in the EU but not at a registered breeder	1455	3.55%
Animals born in rest of world	329	0.8%
Total	**40998**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	35221	905	36126
Rats	3133	2	3135
Other Rodents	140		140
Rabbits	36		36
Pigs	155		155
Sheep	12	18	30
Other Mammals	32		32
Domestic fowl	120		120
Other birds		56	56
Zebra fish	906	6	912
Other Fish	793	36	829
Cephalopods	450		450
Total	**40998**	**1023**	**42021**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	36214	86.18%
Translational and applied research	5117	12.18%
Regulatory use and Routine production	298	0.71%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	392	0.93%
Total	**42021**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	3147	8.69%
Cardiovascular Blood and Lymphatic System	1202	3.32%
Nervous System	4877	13.47%
Respiratory System	83	0.23%
Gastrointestinal System including Liver	683	1.89%
Musculoskeletal System	173	0.48%
Immune System	20680	57.1%
Urogenital/Reproductive System	36	0.1%
Endocrine System/Metabolism	1437	3.97%
Multisystemic	153	0.42%
Ethology / Animal Behaviour /Animal Biology	1277	3.53%
Other basic research	2466	6.81%
Total	**36214**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	162	3.17%
Human Infectious Disorders	403	7.88%
Human Cardiovascular Disorders	68	1.33%
Human Nervous and Mental Disorders	1973	38.56%
Human Gastrointestinal Disorders including Liver	102	1.99%
Human Musculoskeletal Disorders	127	2.48%
Human Sensory Organ Disorders (skin, eyes and ears)	233	4.55%
Human Endocrine/Metabolism Disorders	36	0.7%
Animal Diseases and Disorders	3	0.06%
Animal Welfare	604	11.8%
Diagnosis of diseases	914	17.86%
Non-regulatory toxicology and ecotoxicology	492	9.62%
Total	**5117**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	298	100%
Total	**298**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	126	42.28%
Safety testing in food and feed area	172	57.72%
Total	**298**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Chronic toxicity	126	100%
Total	**126**	**100.00%**

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Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for veterinary use and their residues	126	42.28%
Food legislation including food contact material	172	57.72%
Total	**298**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	298	100%
Total	**298**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	40998	97.57%
Yes	1023	2.43%
Total	**42021**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2017	4.8%
Mild [up to and including]	17515	41.68%
Moderate	12114	28.83%
Severe	10375	24.69%
Total	**42021**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	27193	64.71%
Genetically altered without a harmful phenotype	13750	32.72%
Genetically altered with a harmful phenotype	1078	2.57%
Total	**42021**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	495	39	534
Total	**495**	**39**	**534**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	256	47.94%
Moderate	237	44.38%
Severe	41	7.68%
Total	**534**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	17	3.18%
Genetically altered without a harmful phenotype	502	94.01%
Genetically altered with a harmful phenotype	15	2.81%
Total	**534**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	83	18.49%
Cardiovascular Blood and Lymphatic System	3	0.67%
Nervous System	75	16.7%
Immune System	288	64.14%
Total	**449**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	85	100%
Total	**85**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	9447		9447
Zebra fish	368		368
Total	**9815**		**9815**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	9626	98.07%
Moderate	189	1.93%
Total	**9815**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	3347	34.1%
Genetically altered without a harmful phenotype	6214	63.31%
Genetically altered with a harmful phenotype	254	2.59%
Total	**9815**	**100.00%**

Member State: Romania, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	7975	55.86%
Rats	4367	30.59%
Guinea-Pigs	792	5.55%
Hamsters (Syrian)	150	1.05%
Rabbits	318	2.23%
Pigs	58	0.41%
Sheep	85	0.6%
Domestic fowl	280	1.96%
Other birds	23	0.16%
Rana	230	1.61%
Total	**14278**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12356	86.54%
Animals born in the EU but not at a registered breeder	1922	13.46%
Total	**14278**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	7975		7975
Rats	4367		4367
Guinea-Pigs	792		792
Hamsters (Syrian)	150		150
Rabbits	318	186	504
Horses, donkeys and cross-breeds		2	2
Pigs	58		58
Sheep	85	124	209
Cattle		2	2
Domestic fowl	280	50	330
Other birds	23		23
Rana	230		230
Total	**14278**	**364**	**14642**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	5381	36.75%
Translational and applied research	5500	37.56%
Regulatory use and Routine production	2522	17.22%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1239	8.46%
Total	**14642**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1525	28.34%
Cardiovascular Blood and Lymphatic System	539	10.02%
Nervous System	634	11.78%
Gastrointestinal System including Liver	165	3.07%
Musculoskeletal System	339	6.3%
Immune System	1349	25.07%
Urogenital/Reproductive System	70	1.3%
Sensory Organs (skin, eyes and ears)	10	0.19%
Endocrine System/Metabolism	318	5.91%
Multisystemic	342	6.36%
Ethology / Animal Behaviour /Animal Biology	90	1.67%
Total	**5381**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	114	2.07%
Human Cardiovascular Disorders	211	3.84%
Human Gastrointestinal Disorders including Liver	286	5.2%
Human Musculoskeletal Disorders	260	4.73%
Human Immune Disorders	275	5%
Human Sensory Organ Disorders (skin, eyes and ears)	121	2.2%
Human Endocrine/Metabolism Disorders	690	12.55%
Animal Diseases and Disorders	74	1.35%
Diagnosis of diseases	3040	55.27%
Non-regulatory toxicology and ecotoxicology	429	7.8%
Total	**5500**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1789	70.94%
Toxicity and other safety testing including pharmacology	106	4.2%
Routine production	627	24.86%
Total	**2522**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	721	40.3%
Pyrogenicity testing	234	13.08%
Batch potency testing	753	42.09%
Other quality controls	81	4.53%
Total	**1789**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	20	18.87%
Ecotoxicity	86	81.13%
Total	**106**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	20	100%
Total	**20**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Chronic toxicity	86	100%
Total	**86**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	914	48.23%
Legislation on medicinal products for veterinary use and their residues	875	46.17%
Medical devices legislation	86	4.54%
Food legislation including food contact material	20	1.06%
Total	**1895**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1513	79.84%
Legislation satisfying Non-EU requirements only	382	20.16%
Total	**1895**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	587	93.62%
Other product types	40	6.38%
Total	**627**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	14278	97.51%
Yes	364	2.49%
Total	**14642**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2110	14.41%
Mild [up to and including]	5061	34.56%
Moderate	6094	41.62%
Severe	1377	9.4%
Total	**14642**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	14289	97.59%
Genetically altered without a harmful phenotype	353	2.41%
Total	**14642**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Slovakia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	5547	37.72%
Rats	7619	51.81%
Guinea-Pigs	1036	7.05%
Mongolian gerbil	9	0.06%
Rabbits	195	1.33%
Cats	11	0.07%
Cattle	1	0.01%
Domestic fowl	228	1.55%
Other birds	59	0.4%
Total	**14705**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	14705	100%
Total	**14705**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	5547		5547
Rats	7619		7619
Guinea-Pigs	1036		1036
Mongolian gerbil	9		9
Rabbits	195	31	226
Cats	11		11
Sheep		2	2
Cattle	1		1
Domestic fowl	228	5	233
Other birds	59		59
Total	**14705**	**38**	**14743**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	10819	73.38%
Translational and applied research	1046	7.09%
Regulatory use and Routine production	2822	19.14%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	56	0.38%
Total	**14743**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	316	2.92%
Cardiovascular Blood and Lymphatic System	932	8.61%
Nervous System	4076	37.67%
Respiratory System	607	5.61%
Gastrointestinal System including Liver	180	1.66%
Musculoskeletal System	19	0.18%
Immune System	424	3.92%
Urogenital/Reproductive System	1175	10.86%
Sensory Organs (skin, eyes and ears)	9	0.08%
Endocrine System/Metabolism	610	5.64%
Multisystemic	782	7.23%
Ethology / Animal Behaviour /Animal Biology	595	5.5%
Other basic research	1094	10.11%
Total	**10819**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	20	1.91%
Human Nervous and Mental Disorders	528	50.48%
Human Immune Disorders	21	2.01%
Human Urogenital/Reproductive Disorders	10	0.96%
Human Sensory Organ Disorders (skin, eyes and ears)	27	2.58%
Human Endocrine/Metabolism Disorders	60	5.74%
Animal Diseases and Disorders	374	35.76%
Diagnosis of diseases	6	0.57%
Total	**1046**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1014	35.93%
Toxicity and other safety testing including pharmacology	1777	62.97%
Routine production	31	1.1%
Total	**2822**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	867	85.5%
Batch potency testing	147	14.5%
Total	**1014**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	653	36.75%
Skin sensitisation	542	30.5%
Repeated dose toxicity	460	25.89%
Reproductive toxicity	122	6.87%
Total	**1777**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	603	92.34%
Non lethal methods	50	7.66%
Total	**653**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	280	60.87%
29 - 90 days	180	39.13%
Total	**460**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1269	45.47%
Legislation on medicinal products for veterinary use and their residues	133	4.77%
Medical devices legislation	64	2.29%
Industrial chemicals legislation	946	33.89%
Plant protection product legislation	9	0.32%
Food legislation including food contact material	190	6.81%
Feed legislation including legislation for the safety of target animals, workers and environment	180	6.45%
Total	**2791**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2791	100%
Total	**2791**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	31	100%
Total	**31**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	14705	99.74%
Yes	38	0.26%
Total	**14743**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	1101	7.47%
Mild [up to and including]	4325	29.34%
Moderate	8963	60.79%
Severe	354	2.4%
Total	**14743**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	13516	91.68%
Genetically altered without a harmful phenotype	242	1.64%
Genetically altered with a harmful phenotype	985	6.68%
Total	**14743**	**100.00%**

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Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	540		540
Rats	320		320
Total	**860**		**860**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	860	100%
Total	**860**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	588	68.37%
Genetically altered without a harmful phenotype	18	2.09%
Genetically altered with a harmful phenotype	254	29.53%
Total	**860**	**100.00%**

Member State: Slovenia, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	3998	88.57%
Rats	226	5.01%
Rabbits	76	1.68%
Pigs	80	1.77%
Sheep	26	0.58%
Domestic fowl	10	0.22%
Other Fish	98	2.17%
Total	**4514**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4514	100%
Total	**4514**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	3998	510	4508
Rats	226		226
Rabbits	76	59	135
Horses, donkeys and cross-breeds		2	2
Pigs	80		80
Sheep	26	2	28
Domestic fowl	10		10
Other Fish	98		98
Total	**4514**	**573**	**5087**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1035	20.35%
Translational and applied research	1731	34.03%
Regulatory use and Routine production	2183	42.91%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	16	0.31%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	122	2.4%
Total	**5087**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	149	14.4%
Nervous System	70	6.76%
Gastrointestinal System including Liver	150	14.49%
Musculoskeletal System	34	3.29%
Immune System	102	9.86%
Endocrine System/Metabolism	375	36.23%
Multisystemic	59	5.7%
Ethology / Animal Behaviour /Animal Biology	48	4.64%
Other basic research	48	4.64%
Total	**1035**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1552	89.66%
Human Endocrine/Metabolism Disorders	65	3.76%
Diagnosis of diseases	114	6.59%
Total	**1731**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2101	96.24%
Toxicity and other safety testing including pharmacology	82	3.76%
Total	**2183**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	272	12.95%
Pyrogenicity testing	59	2.81%
Batch potency testing	1770	84.25%
Total	**2101**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics	82	100%
Total	**82**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2183	100%
Total	**2183**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2183	100%
Total	**2183**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

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Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	4514	88.74%
Yes	573	11.26%
Total	**5087**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	44	0.86%
Mild [up to and including]	4317	84.86%
Moderate	637	12.52%
Severe	89	1.75%
Total	**5087**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	4736	93.1%
Genetically altered without a harmful phenotype	288	5.66%
Genetically altered with a harmful phenotype	63	1.24%
Total	**5087**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	55		55
Total	**55**		**55**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	55	100%
Total	**55**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	55	100%
Total	**55**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Other Human Disorders	55	100%
Total	**55**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Member State: Spain, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	465870	65.1%
Rats	55826	7.8%
Guinea-Pigs	6411	0.9%
Hamsters (Syrian)	599	0.08%
Other Rodents	141	0.02%
Rabbits	22205	3.1%
Cats	178	0.02%
Dogs	1045	0.15%
Ferrets	164	0.02%
Other carnivores	25	0%
Horses, donkeys and cross-breeds	46	0.01%
Pigs	8655	1.21%
Goats	354	0.05%
Sheep	1715	0.24%
Cattle	1138	0.16%
Cynomolgus monkey	246	0.03%
Other Mammals	99	0.01%
Domestic fowl	82047	11.46%
Other birds	2385	0.33%
Reptiles	1003	0.14%
Rana	18	0%
Xenopus	1204	0.17%
Other Amphibians	1996	0.28%
Zebra fish	19941	2.79%
Other Fish	42320	5.91%
Cephalopods	20	0%
Total	**715651**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	668867	93.49%
Animals born in the EU but not at a registered breeder	45911	6.42%
Animals born in rest of Europe	31	0%
Animals born in rest of world	596	0.08%
Total	**715405**	**100.00%**

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Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born in Asia	104	42.28%
Animals born in Africa	142	57.72%
Total	**246**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	2	0.81%
F2 or greater	244	99.19%
Total	**246**	**100.00%**

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	465870	1335	467205
Rats	55826	162	55988
Guinea-Pigs	6411	336	6747
Hamsters (Syrian)	599		599
Other Rodents	141		141
Rabbits	22205	3726	25931
Cats	178	353	531
Dogs	1045	431	1476
Ferrets	164		164
Other carnivores	25		25
Horses, donkeys and cross-breeds	46	15	61
Pigs	8655		8655
Goats	354	15	369
Sheep	1715	238	1953
Cattle	1138	562	1700
Cynomolgus monkey	246	205	451
Other Mammals	99		99
Domestic fowl	82047	60	82107
Other birds	2385	150	2535
Reptiles	1003		1003
Rana	18		18
Xenopus	1204		1204
Other Amphibians	1996		1996
Zebra fish	19941	1434	21375
Other Fish	42320	1160	43480
Cephalopods	20		20
Total	**715651**	**10182**	**725833**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	310014	42.71%
Translational and applied research	277423	38.22%
Regulatory use and Routine production	120192	16.56%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6048	0.83%
Preservation of species	371	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	11785	1.62%
Total	**725833**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	26149	8.43%
Cardiovascular Blood and Lymphatic System	25464	8.21%
Nervous System	76225	24.59%
Respiratory System	2457	0.79%
Gastrointestinal System including Liver	8392	2.71%
Musculoskeletal System	6847	2.21%
Immune System	23703	7.65%
Urogenital/Reproductive System	6421	2.07%
Sensory Organs (skin, eyes and ears)	4396	1.42%
Endocrine System/Metabolism	22459	7.24%
Multisystemic	33719	10.88%
Ethology / Animal Behaviour /Animal Biology	71415	23.04%
Other basic research	2367	0.76%
Total	**310014**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	113728	40.99%
Human Infectious Disorders	13579	4.89%
Human Cardiovascular Disorders	6440	2.32%
Human Nervous and Mental Disorders	20809	7.5%
Human Respiratory Disorders	2713	0.98%
Human Gastrointestinal Disorders including Liver	8755	3.16%
Human Musculoskeletal Disorders	2052	0.74%
Human Immune Disorders	4675	1.69%
Human Urogenital/Reproductive Disorders	1160	0.42%
Human Sensory Organ Disorders (skin, eyes and ears)	15749	5.68%
Human Endocrine/Metabolism Disorders	15631	5.63%
Other Human Disorders	1651	0.6%
Animal Diseases and Disorders	50632	18.25%
Animal Welfare	8413	3.03%
Diagnosis of diseases	9346	3.37%
Plant diseases	10	0%
Non-regulatory toxicology and ecotoxicology	2080	0.75%
Total	**277423**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68653	57.12%
Other efficacy and tolerance testing	2121	1.76%
Toxicity and other safety testing including pharmacology	48164	40.07%
Routine production	1254	1.04%
Total	**120192**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	23330	33.98%
Pyrogenicity testing	9472	13.8%
Batch potency testing	31416	45.76%
Other quality controls	4435	6.46%
Total	**68653**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	11069	22.98%
Skin irritation/corrosion	43	0.09%
Skin sensitisation	616	1.28%
Eye irritation/corrosion	11	0.02%
Repeated dose toxicity	6225	12.92%
Carcinogenicity	56	0.12%
Genotoxicity	22	0.05%
Developmental toxicity	759	1.58%
Neurotoxicity	2017	4.19%
Kinetics	3364	6.98%
Pharmaco-dynamics (incl safety pharmacology)	1476	3.06%
Ecotoxicity	156	0.32%
Safety testing in food and feed area	21778	45.22%
Target animal safety	486	1.01%
Other toxicity/safety testing	86	0.18%
Total	**48164**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10180	91.97%
Non lethal methods	889	8.03%
Total	**11069**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1906	30.62%
29 - 90 days	3714	59.66%
> 90 days	605	9.72%
Total	**6225**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	124	79.49%
Reproductive ecotoxicity	32	20.51%
Total	**156**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	32259	27.12%
Legislation on medicinal products for veterinary use and their residues	61342	51.57%
Medical devices legislation	138	0.12%
Industrial chemicals legislation	3194	2.69%
Plant protection product legislation	28	0.02%
Biocides legislation	56	0.05%
Food legislation including food contact material	21850	18.37%
Feed legislation including legislation for the safety of target animals, workers and environment	68	0.06%
Other legislation	3	0%
Total	**118938**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	106010	89.13%
Legislation satisfying national requirements only [within EU]	4057	3.41%
Legislation satisfying Non-EU requirements only	8871	7.46%
Total	**118938**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	54	4.31%
Monoclonal antibody by mouse ascites method	55	4.39%
Other product types	1145	91.31%
Total	**1254**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	715651	98.6%
Yes	10182	1.4%
Total	**725833**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	40892	5.63%
Mild [up to and including]	355722	49.01%
Moderate	266570	36.73%
Severe	62649	8.63%
Total	**725833**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	501844	69.14%
Genetically altered without a harmful phenotype	201157	27.71%
Genetically altered with a harmful phenotype	22832	3.15%
Total	**725833**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	17749	70	17819
Rats	48		48
Pigs	1		1
Zebra fish	4886		4886
Other Fish	1187		1187
Total	**23871**	**70**	**23941**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	176	0.74%
Mild [up to and including]	16644	69.52%
Moderate	5213	21.77%
Severe	1908	7.97%
Total	**23941**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	9606	40.12%
Genetically altered without a harmful phenotype	13230	55.26%
Genetically altered with a harmful phenotype	1105	4.62%
Total	**23941**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	2268	11.63%
Cardiovascular Blood and Lymphatic System	800	4.1%
Nervous System	2745	14.08%
Gastrointestinal System including Liver	493	2.53%
Musculoskeletal System	150	0.77%
Immune System	956	4.9%
Urogenital/Reproductive System	127	0.65%
Sensory Organs (skin, eyes and ears)	5887	30.2%
Endocrine System/Metabolism	175	0.9%
Multisystemic	4093	21%
Ethology / Animal Behaviour /Animal Biology	1800	9.23%
Total	**19494**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	2869	64.52%
Human Nervous and Mental Disorders	585	13.15%
Human Immune Disorders	418	9.4%
Human Sensory Organ Disorders (skin, eyes and ears)	52	1.17%
Human Endocrine/Metabolism Disorders	21	0.47%
Diagnosis of diseases	502	11.29%
Total	**4447**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	38443		38443
Zebra fish	14759		14759
Total	**53202**		**53202**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	135	0.25%
Mild [up to and including]	42728	80.31%
Moderate	8998	16.91%
Severe	1341	2.52%
Total	**53202**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1285	2.42%
Genetically altered without a harmful phenotype	29469	55.39%
Genetically altered with a harmful phenotype	22448	42.19%
Total	**53202**	**100.00%**

Member State: Sweden, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	193965	67.99%
Rats	19055	6.68%
Guinea-Pigs	409	0.14%
Hamsters (Syrian)	34	0.01%
Other Rodents	5	0%
Rabbits	1573	0.55%
Cats	104	0.04%
Dogs	279	0.1%
Other carnivores	124	0.04%
Horses, donkeys and cross-breeds	17	0.01%
Pigs	1220	0.43%
Goats	30	0.01%
Sheep	35	0.01%
Cattle	493	0.17%
Cynomolgus monkey	2	0%
Rhesus monkey	23	0.01%
Other Mammals	192	0.07%
Domestic fowl	1452	0.51%
Other birds	10657	3.74%
Rana	308	0.11%
Xenopus	231	0.08%
Other Amphibians	2694	0.94%
Zebra fish	18461	6.47%
Other Fish	33940	11.9%
Total	**285303**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	217256	76.16%
Animals born in the EU but not at a registered breeder	64066	22.46%
Animals born in rest of Europe	1608	0.56%
Animals born in rest of world	2348	0.82%
Total	**285278**	**100.00%**

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born in Asia	6	24%
Animals born in America	19	76%
Total	**25**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	25	100%
Total	**25**	**100.00%**

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Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	193965	1228	195193
Rats	19055	246	19301
Guinea-Pigs	409		409
Hamsters (Syrian)	34		34
Other Rodents	5		5
Rabbits	1573	1	1574
Cats	104		104
Dogs	279	107	386
Other carnivores	124	16	140
Horses, donkeys and cross-breeds	17	24	41
Pigs	1220	337	1557
Goats	30		30
Sheep	35		35
Cattle	493	927	1420
Cynomolgus monkey	2		2
Rhesus monkey	23		23
Other Mammals	192	135	327
Domestic fowl	1452		1452
Other birds	10657	612	11269
Rana	308		308
Xenopus	231	30	261
Other Amphibians	2694		2694
Zebra fish	18461	880	19341
Other Fish	33940		33940
Total	**285303**	**4543**	**289846**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	202004	69.69%
Translational and applied research	52637	18.16%
Regulatory use and Routine production	2424	0.84%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	27916	9.63%
Preservation of species	617	0.21%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4248	1.47%
Total	**289846**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	20290	10.04%
Cardiovascular Blood and Lymphatic System	36103	17.87%
Nervous System	48921	24.22%
Respiratory System	7362	3.64%
Gastrointestinal System including Liver	1383	0.68%
Musculoskeletal System	2641	1.31%
Immune System	22592	11.18%
Urogenital/Reproductive System	1521	0.75%
Sensory Organs (skin, eyes and ears)	3150	1.56%
Endocrine System/Metabolism	25884	12.81%
Multisystemic	6172	3.06%
Ethology / Animal Behaviour /Animal Biology	16914	8.37%
Other basic research	9071	4.49%
Total	**202004**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	9717	18.46%
Human Infectious Disorders	1328	2.52%
Human Cardiovascular Disorders	4936	9.38%
Human Nervous and Mental Disorders	9654	18.34%
Human Respiratory Disorders	4988	9.48%
Human Musculoskeletal Disorders	862	1.64%
Human Immune Disorders	9224	17.52%
Human Urogenital/Reproductive Disorders	255	0.48%
Human Sensory Organ Disorders (skin, eyes and ears)	500	0.95%
Human Endocrine/Metabolism Disorders	5501	10.45%
Other Human Disorders	2323	4.41%
Animal Diseases and Disorders	704	1.34%
Animal Welfare	105	0.2%
Diagnosis of diseases	542	1.03%
Non-regulatory toxicology and ecotoxicology	1998	3.8%
Total	**52637**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	773	31.89%
Other efficacy and tolerance testing	235	9.69%
Toxicity and other safety testing including pharmacology	1416	58.42%
Total	**2424**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch potency testing	773	100%
Total	**773**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	113	7.98%
Kinetics	1303	92.02%
Total	**1416**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	113	100%
Total	**113**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1651	68.11%
Legislation on medicinal products for veterinary use and their residues	773	31.89%
Total	**2424**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2424	100%
Total	**2424**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	285303	98.43%
Yes	4543	1.57%
Total	**289846**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	9102	3.14%
Mild [up to and including]	92527	31.92%
Moderate	153733	53.04%
Severe	34484	11.9%

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Severity	Number of uses	Percentage
Total	**289846**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	144621	49.9%
Genetically altered without a harmful phenotype	118948	41.04%
Genetically altered with a harmful phenotype	26277	9.07%
Total	**289846**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	22641	788	23429
Zebra fish	8546	1271	9817
Total	**31187**	**2059**	**33246**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	222	0.67%
Mild [up to and including]	15644	47.06%
Moderate	10806	32.5%
Severe	6574	19.77%
Total	**33246**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	4166	12.53%
Genetically altered without a harmful phenotype	18428	55.43%
Genetically altered with a harmful phenotype	10652	32.04%
Total	**33246**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	2259	7.49%
Cardiovascular Blood and Lymphatic System	8399	27.84%
Nervous System	4504	14.93%
Gastrointestinal System including Liver	148	0.49%
Musculoskeletal System	1579	5.23%
Immune System	602	2%
Urogenital/Reproductive System	5022	16.65%
Endocrine System/Metabolism	2171	7.2%
Multisystemic	4029	13.35%
Other basic research	1457	4.83%
Total	**30170**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	1124	36.54%
Human Cardiovascular Disorders	1547	50.29%
Human Nervous and Mental Disorders	83	2.7%
Human Respiratory Disorders	89	2.89%
Human Immune Disorders	47	1.53%
Human Endocrine/Metabolism Disorders	186	6.05%
Total	**3076**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	1659		1659
Rats	20		20
Total	**1679**		**1679**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	1679	100%
Total	**1679**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1183	70.46%
Genetically altered without a harmful phenotype	496	29.54%
Total	**1679**	**100.00%**

Member State: United Kingdom, 2017

Part 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1103996	60.03%
Rats	231775	12.6%
Guinea-Pigs	22560	1.23%
Hamsters (Syrian)	1126	0.06%
Mongolian gerbil	307	0.02%
Other Rodents	2325	0.13%
Rabbits	9580	0.52%
Cats	74	0%
Dogs	2518	0.14%
Ferrets	405	0.02%
Other carnivores	235	0.01%
Horses, donkeys and cross-breeds	288	0.02%
Pigs	4476	0.24%
Goats	280	0.02%
Sheep	5346	0.29%
Cattle	8489	0.46%
Marmoset and tamarins	110	0.01%
Cynomolgus monkey	2023	0.11%
Rhesus monkey	82	0%
Other Mammals	792	0.04%
Domestic fowl	124629	6.78%
Other birds	6258	0.34%
Reptiles	92	0.01%
Rana	108	0.01%
Xenopus	2530	0.14%
Other Amphibians	522	0.03%
Zebra fish	216671	11.78%
Other Fish	91482	4.97%
Total	**1839079**	**100.00%**

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1710834	93.14%
Animals born in the EU but not at a registered breeder	112655	6.13%
Animals born in rest of Europe	3229	0.18%
Animals born in rest of world	10146	0.55%
Total	**1836864**	**100.00%**

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Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	253	11.42%
Animals born in Asia	616	27.81%
Animals born in Africa	1346	60.77%
Total	**2215**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	1	0.05%
F2 or greater	587	26.5%
Self-sustaining colony	1627	73.45%
Total	**2215**	**100.00%**

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1103996	944	1104940
Rats	231775	3006	234781
Guinea-Pigs	22560		22560
Hamsters (Syrian)	1126		1126
Mongolian gerbil	307	4	311
Other Rodents	2325	2	2327
Rabbits	9580	864	10444
Cats	74	214	288
Dogs	2518	1431	3949
Ferrets	405		405
Other carnivores	235	9	244
Horses, donkeys and cross-breeds	288	10312	10600
Pigs	4476	142	4618
Goats	280	24	304
Sheep	5346	42583	47929
Cattle	8489	596	9085
Marmoset and tamarins	110	56	166
Cynomolgus monkey	2023	639	2662
Rhesus monkey	82	50	132
Other Mammals	792	12	804
Domestic fowl	124629	27	124656
Other birds	6258	471	6729
Reptiles	92		92
Rana	108		108
Xenopus	2530	4923	7453
Other Amphibians	522	11	533
Zebra fish	216671	439	217110
Other Fish	91482	150	91632
Total	**1839079**	**66909**	**1905988**

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1058370	55.53%
Translational and applied research	326965	17.15%
Regulatory use and Routine production	505504	26.52%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	11901	0.62%
Preservation of species	1925	0.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1235	0.06%
Forensic enquiries	88	0%
Total	**1905988**	**100.00%**

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	130655	12.34%
Cardiovascular Blood and Lymphatic System	67776	6.4%
Nervous System	243752	23.03%
Respiratory System	10995	1.04%
Gastrointestinal System including Liver	22962	2.17%
Musculoskeletal System	24477	2.31%
Immune System	213921	20.21%
Urogenital/Reproductive System	28064	2.65%
Sensory Organs (skin, eyes and ears)	17935	1.69%
Endocrine System/Metabolism	25990	2.46%
Multisystemic	80548	7.61%
Ethology / Animal Behaviour /Animal Biology	64369	6.08%
Other basic research	126926	11.99%
Total	**1058370**	**100.00%**

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	86658	26.5%
Human Infectious Disorders	69473	21.25%
Human Cardiovascular Disorders	4173	1.28%
Human Nervous and Mental Disorders	42005	12.85%
Human Respiratory Disorders	12633	3.86%
Human Gastrointestinal Disorders including Liver	3943	1.21%
Human Musculoskeletal Disorders	5958	1.82%
Human Immune Disorders	6481	1.98%
Human Urogenital/Reproductive Disorders	3061	0.94%
Human Sensory Organ Disorders (skin, eyes and ears)	10774	3.3%
Human Endocrine/Metabolism Disorders	7815	2.39%
Other Human Disorders	10802	3.3%
Animal Diseases and Disorders	21921	6.7%
Animal Welfare	2843	0.87%
Diagnosis of diseases	3476	1.06%
Non-regulatory toxicology and ecotoxicology	34949	10.69%
Total	**326965**	**100.00%**

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	145113	28.71%
Other efficacy and tolerance testing	24606	4.87%
Toxicity and other safety testing including pharmacology	196061	38.79%
Routine production	139724	27.64%
Total	**505504**	**100.00%**

Regulatory uses - Quality control (including batch safety and potency testing)

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	18401	12.68%
Pyrogenicity testing	1125	0.78%
Batch potency testing	114151	78.66%
Other quality controls	11436	7.88%
Total	**145113**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16580	8.46%
Skin irritation/corrosion	112	0.06%
Skin sensitisation	2942	1.5%
Eye irritation/corrosion	63	0.03%
Repeated dose toxicity	40429	20.62%
Carcinogenicity	8067	4.11%
Genotoxicity	5314	2.71%
Reproductive toxicity	61241	31.24%
Developmental toxicity	34779	17.74%
Neurotoxicity	314	0.16%
Kinetics	3124	1.59%
Pharmaco-dynamics (incl safety pharmacology)	5309	2.71%
Ecotoxicity	11444	5.84%
Safety testing in food and feed area	183	0.09%
Target animal safety	1360	0.69%
Other toxicity/safety testing	4800	2.45%
Total	**196061**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10622	64.07%
Other lethal methods	98	0.59%
Non lethal methods	5860	35.34%
Total	**16580**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	21572	53.36%
29 - 90 days	11727	29.01%
> 90 days	7130	17.64%
Total	**40429**	**100.00%**

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3653	31.92%
Chronic toxicity	6320	55.23%
Reproductive ecotoxicity	514	4.49%
Endocrine activity	84	0.73%
Bioaccumulation	873	7.63%
Total	**11444**	**100.00%**

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	208034	56.87%
Legislation on medicinal products for veterinary use and their residues	34282	9.37%
Medical devices legislation	562	0.15%
Industrial chemicals legislation	86097	23.54%
Plant protection product legislation	18417	5.03%
Biocides legislation	292	0.08%
Food legislation including food contact material	1688	0.46%
Feed legislation including legislation for the safety of target animals, workers and environment	14831	4.05%
Other legislation	1577	0.43%
Total	**365780**	**100.00%**

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	338692	92.59%
Legislation satisfying national requirements only [within EU]	1651	0.45%
Legislation satisfying Non-EU requirements only	25437	6.95%
Total	**365780**	**100.00%**

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	55197	39.5%
Other product types	84527	60.5%
Total	**139724**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1839079	96.49%
Yes	66909	3.51%
Total	**1905988**	**100.00%**

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	135307	7.1%
Mild [up to and including]	1171215	61.45%
Moderate	504038	26.44%
Severe	95428	5.01%
Total	**1905988**	**100.00%**

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Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1182220	62.03%
Genetically altered without a harmful phenotype	596728	31.31%
Genetically altered with a harmful phenotype	127040	6.67%
Total	**1905988**	**100.00%**

Part 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	213555	393	213948
Rats	131		131
Pigs	124		124
Sheep	17		17
Domestic fowl	647		647
Xenopus	250		250
Zebra fish	49941	82	50023
Other Fish	34		34
Total	**264699**	**475**	**265174**

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	201	0.08%
Mild [up to and including]	241543	91.09%
Moderate	21638	8.16%
Severe	1792	0.68%
Total	**265174**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	56940	21.47%
Genetically altered without a harmful phenotype	191024	72.04%
Genetically altered with a harmful phenotype	17210	6.49%
Total	**265174**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	45369	17.71%
Cardiovascular Blood and Lymphatic System	10621	4.15%
Nervous System	29420	11.48%
Respiratory System	659	0.26%
Gastrointestinal System including Liver	3235	1.26%
Musculoskeletal System	3946	1.54%
Immune System	32311	12.61%
Urogenital/Reproductive System	6774	2.64%
Sensory Organs (skin, eyes and ears)	5542	2.16%
Endocrine System/Metabolism	3421	1.34%
Multisystemic	92818	36.23%
Ethology / Animal Behaviour /Animal Biology	2854	1.11%
Other basic research	19201	7.5%
Total	**256171**	**100.00%**

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	4221	46.88%
Human Infectious Disorders	730	8.11%
Human Cardiovascular Disorders	201	2.23%
Human Nervous and Mental Disorders	349	3.88%
Human Musculoskeletal Disorders	155	1.72%
Human Immune Disorders	873	9.7%
Human Urogenital/Reproductive Disorders	480	5.33%
Human Sensory Organ Disorders (skin, eyes and ears)	80	0.89%
Other Human Disorders	48	0.53%
Animal Diseases and Disorders	1586	17.62%
Non-regulatory toxicology and ecotoxicology	280	3.11%
Total	**9003**	**100.00%**

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	346497	1	346498
Rats	2919		2919
Domestic fowl	367		367
Xenopus	195	197	392
Zebra fish	52401	612	53013
Other Fish	524		524
Total	**402903**	**810**	**403713**

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	272	0.07%
Mild [up to and including]	328866	81.46%
Moderate	33725	8.35%
Severe	40850	10.12%
Total	**403713**	**100.00%**

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	24437	6.05%
Genetically altered without a harmful phenotype	315057	78.04%
Genetically altered with a harmful phenotype	64219	15.91%
Total	**403713**	**100.00%**

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PART 5/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

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V.4. Member State comparative tables for 2017

Introduction

Based on the recalculated Member State data, three comparative tables are provided for 2017 covering:

- **Numbers of animals**, by species, used for purposes of research, testing, routine production and education (including training)
- **Numbers of all uses** (first and any subsequent reuse) of animals, by species, for the purposes of research, testing, routine production and education (including training)
- Numbers and uses of animals, by species, for the **creation and maintenance of genetically altered animals**

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Table 1.1: Numbers of animals used for the first time for research, testing, routine production and educational purposes by species and Member State (Part 1) (2017)

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals															
Rodents															
Mice	169,345	306,605	989	1,209	71,954	1,171,550	159,566	2,168	21,190	465,870	48,580	1,011,925	19,710	65,368	205,849
Rats	5,309	23,207	1,892	0	24,809	245,998	37,955	296	2,435	55,826	13,467	173,535	7,638	33,255	16,858
Guinea-Pigs	1,127	15,539	1,841	0	1,377	14,349	2,932	0	6	6,411	9	44,976	16	5,731	518
Hamsters (Syrian)	0	1,147	0	0	15	1,217	282	0	0	599	149	6,529	0	0	0
Hamsters (Chinese)	0	0	0	0	0	8	0	0	0	0	0	167	0	0	0
Mongolian gerbil	0	174	0	0	46	4,154	0	0	0	0	0	429	0	0	0
Other rodents	998	115	0	0	635	9,950	3	0	0	141	690	857	0	0	0
Rabbits															
Rabbits	10,367	57,849	568	0	2,031	89,147	2,439	0	213	22,205	223	124,544	426	1,343	400
Carnivores															
Cats	61	53	30	0	121	431	0	0	0	178	311	315	0	16	0
Dogs	149	334	0	0	437	1,720	69	0	23	1,045	3,035	2,752	0	359	46
Ferrets	0	26	0	0	1	172	4	0	0	164	0	148	0	4	442
Other carnivores	0	0	0	0	1	535	935	0	0	25	107	24	0	0	0
Farm animals															
Horses, donkeys and cross-breeds	349	135	0	0	90	1,013	55	0	0	46	30	109	0	0	59
Pigs	2,040	4,847	20	0	1,893	16,069	5,481	4	283	8,655	632	9,261	2	2,078	1,519
Goats	20	77	0	0	91	195	1	0	0	354	0	311	0	0	11
Sheep	139	628	340	0	524	2,832	56	0	8	1,715	1,319	2,633	28	0	1,189
Cattle	904	1,354	15	0	1,413	5,842	3,663	16	3	1,138	207	956	30	12	2,805
Non-human primates															
Prosimians	0	0	0	0	0	12	0	0	0	0	0	86	0	0	0
Marmoset and tamarins	0	0	0	0	0	197	0	0	0	0	0	131	0	0	0
Squirrel monkey	0	0	0	0	0	1	0	0	0	0	0	7	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	0	0	0	0	0	2,387	0	0	0	246	0	2,001	0	0	0
Rhesus monkey	0	9	0	0	0	67	0	0	0	0	0	26	0	2	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	33	0	0	0
Baboons	0	0	0	0	0	14	0	0	0	0	0	11	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	9	0	0	0
Other mammals															
Other mammals	102	77	0	0	0	1,259	28	0	0	99	1,521	18,125	0	0	0
Birds															
Domestic fowl	3,895	39,661	680	0	21,166	24,463	402	0	6	82,047	8,485	42,582	255	20,575	40
Other birds	1,810	6,887	0	0	4,234	11,339	408	180	0	2,385	404	26,997	0	2,084	823
Reptiles															
Reptiles	0	42	0	0	558	351	269	0	0	1,003	0	14	0	0	0
Amphibians															
Rana	0	0	2,306	0	0	377	0	0	0	18	0	118	0	0	0
Xenopus	941	866	0	0	50	3,405	75	0	0	1,204	0	3,570	0	0	18
Other amphibians	912	71	0	0	531	2,652	47	0	0	1,996	0	742	0	0	0
Fish															
Zebra fish	8,112	23,912	0	0	5,414	87,413	1,587	0	1,859	19,941	6,454	16,199	0	928	236
Other fish	4,596	23,538	0	0	74,753	94,180	15,538	0	16,250	42,320	11,729	267,714	0	1,174	9,755
Cephalopods															
Cephalopods	0	0	0	0	0	0	0	0	33	20	0	1	0	0	0
Totals															
Total	**211,176**	**507,153**	**8,681**	**1,209**	**212,144**	**1,793,299**	**231,795**	**2,664**	**42,309**	**715,651**	**97,352**	**1,757,837**	**28,105**	**132,929**	**240,568**
% of total	**2.2**	**5.4**	**0.1**	**0**	**2.3**	**19.1**	**2.5**	**0**	**0.5**	**7.6**	**1**	**18.7**	**0.3**	**1.4**	**2.6**

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Table 1.2: Numbers of animals used for the first time for research, testing, routine production and educational purposes by species and Member State (Part2) (2017)

		IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals																
	Rodents															
	Mice	347,361	1,718	5,348	3,332	0	188,238	88,894	35,221	7,975	193,965	3,998	5,547	1,103,996	**5,707,471**	**60.8**
	Rats	117,203	391	96	1,795	0	89,294	28,865	3,133	4,367	19,055	226	7,619	231,775	**1,146,299**	**12.2**
	Guinea-Pigs	14,246	15	0	0	0	5,702	5,232	0	792	409	0	1,036	22,560	**144,824**	**1.5**
	Hamsters (Syrian)	277	0	0	0	0	1,025	150	0	150	34	0	0	1,126	**12,700**	**0.1**
	Hamsters (Chinese)	0	0	0	0	0	12	0	0	0	0	0	0	0	**187**	**0**
	Mongolian gerbil	0	0	0	0	0	0	120	0	0	0	0	9	307	**5,239**	**0.1**
	Other rodents	647	0	0	0	0	736	7,930	140	0	5	0	0	2,325	**25,172**	**0.3**
	Rabbits															
	Rabbits	18,146	13	0	0	0	9,551	718	36	318	1,573	76	195	9,580	**351,961**	**3.7**
	Carnivores															
	Cats	0	0	0	0	0	174	0	0	0	104	0	11	74	**1,879**	**0**
	Dogs	373	0	0	0	0	549	0	0	0	279	0	0	2,518	**13,688**	**0.1**
	Ferrets	42	0	0	0	0	608	0	0	0	0	0	0	405	**2,016**	**0**
	Other carnivores	0	0	0	0	0	270	130	0	0	124	0	0	235	**2,386**	**0**
	Farm animals															
	Horses, donkeys and cross-breeds	0	0	0	0	0	173	50	0	0	17	0	0	288	**2,414**	**0**
	Pigs	1,559	68	0	22	0	9,587	1,513	155	58	1,220	80	0	4,476	**71,522**	**0.8**
	Goats	0	0	0	0	0	176	17	0	0	30	0	0	280	**1,563**	**0**
	Sheep	120	15	0	0	0	531	1,231	12	85	35	26	0	5,346	**18,812**	**0.2**
	Cattle	270	0	0	0	0	2,629	403	0	0	493	0	1	8,489	**30,643**	**0.3**
	Non-human primates															
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	**98**	**0**
	Marmoset and tamarins	0	0	0	0	0	27	0	0	0	0	0	0	110	**465**	**0**
	Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	**8**	**0**
	Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	3	0	0	0	0	0	0	**3**	**0**
	Cynomolgus monkey	545	0	0	0	0	23	0	0	0	2	0	0	2,023	**7,227**	**0.1**
	Rhesus monkey	3	0	0	0	0	141	0	0	0	23	0	0	82	**353**	**0**
	Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	**33**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	**25**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	14	0	0	0	0	0	0	**23**	**0**
	Other mammals															
	Other mammals	24	0	0	140	0	3,305	639	32	0	192	0	0	792	**26,335**	**0.3**
Birds																
	Domestic fowl	33,358	0	0	0	0	55,152	5,067	120	280	1,452	10	228	124,629	**464,553**	**4.9**
	Other birds	420	26	0	0	0	17,946	6,470	0	23	10,657	0	59	6,258	**99,410**	**1.1**
Reptiles																
	Reptiles	0	0	0	0	0	294	314	0	0	0	0	0	92	**2,937**	**0**
Amphibians																
	Rana	0	0	0	0	0	0	20	0	230	308	0	0	108	**3,485**	**0**
	Xenopus	371	0	0	0	0	278	0	0	0	231	0	0	2,530	**13,539**	**0.1**
	Other amphibians	0	0	0	0	0	60	456	0	0	2,694	0	0	522	**10,683**	**0.1**
Fish																
	Zebra fish	19,415	0	19,849	0	0	51,456	950	906	0	18,461	0	0	216,671	**499,763**	**5.3**
	Other fish	10,079	520	0	0	250	15,842	5,381	793	0	33,940	98	0	91,482	**719,932**	**7.7**
Cephalopods																
	Cephalopods	10	0	0	0	0	0	0	450	0	0	0	0	0	**514**	**0**
Totals																
	Total	**564,469**	**2,766**	**25,293**	**5,289**	**250**	**453,779**	**154,567**	**40,998**	**14,278**	**285,303**	**4,514**	**14,705**	**1,839,079**	**9,388,162**	**100**
	%	**6**	**0**	**0.3**	**0.1**	**0**	**4.8**	**1.6**	**0.4**	**0.2**	**3**	**0**	**0.2**	**19.6**	**100**	

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Table 2.1: All uses (first use and all subsequent reuses) of animals for research, testing, routine production and educational purposes by species and Member State (Part 1) (2017)

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals															
Rodents															
Mice	169,908	306,919	989	1,209	72,996	1,188,709	160,422	2,168	21,519	467,205	48,631	1,028,083	19,710	65,714	205,849
Rats	5,309	23,604	1,892	0	24,855	250,479	38,498	296	2,438	55,988	13,467	179,613	7,700	33,946	16,858
Guinea-Pigs	1,154	15,541	1,841	0	1,383	14,851	2,947	0	6	6,747	9	45,034	21	5,765	518
Hamsters (Syrian)	8	1,147	0	0	15	1,222	282	0	0	599	149	6,529	0	0	0
Hamsters (Chinese)	0	0	0	0	0	8	0	0	0	0	0	167	0	0	0
Mongolian gerbil	41	174	0	0	46	4,255	0	0	0	0	0	429	0	0	0
Other rodents	998	115	0	0	635	9,950	3	0	0	141	690	957	0	0	0
Rabbits															
Rabbits	10,388	57,888	568	0	2,133	92,644	2,443	0	213	25,931	227	126,898	426	1,431	400
Carnivores															
Cats	61	61	30	0	132	718	0	0	8	531	311	867	0	16	0
Dogs	203	1,856	0	0	637	3,330	214	0	41	1,476	3,061	4,096	0	463	89
Ferrets	0	26	0	0	1	196	4	0	0	164	0	148	0	4	442
Other carnivores	0	0	0	0	1	535	1,035	0	0	25	107	27	0	0	0
Farm animals															
Horses, donkeys and cross-breeds	521	234	0	0	105	1,209	119	0	0	61	77	305	25	0	60
Pigs	2,040	4,970	20	0	2,447	17,283	5,801	4	289	8,655	632	10,346	2	2,405	1,547
Goats	22	78	0	0	97	212	1	0	0	369	0	838	0	0	11
Sheep	149	666	340	0	918	3,053	66	0	8	1,953	1,319	5,396	39	0	1,321
Cattle	908	1,558	15	0	2,734	6,332	3,677	16	3	1,700	216	1,777	30	33	3,244
Non-human primates															
Prosimians	0	0	0	0	0	87	0	0	0	0	0	86	0	0	0
Marmoset and tamarins	0	0	0	0	0	214	0	0	0	0	0	224	0	0	0
Squirrel monkey	0	0	0	0	0	1	0	0	0	0	0	7	0	0	0
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	0	0	0	0	0	3,002	0	0	0	451	0	3,279	0	0	0
Rhesus monkey	0	44	0	0	0	117	0	0	1	0	0	71	0	2	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	15	0	0	0	0	0	38	0	0	0
Baboons	0	0	0	0	0	14	0	0	0	0	0	32	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	12	0	0	0	0	0	9	0	0	0
Other mammals															
Other mammals	102	140	0	0	0	1,352	28	0	0	99	1,533	18,525	0	0	0
Birds															
Domestic fowl	3,895	39,674	680	0	21,217	24,920	466	0	6	82,107	8,485	43,144	255	25,169	40
Other birds	1,819	7,138	0	0	4,260	12,000	408	180	0	2,535	404	27,225	0	2,084	823
Reptiles															
Reptiles	0	181	0	0	558	369	289	0	0	1,003	0	3,462	0	0	0
Amphibians															
Rana	0	0	2,306	0	0	377	4	0	0	18	0	118	0	0	0
Xenopus	972	918	0	0	50	4,546	285	0	0	1,204	0	4,897	0	0	18
Other amphibians	912	323	0	0	531	2,652	47	0	0	1,996	0	742	0	0	0
Fish															
Zebra fish	8,112	23,912	0	0	5,414	87,413	1,587	0	1,859	21,375	6,454	16,799	0	1,676	236
Other fish	4,630	24,027	0	0	74,861	94,210	15,606	0	16,346	43,480	11,729	268,074	0	1,174	9,787
Cephalopods															
Cephalopods	0	0	0	0	0	0	0	0	33	20	0	1	0	0	0
Totals															
Total	**212,152**	**511,194**	**8,681**	**1,209**	**216,026**	**1,826,287**	**234,232**	**2,664**	**42,770**	**725,833**	**97,501**	**1,798,243**	**28,208**	**139,882**	**241,243**
%	**2.2**	**5.3**	**0.1**	**0**	**2.3**	**19.1**	**2.4**	**0**	**0.4**	**7.6**	**1**	**18.8**	**0.3**	**1.5**	**2.5**

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Table 2.2: All uses (first use and all subsequent reuses) of animals for research, testing, routine production and educational purposes by species and Member State (Part2) (2017)

	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals															
Rodents															
Mice	347,844	1,718	5,572	3,332	0	194,144	89,191	36,126	7,975	195,193	4,508	5,547	1,104,940	**5,756,121**	**60.1**
Rats	117,541	391	96	1,795	0	91,099	28,873	3,135	4,367	19,301	226	7,619	234,781	**1,164,167**	**12.1**
Guinea-Pigs	14,357	15	0	0	0	5,816	5,235	0	792	409	0	1,036	22,560	**146,037**	**1.5**
Hamsters (Syrian)	277	0	0	0	0	1,035	150	0	150	34	0	0	1,126	**12,723**	**0.1**
Hamsters (Chinese)	0	0	0	0	0	12	0	0	0	0	0	0	0	**187**	**0**
Mongolian gerbil	0	0	0	0	0	0	120	0	0	0	0	9	311	**5,385**	**0.1**
Other rodents	647	0	0	0	0	736	8,108	140	0	5	0	0	2,327	**25,452**	**0.3**
Rabbits															
Rabbits	19,325	13	0	0	0	9,764	820	36	504	1,574	135	226	10,444	**364,431**	**3.8**
Carnivores															
Cats	0	0	0	0	0	200	0	0	0	104	0	11	288	**3,338**	**0**
Dogs	639	0	0	0	0	909	10	0	0	386	0	0	3,949	**21,359**	**0.2**
Ferrets	42	0	0	0	0	680	0	0	0	0	0	0	405	**2,112**	**0**
Other carnivores	0	0	0	0	0	270	130	0	0	140	0	0	244	**2,514**	**0**
Farm animals															
Horses, donkeys and cross-breeds	17	0	0	0	0	173	73	0	2	41	2	0	10,600	**13,624**	**0.1**
Pigs	1,621	68	0	22	0	9,738	1,517	155	58	1,557	80	0	4,618	**75,875**	**0.8**
Goats	23	0	0	0	0	259	24	0	0	30	0	0	304	**2,268**	**0**
Sheep	192	15	0	0	0	558	1,301	30	209	35	28	2	47,929	**65,527**	**0.7**
Cattle	279	0	0	0	0	3,833	413	0	2	1,420	0	1	9,085	**37,276**	**0.4**
Non-human primates															
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	**173**	**0**
Marmoset and tamarins	1	0	0	0	0	41	0	0	0	0	0	0	166	**646**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	**8**	**0**
Other species of new world monkeys (Ceboidea)	0	0	0	0	0	0	3	0	0	0	0	0	0	**3**	**0**
Cynomolgus monkey	569	0	0	0	0	42	0	0	0	2	0	0	2,662	**10,007**	**0.1**
Rhesus monkey	4	0	0	0	0	234	0	0	0	23	0	0	132	**628**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	**53**	**0**
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	**46**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	14	0	0	0	0	0	0	**35**	**0**
Other mammals															
Other mammals	30	0	0	140	0	3,315	639	32	0	327	0	0	804	**27,066**	**0.3**
Birds															
Domestic fowl	34,715	0	0	0	0	55,371	5,067	120	330	1,452	10	233	124,656	**472,012**	**4.9**
Other birds	420	26	0	0	0	18,322	6,566	56	23	11,269	0	59	6,729	**102,346**	**1.1**
Reptiles															
Reptiles	0	0	0	0	0	294	314	0	0	0	0	0	92	**6,562**	**0.1**
Amphibians															
Rana	0	0	0	0	0	9	20	0	230	308	0	0	108	**3,498**	**0**
Xenopus	401	0	0	0	0	438	0	0	0	261	0	0	7,453	**21,443**	**0.2**
Other amphibians	0	0	0	0	0	60	456	0	0	2,694	0	0	533	**10,946**	**0.1**
Fish															
Zebra fish	19,508	0	19,849	0	0	51,676	950	912	0	19,341	0	0	217,110	**504,183**	**5.3**
Other fish	10,715	520	0	0	250	15,887	5,381	829	0	33,940	98	0	91,632	**723,176**	**7.5**
Cephalopods															
Cephalopods	10	0	0	0	0	0	0	450	0	0	0	0	0	**514**	**0**
Totals															
Total	**569,177**	**2,766**	**25,517**	**5,289**	**250**	**464,915**	**155,375**	**42,021**	**14,642**	**289,846**	**5,087**	**14,743**	**1,905,988**	**9,581,741**	**100**
%	**5.9**	**0**	**0.3**	**0.1**	**0**	**4.9**	**1.6**	**0.4**	**0.2**	**3**	**0.1**	**0.2**	**19.9**	**100**	

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Table 3.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species, reuse and Member State[1] (2017)

	Reuse[2]	AT	BE	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LU	NL	PL	PT	SE	SI	UK	Total	%
Mice	No	14,373	24,875	9,007	117,993	3,686	16	3,960	17,749	4,155	36,512	0	162	586	7,799	0	10,790	188	495	22,641	55	213,555	**488,597**	**99.6**
	Yes	0	0	216	432	0	0	0	70	0	180	0	0	0	0	0	2	0	39	788	0	393	**2,120**	**0.4**
	Total	**14,373**	**24,875**	**9,223**	**118,425**	**3,686**	**16**	**3,960**	**17,819**	**4,155**	**36,692**	**0**	**162**	**586**	**7,799**	**0**	**10,792**	**188**	**534**	**23,429**	**55**	**213,948**	**490,717**	**100.0**
Rats	No	0	222	2,112	3,396	0	72	0	48	5	3,346	0	0	0	510	0	9	109	0	0	0	131	**9,960**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**222**	**2,112**	**3,396**	**0**	**72**	**0**	**48**	**5**	**3,346**	**0**	**0**	**0**	**510**	**0**	**9**	**109**	**0**	**0**	**0**	**131**	9,960	**100.0**
Rabbits	No	0	0	0	17	0	0	0	0	0	306	0	152	0	0	0	0	0	0	0	0	0	**475**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**17**	**0**	**0**	**0**	**0**	**0**	**306**	**0**	**152**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	475	**100.0**
Pigs	No	0	0	0	61	2	0	0	1	0	0	0	0	0	36	0	0	0	0	0	0	124	**224**	**98.7**
	Yes	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**3**	**1.3**
	Total	**0**	**0**	**0**	**64**	**2**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**124**	227	**100.0**
Sheep	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	17	**17**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**17**	17	**100.0**
Marmoset and tamarins	No	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**10**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	10	**100.0**
Other mammals	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	61	0	0	0	0	**61**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**61**	**0**	**0**	**0**	**0**	61	**100.0**
Domestic fowl	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	647	**647**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**647**	647	**100.0**
Xenopus	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	250	**250**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**250**	250	**100.0**
Zebra fish	No	8,185	3,544	0	48,540	0	0	0	4,886	699	5,080	230	0	0	0	77	167	0	0	8,546	0	49,941	**129,895**	**86.3**
	Yes	0	979	14,351	3,451	0	0	0	0	0	0	0	567	0	0	0	0	0	0	1,271	0	82	**20,701**	**13.7**
	Total	**8,185**	**4,523**	**14,351**	**51,991**	**0**	**0**	**0**	**4,886**	**699**	**5,080**	**230**	**567**	**0**	**0**	**77**	**167**	**0**	**0**	**9,817**	**0**	**50,023**	150,596	**100.0**
Other fish	No	0	0	0	3,348	0	0	0	1,187	0	0	0	0	0	0	0	0	0	0	0	0	34	**4,569**	**100.0**
	Yes	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**3,348**	**0**	**0**	**0**	**1,187**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**34**	4,569	**100.0**
All Species	**No**	**22,558**	**28,641**	**11,119**	**173,365**	**3,688**	**88**	**3,960**	**23,871**	**4,859**	**45,244**	**230**	**314**	**586**	**8,345**	**77**	**10,966**	**358**	**495**	**31,187**	**55**	**264,699**	**634,705**	**96.5**
	Yes	**0**	**979**	**14,567**	**3,886**	**0**	**0**	**0**	**70**	**0**	**180**	**0**	**567**	**0**	**0**	**0**	**2**	**0**	**39**	**2,059**	**0**	**475**	**22,824**	**3.5**
	Total	**22,558**	**29,620**	**25,686**	**177,251**	**3,688**	**88**	**3,960**	**23,941**	**4,859**	**45,424**	**230**	**881**	**586**	**8,345**	**77**	**10,968**	**358**	**534**	**33,246**	**55**	**265,174**	**657,529**	**100.0**

Table notes:

1) Table includes only those Member States that have reported data for this purpose

2) Reuse "No" = numbers of animals used for the first time;
Reuse "Yes" = all subsequent reuses;
Total = numbers of all uses.

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Table 3.2: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and Member State[1)] (2017)

	Reuse[2)]	AT	BE	CZ	DE	DK	EE	ES	FI	FR	HR	IE	IT	LU	NL	PL	PT	SE	SK	UK	Total	%
Mice	No	28,632	2,249	0	61,184	29	394	38,443	215	69,742	96	473	2,485	0	1,057	501	9,447	1,659	540	346,497	**563,643**	**100.0**
	Yes	0	11	0	129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	**141**	**0.0**
	Total	**28,632**	**2,260**	**0**	**61,313**	**29**	**394**	**38,443**	**215**	**69,742**	**96**	**473**	**2,485**	**0**	**1,057**	**501**	**9,447**	**1,659**	**540**	**346,498**	563,784	100.0
Rats	No	729	0	0	1,574	0	0	0	0	755	0	0	53	0	429	0	0	20	320	2,919	**6,799**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**729**	**0**	**0**	**1,574**	**0**	**0**	**0**	**0**	**755**	**0**	**0**	**53**	**0**	**429**	**0**	**0**	**20**	**320**	**2,919**	6,799	100.0
Dogs	No	0	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	**10**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	10	100.0
Domestic fowl	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	367	**367**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**367**	367	100.0
Xenopus	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	195	**195**	**49.7**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	197	**197**	**50.3**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**392**	392	100.0
Zebra fish	No	0	0	0	2,272	0	0	14,759	0	0	0	0	0	247	181	0	368	0	0	52,401	**70,228**	**99.1**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	612	**612**	**0.9**
	Total	**0**	**0**	**0**	**2,272**	**0**	**0**	**14,759**	**0**	**0**	**0**	**0**	**0**	**247**	**181**	**0**	**368**	**0**	**0**	**53,013**	70,840	100.0
Other fish	No	0	0	0	116	0	0	0	0	0	0	0	0	0	0	0	0	0	0	524	**640**	**100.0**
	Yes	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**116**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**524**	640	100.0
All Species	**No**	**29,361**	**2,249**	**0**	**65,146**	**29**	**394**	**53,202**	**215**	**70,507**	**96**	**473**	**2,538**	**247**	**1,667**	**501**	**9,815**	**1,679**	**860**	**402,903**	**641,882**	**99.9**
	Yes	**0**	**11**	**0**	**129**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**810**	**950**	**0.1**
	Total	**29,361**	**2,260**	**0**	**65,275**	**29**	**394**	**53,202**	**215**	**70,507**	**96**	**473**	**2,538**	**247**	**1,667**	**501**	**9,815**	**1,679**	**860**	**403,713**	642,832	100.0

Table notes:

1) Table includes only those Member States that have reported data for this purpose

2) Reuse "No" = numbers of animals used for the first time;
Reuse "Yes" = all subsequent reuses;
Total = numbers of all uses.

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