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PART 1/2

COMMISSION STAFF WORKING DOCUMENT

Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2018

Report of statistical information on the use of animals for scientific purposes

Report of statistical information on the use of animals for scientific purposes

I. Executive Summary

This report presents statistical data on the use of animals for scientific purposes in the Member States of the European Union and Norway during 2018 under Directive 2010/63/EU[1] ("the Directive") on the protection of animals used for scientific purposes.

The presentation of data follows that of the previous report distinguishing animals used directly in research, testing, routine production and for educational (including training) purposes ("research and testing" from here on), from those used for the creation and maintenance of genetically altered animals in support of Union research needs.

The first statistical report under the Directive covered years 2015-2017. The data were submitted by the 28 Member States of the Union at the time. This current report also incorporates data from Norway, bringing the number of reporting countries to 29. The data from the United Kingdom continue to be included in this and the forthcoming 2019 report. It is important, therefore, that any comparisons with previous years are made using the same reporting countries.

I.1. Numbers and origins of animals

In 2018, the total number of animals used for the first time **in research and testing** covering the 29 countries is 10.6 million. However, when excluding the new data from Norway, there is a further 5% decrease from 2017 bringing the total number of animals used in research and testing in EU-28, for the first time, below 9 million animals.

	2015	2016	2017	2018 (EU-28)	2018 (EU-28 incl. NO)[2]
Total	9,590,379	9,817,946	9,388,162	**8,921,758**	**10,572,305**

Table 1: Total numbers of animals used for the first time for research, testing, routine production and education purposes in the Union between 2015 and 2018

The number of animals used for the first time for **the creation and maintenance of genetically altered (GA) animal lines** to meet the research needs in the Union is around 1.5 million. The fluctuation in the numbers of animals reported under GA maintenance is likely to be the result of a better understanding of the reporting requirements which are particularly complex. The increase of 290,847 uses under this category between 2017 and 2018 includes an increase of 250,490 from a single Member State. The additional data from Norway have not significantly impacted these categories.

	2015	2016	2017	2018

[1] Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79

[2] NO: including data from Norway

GA creation	591,033	493,156	634,705	588,062
GA maintenance	996,993	700,536	641,882	932,729
Total GA creation and maintenance	**1,588,025**	**1,193,692**	**1,276,587**	**1,520,791**

Table 2: Total numbers of animals used for the creation and maintenance of genetically altered animal lines

As to the distribution of species that were used for the first time in research and testing, the proportions remain relatively stable when compared with previous years.

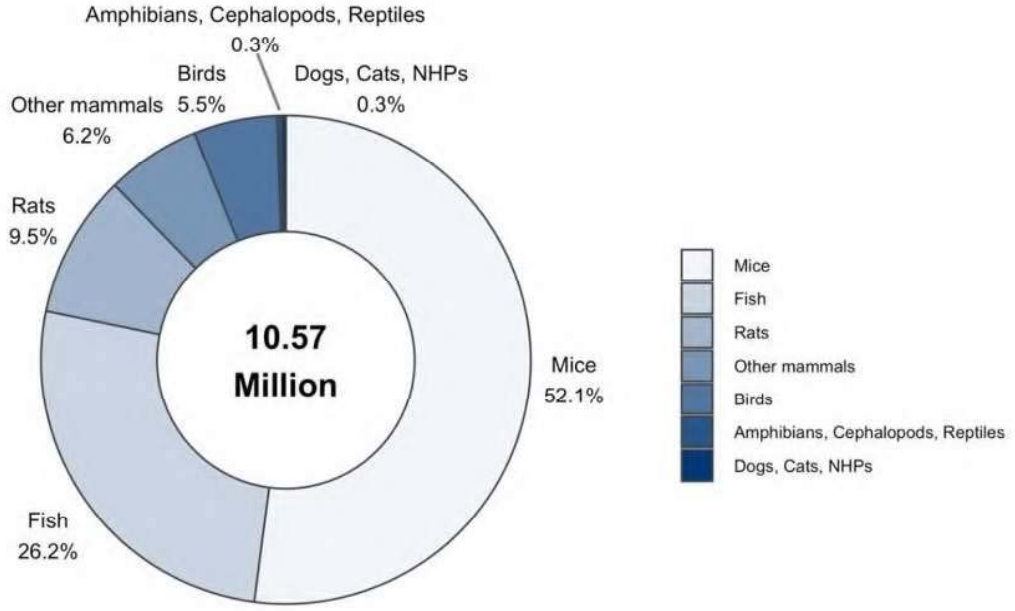


Figure 1: Numbers of animals used for the first time by main classes of species in 2018

Compared to 2017, the numbers of farm animals increased (+10%) as well as dogs (+29%) and "Other carnivores" (+38%). The use of non-human primates also increased slightly (+4%). Uses of other species decreased, such as guinea-pigs (-10%) and "Other rodents" (-17%).

The origin of animals is reported. Animals bred outside the Union do not benefit from the accommodation and care standards provided by the Directive. Moreover, an increase in transport times may negatively impact their welfare.

In 2018, almost 89% of the animals used for scientific purposes were born in the Union at registered breeders and less than 3% were born outside of the Union (either in the rest of Europe or outside of Europe). The category 'animals born in the Union but not at a registered breeder' and 'animals born in rest of Europe' had a slight increase which seems to originate partly from the increase in the use of fish

from the “other fish” category that could be explained by the use of fish coming from fish farms or from the wild.

The Directive provides additional protection for non-human primates (NHP) due to their genetic proximity to human beings, their highly developed social skills and capacity to experience pain, suffering and distress. In order to end the capturing of animals from the wild including for the purposes of breeding, the Directive requires moving towards using NHPs that have been bred, ultimately, in self-sustaining colonies, from parents who themselves have been bred in captivity.

In 2018, the origin of non-human primates remains stable coming from Africa, Asia and Union-registered breeders. Compared to 2017, the proportion of non-human primates coming from self-sustaining colonies decreased slightly (-1%). However, consistent with the Directive objectives, the proportion of those being second or higher generation purpose-bred continued to increase (+3%) and those of first-generation purpose-bred decrease (-2%).

I.2. Uses of animals in research and testing

In 2018, 10.81 million uses of animals for scientific purposes were reported, including the data from Norway. As in previous years, the main purpose was research (74%) of which 46% of all uses were carried out for basic research and 28% for translational and applied research purposes. A further 18% of animal uses were for regulatory use to satisfy legislative requirements, followed by routine production (5%).

Compared with 2017, the most significant changes noted as a result from the inclusion of the data from Norway are an increase in the numbers of uses in both basic (+ 14%), translational and applied research (+35%), protection of the natural environment in the interest of the health or welfare of human beings or animals (+7%) and preservation of species (+7%). This can be clearly seen in the figure below.

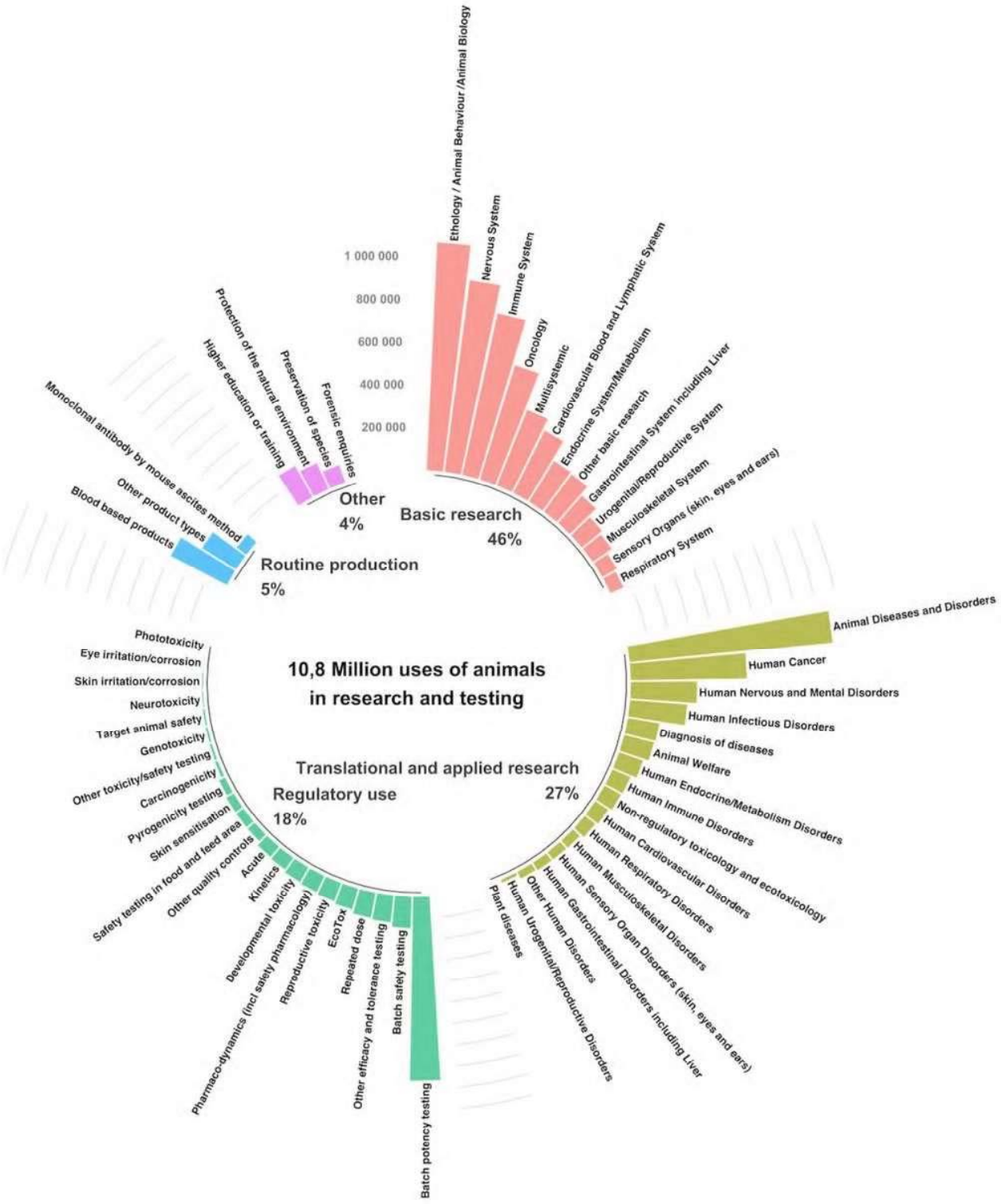


Figure 2: All uses of animals for research and testing in 2018

In reference to the actual severities reported for each use of an animal, these remain rather stable in 2018. As in 2017, just over half of uses were reported as 'mild' (up to and including), 34% as 'moderate', and 10% as 'severe'. 6% of uses were reported as 'non-recovery'.

There were some marginal changes; the number of uses reported as severe and mild decreased proportionally in 2018 (-1%) while moderate uses increased (+2%).

	2017	2018 (EU)	2018 (EU-28 incl. NO)
Non-recovery	6% (621,054)	6% (534,999)	6% (612,094)
Mild [up to and including]	51% (4,865,721)	49% (4,522,747)	50% (5,469,214)
Moderate	32% (3,071,828)	34% (3,096,460)	34% (3,658,621)
Severe	11% (1,023,138)	11% (983,237)	10% (1,064,925)
Total	**100% (9,581,741)**	**100% (9,137,443)**	**100% (10,804,854)**

Table 3: Severity of uses

The graphical presentation below shows the purpose areas with most severe uses. In 2018, most of these were conducted for regulatory purposes (32% of all uses), while routine production was mostly mild. Uses in translational and applied research tended to be more severe than those reported in basic research. When analysing all the sub-categories of purposes, batch potency testing continue to result in the highest number of severe uses (over 253,000 uses). Looking at the proportion of severe uses within a sub-category: the production of monoclonal antibodies was the highest (94% of all uses for this purpose), followed by diagnosis of diseases (41%) and acute toxicity studies in the area of ecotoxicity (38%).

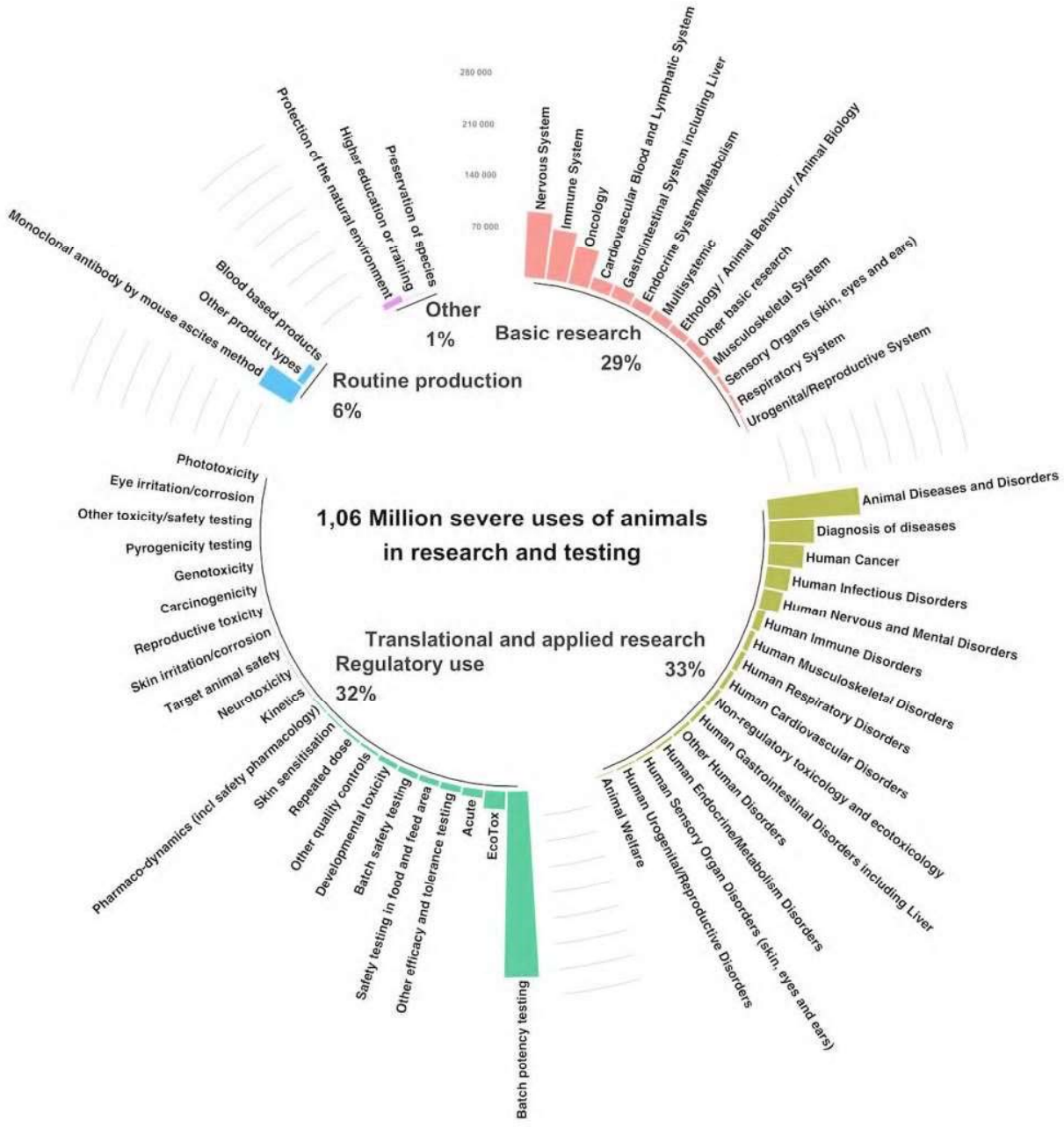


Figure 3: Severe uses of animals for research and testing in 2018

As in previous years, concerning the testing carried out to satisfy regulatory toxicity, safety and efficacy information requirements, the main legislative instruments were for medicinal products for human use (64%), veterinary medicinal products (16%) and industrial chemicals (8%), the last having decreased from 11% in 2017. The majority of regulatory uses continue to be performed to comply with regulatory requirements originating from the Union (95%).

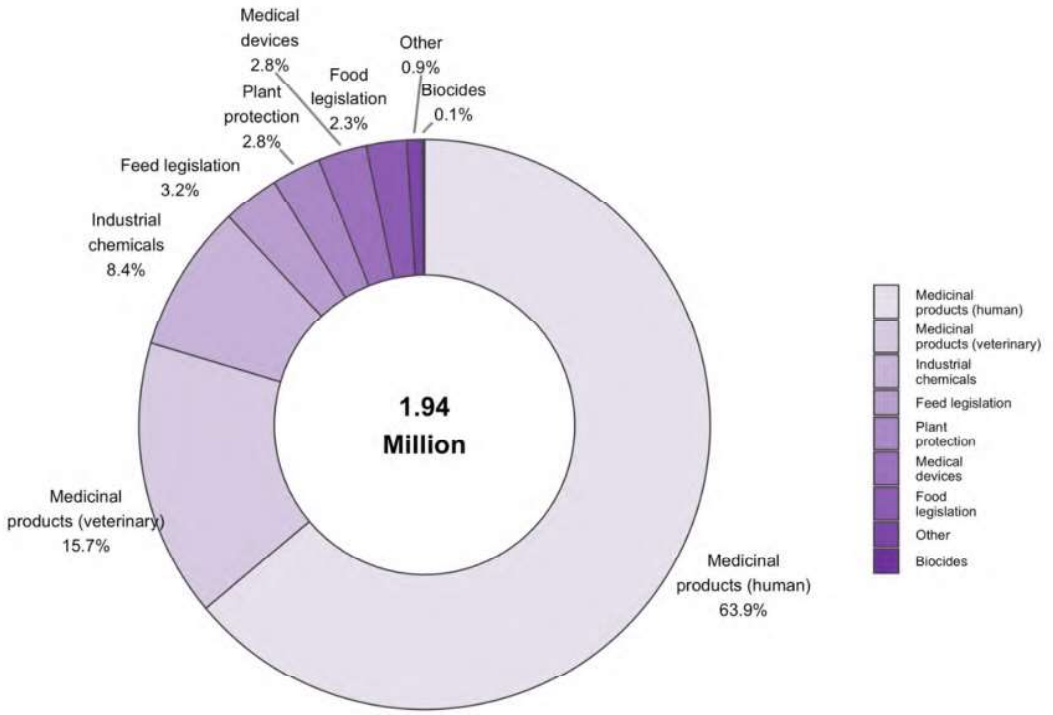


Figure 4: Regulatory uses by type of legislation in 2018

In line with the principle of the Three Rs, the total number of animals used in procedures can be reduced by performing more than one procedure on an animal, however, under strict conditions taking into account the lifetime experience of the individual animal. The reuses remained stable at 2% of all uses. Proportionally, large mammals are reused more often, such as horses, donkeys and cross-breeds, sheep, cats, dogs and non-human primates. Routine production continues to have the largest proportion of reuses (12%).

Surprisingly in 2018, the number of genetically altered animals used in research and testing decreased slightly from 28% to 24%. Most of this can be explained by the inclusion of data from Norway which include large number of conventional (not genetically altered) fish use. Of the 2.53 million uses that were carried out on animals that were genetically altered, 16% exhibited a harmful phenotypic alteration. Zebra fish and mice were the most common genetically altered species with 60% and 39% of these genetically altered respectively.

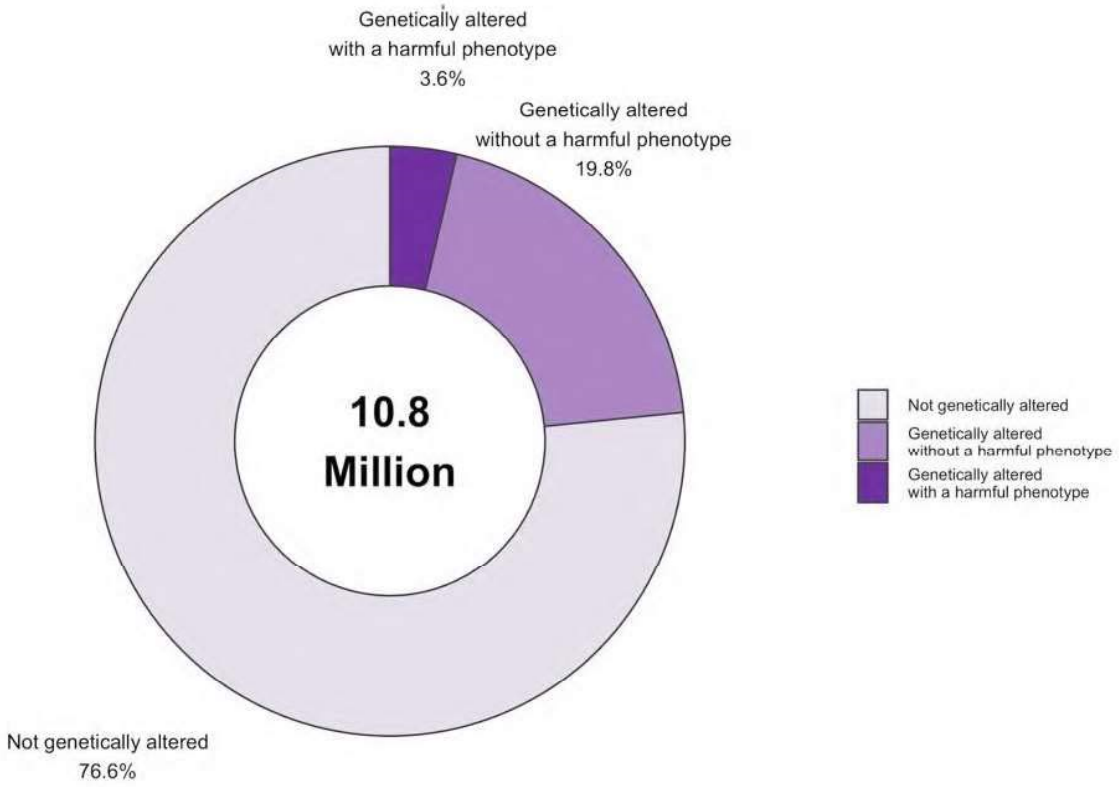


Figure 5: Genetic status of animals used in research and testing in 2018

Genetically altered animals are used almost exclusively for research purposes with basic research accounting for 74% of uses of genetically altered animals.

I.3. Creation and maintenance of genetically altered animal lines for research purposes

In 2018, the uses for the creation of new genetically altered animal lines decreased by 10% from 658,000 to 592,000 uses. The main species used for this purpose were mice and zebra fish, 75% and 20% respectively. As in 2017, other species include, among others, rats, other species of fish, and xenopus, as well as 10 marmosets.

In 2018, 92% of the new genetically altered lines were created for purposes covered under basic research, multisystemic research (21%), nervous system (17%) and oncology (16%) continuing to be the main purposes. The most important sub-category under translational and applied research for which new genetically altered animal lines were created was human cancer (20%).

Category ‘maintenance of colonies of genetically altered animals of established lines’ continues to fluctuate. It includes animals 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. It also includes genetically altered animals during maintenance of an established line, irrespective of whether

the line is of non-harmful or harmful phenotype, for which the genotype has been confirmed using an invasive method of tissue sampling.

The uses of animals for this purposes decreased significantly between 2015 and 2017, from 1 million to 643K, but returning to 933K uses in 2018. The fluctuation is likely to be the result of the complexity of the reporting requirements and problems in their uniform understanding. The forthcoming Union guidance (working) document prepared by the Commission together with the Member States and stakeholder on genetically altered animals, which includes a section on reporting obligations, is intended to improve the quality of reporting under this category.

I.4. Conclusions

The number of animals used in research and testing by the Union Member States in 2018, fell for the first time since the beginning of Union statistical reports (1991[3]), below 9 million animals. This confirms the continuation of a downward trend. Also in other areas, a positive trend has continued such as moving towards second and higher generation purpose bred non-human primates, even if their use has slightly increased.

The novel aspect of the 2018 report, however, is the inclusion of data from Norway. This has had some moderate impact also at Union level, especially on the proportional distribution of purposes for which animals are used, as well as a clear increase in the use of fish.

Collaborative efforts need to continue in areas where alternative methods are available for regulatory testing, such as for the use of animals for pyrogenicity testing and the production of antibodies, especially by the use of ascites methods. Such use can only be authorised if the project applicant provides robust scientific evidence why the use of alternatives is not possible.

The use and creation of genetically altered animals follow similar patterns to previous years. However, with the current fluctuation of numbers under category 'maintenance of established genetically altered animal lines', it is at present not possible to draw any firm trends.

To take the transparency to the next level, the European Commission has made statistical data mining at Union level available for all interested through an open access EU database, ALURES[4]. During summer 2021, ALURES will be further complemented by a second open access database containing Member State publications of non-technical project summaries.

The statistical data allow identification of areas where replacement and refinement efforts are most urgently needed. The non-technical project summaries provide further understanding of why and how animals are used in these areas. It is hoped that these new unique transparency tools on animal use in the Union will become a valuable information source for stakeholders, such as public and private research organisations and funding bodies, to initiate concerted and strategic initiatives to advance towards the ultimate goal of full replacement as set out by the Directive.

[3] https://ec.europa.eu/environment/chemicals/lab_animals/1-First-report-1994.pdf

[4] https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm

II. BACKGROUND

The objective of the Commission Staff Working Document is to present statistical information on the use of animals in procedures in the European Union and Norway under Directive 2010/63/EU[5] of 22 September 2010 on the protection of animals used for scientific purposes. The obligation to collect statistical data is covered by Article 54(2) of the Directive.

Regulation (EU) 2019/1010[6] ("the Regulation") amended Article 54(2) of the Directive. However, as the collection and submission of data takes place retroactively, 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.

As a result of the amendment to the Directive, also Commission Implementing Decision 2012/707/EU[7], containing the detailed reporting requirements, was required to be updated to accommodate the new obligations. A new Commission Implementing Decision 2020/569/EU[8] was adopted on 16 April 2020 replacing Implementing Decision 2012/707/EU. Although repealed, the data format in 2010/707/EU continues to be followed for data that was collected until end 2020. The first data sets under the revised statistical reporting format will cover the year 2021 and will be submitted to the Commission by 11 November 2022 for publication by the Commission in 2023.

The Regulation moreover removed the obligation of the Commission to submit a formal statistical report to the European Parliament and the Council, replacing it with a Summary report of Member State submissions under the amended rules, though taking effect from 2021 data onwards. Since improved transparency is one of the key objectives of the Directive, the Commission considers it, however, appropriate to continue providing annual Union summary reports (under the previous format) until 2023 when the first set of revised Member State data will be available. From 2023 the Commission will publish summary reports based on the revised data format in Implementing Decision 2020/569/EU.

This current statistical report contains the results of the data collected by all 28 Member States and Norway in 2018. References to "EU" and "EU data" from here on in this report, are therefore to be understood to cover 28 Union Member States and Norway, unless otherwise specified.

III. DATA SUBMITTED AND GENERAL ASSESSMENT

III.1. Data submitted

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

[5] Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79
[6] OJ L 170, 25.6.2019, p. 115–127
[7] OJ L 320, 17.11.2012, p. 33–50
[8] OJ L 129, 24.4.2020, p. 16–50

2010/63/EU of the European Parliament and the Council on the protection of animals used for scientific purposes. This same format will continue to be followed for 2019 and 2020 reports.

III.2. General considerations

This report aims at providing a comprehensive overview on the use of animals in procedures in the European Union and Norway in 2018. The purposes of the use of animals have been analysed, 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 year 2018. On some occasions where the trend analysis provides information on the evolution of the directive's figures. Numbers from previous years (2015-2017) are provided as well to support the comparison between years. 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 Part 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").

For the first time, statistical data from Norway are included in the report. In line with the EEA agreement, Norway transposed the Directive in their national legislation in July 2015. The introduction of data from Norway in the Union report has a clear impact on both the overall numbers, the proportional distribution of species, and in some cases also of the purposes for which animals are used (especially in basic research and translational and applied research). The largest impact is from studies involving fish, where individual studies can use a high numbers of animals. This has two significant consequences: the overall numbers can fluctuate considerably from one year to another. Secondly, high fluctuation in numbers of fish will have a direct impact on the proportional distribution of species at Union level. Where a significant impact (Norwegian data representing over 5% in a given category) has been noted, this is highlighted in the report.

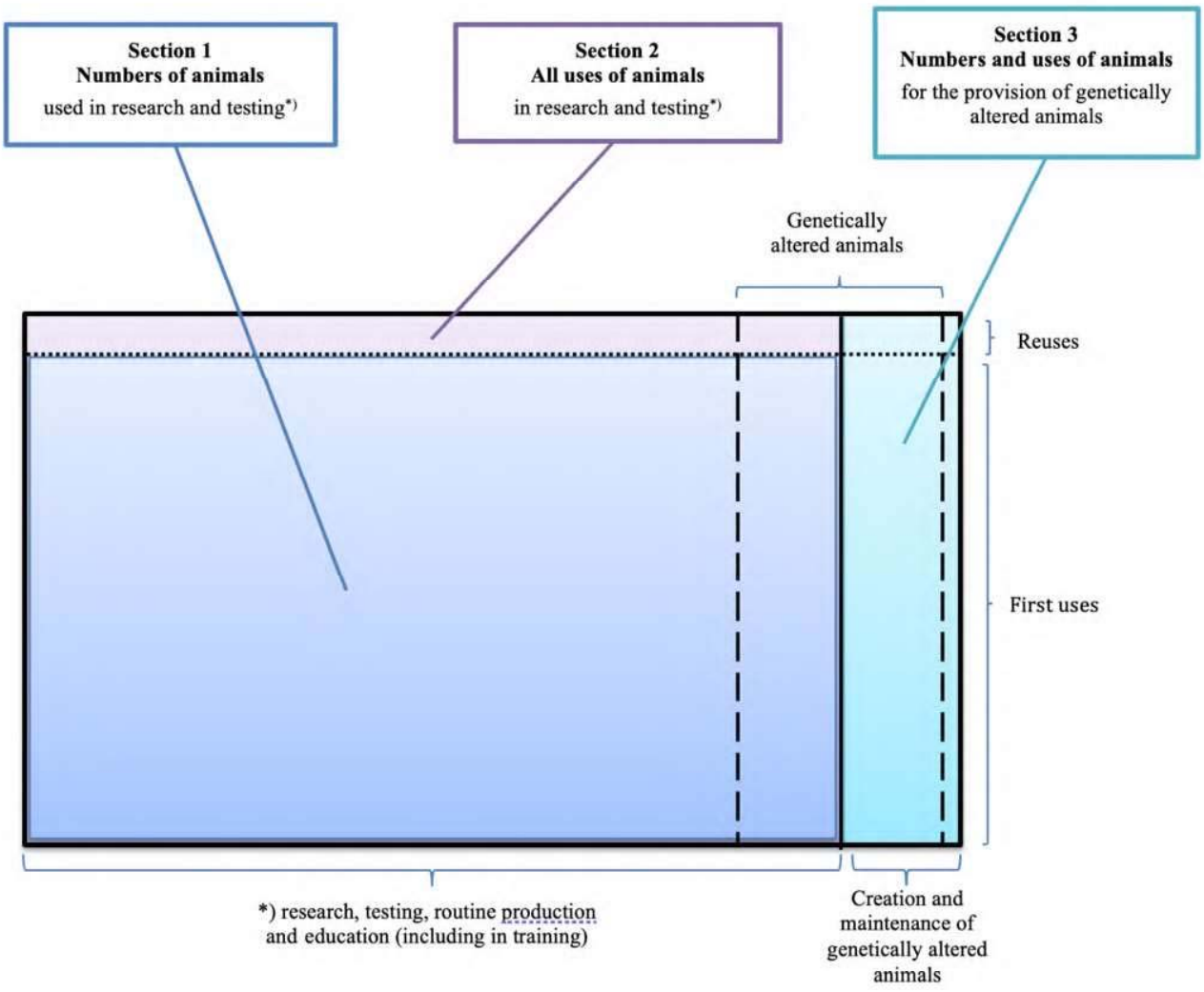
Furthermore, it is important to note that due to the inclusion of data from Norway from this 2018 report onward, direct comparison with the data from previous years is not possible. Comparisons presented in this report are therefore recalculated on the basis of the same countries that reported in previous years (EU-28).

The Commission and Member States continue to work together to address issues and questions arising from reporting obligations to ensure uniform understanding of the revised reporting requirements, such as the reporting of actual severity, animals used for the maintenance of genetically altered animal lines and accurate reporting under different purpose categories.

III.3. Report structure

The objective of this report is 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, Part 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[9] in the Union – Section 1 (IV.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.

[9] 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 IV.4. provides further information on some of the categories of scientific use purposes.

Details of all uses of animals for research, testing, routine production and educational purposes in the Union – Section 2 (IV.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 Union. 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 Union – Section 3 (IV.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.

Part B of this report contains Union level data that have been used as the basis for conclusions in Part A of the report. Part 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;
- 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.

PART A: COMPILATION AND OVERVIEW OF THE UNION DATA IN 2018

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

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.

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

In 2018, the number of animals used for the first time in the Union annually is 10.57 million. This includes the data from Norway bringing the reporting countries from 28 to 29.

	2015	2016	2017	2018 (EU-28)	2018 (EU-28 incl. NO)[10]
Total	9,590,379	9,817,946	9,388,162	**8,921,758**	**10,572,305**

Table 4: Total numbers of animals used for the first time for research, testing, routine production and education purposes in the Union between 2015 and 2018

Figure 6 below illustrates the impact of the data from Norway to past numbers. With 29 countries reporting in 2018, the total number of animals used for the first time is above 10 million. However, when taking into account only the 28 countries that reported between 2015 and 2017, the total number of animals continued to decrease, and was in 2018 for the first time below 9 million (8.92 million), a decrease of 5% compared to 2017.

[10] NO : including data from Norway

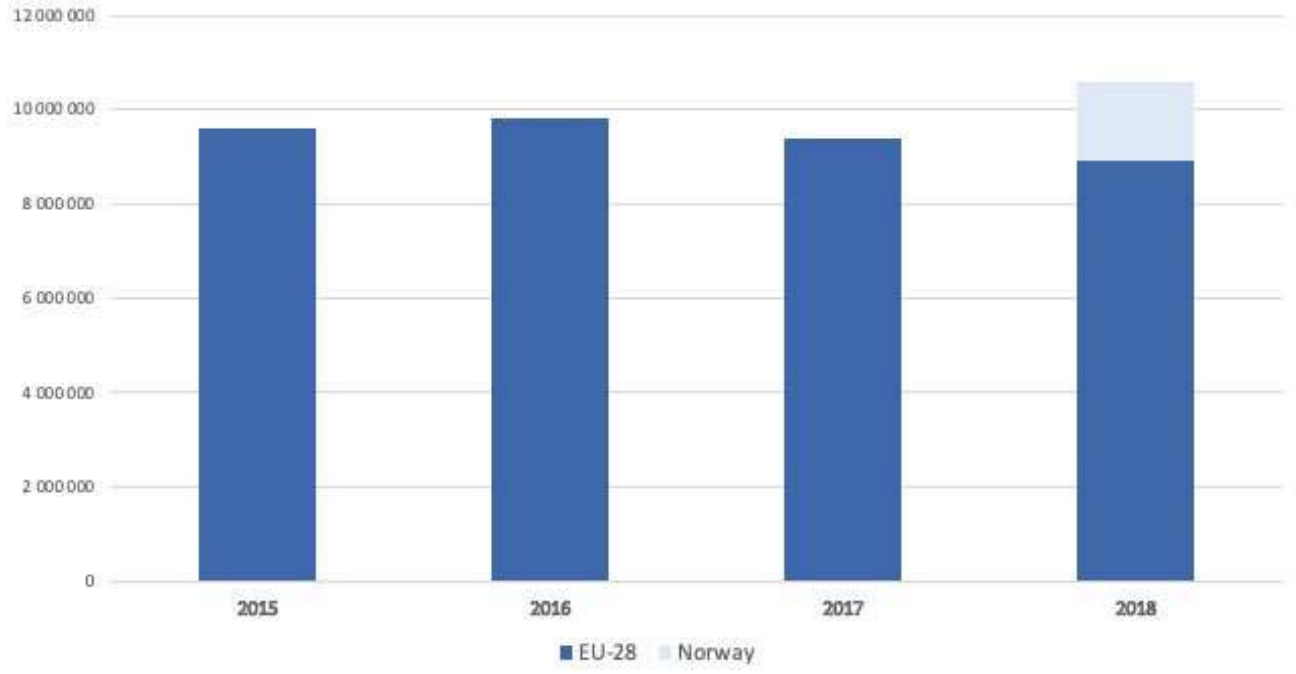


Figure 6: Evolution of total numbers of animals used for the first time for research, testing, routine production and education purposes between 2015 and 2018 within EU-28 and Norway

In 2018, 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 93% 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 7).

With the data from Norway, the repartition of species used for the first time is slightly different compared to 2017, with an increase of fish uses (+13%) and a decrease of mice (-9%), rats (-2%), "Other mammals" (-1%) and birds (-1%) uses.

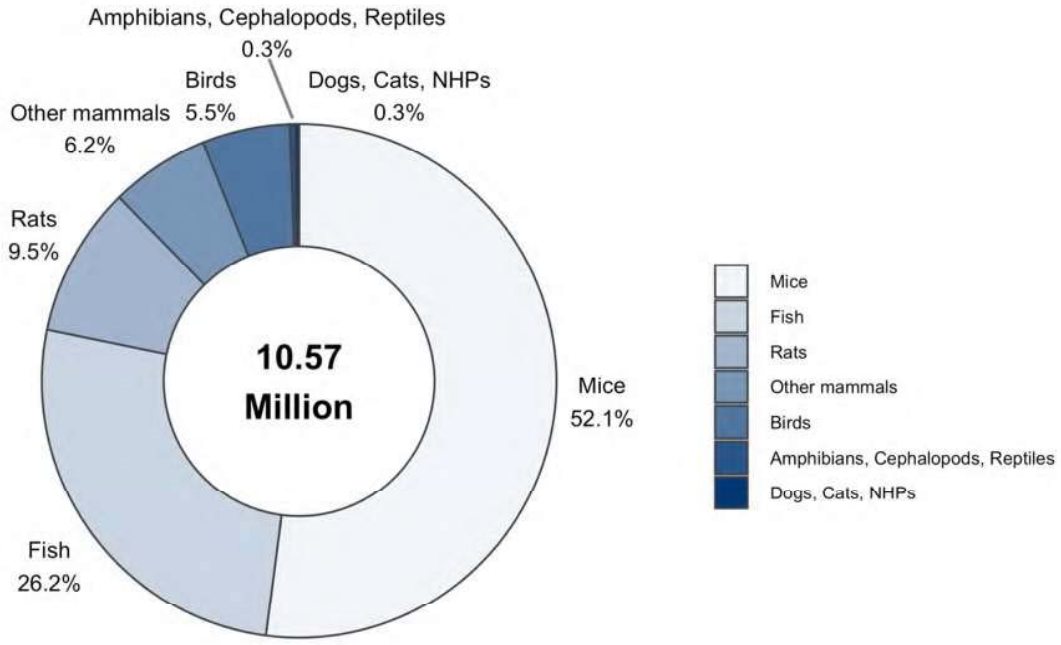


Figure 7: Numbers of animals used for the first time by main classes of species in 2018

Looking at this higher level of grouping in 2018 (table 5), the number of fish increased (+127%) with more than 1.5 million additional animals used compared to 2017 due to the inclusion of data from Norway in 2018. Rats (-15%), "Other mammals" (-5%) and mice (-4%) decreased, while other categories remained stable.

	2018
Mice	5,505,169
Rats	999,246
Other mammals	685,794
Fish	2,765,737
Birds	582,846
Amphibians, Cephalopods, Reptiles	33,513
Total	**10,572,305**

Table 5: Numbers of animals used for the first time by main classes of species

For fish, the Directive distinguishes zebra fish (17% of fish in 2018) from other fish species. The main "other" fish species (2,304,216 in 2018 - Table 7) were salmon, cod and seabass.

For birds, the Directive distinguishes domestic fowl (83% of birds in 2018) from other birds. The main species reported as "Other birds" (101,034 in 2018 – Table 7) were turkey and the Great Tit (*Parus major*).

In this context, it is important to note that from 2021 data onward, further species of fish and turkey have been added as separate categories to reduce the use of "other" categories.[11]

For amphibians, the Directive distinguishes rana (15% of amphibians in 2018) and xenopus (57% of amphibians in 2018) from other amphibians. The main species reported as "Other amphibians" (7,543 – Table 7) was bufo (toads).

First uses of mammals in 2018 are reported in more detail in table 6 below. First uses of mammals decreased (-5%) compared to 2017.

	2018
Mice	5,505,169
Rats	999,246
Guinea-Pigs	129,931
Other rodents	35,967
Rabbits	342,788
Cats	1,554
Dogs	17,711
Other carnivores	6,082
Farm animals	137,234
Non-human primates	8,583
Other mammals	5,944
Total	**7,190,209**

Table 6: 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" (6,082 in 2018) reported were mainly mink while "Other rodents" (35,967) included bank voles and house mice; and "Other mammals" (5,944) mainly Antarctic fur seals and badgers.

In 2018, the numbers of farm animals used for the first time increased (+10%) as well as dogs (+29%), "Other carnivores" (+38%) and non-human primates (+4%). 80% of the increase in first time use of dogs were mainly due to studies of genetic disorders on pet animals originating from one Member State. Uses of other species decreased: guinea-pigs (-10%), "Other rodents" (-17%). After a significant increase of "Other mammals" (bats) uses in 2017, uses came back to 5,944 showing an important decrease (-77%).

The number of non-human primates reported during the period increased (+4%). Species used were prosimians, marmosets and tamarins, squirrel monkey, cynomolgus monkey, rhesus monkey, vervets

[11] Commission Implementing Decision 2020/569/EU, Annex III

(*chlorocebus spp*), 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 the period 2015-2018.

	2018
Mice	5,505,169
Rats	999,246
Guinea-Pigs	129,931
Hamsters (Syrian)	10,813
Hamsters (Chinese)	20
Mongolian gerbil	4,761
Other rodents	20,373
Rabbits	342,788
Cats	1,554
Dogs	17,711
Ferrets	1,507
Other carnivores	4,575
Horses, donkeys and cross-breeds	1,712
Pigs	83,997
Goats	1,501
Sheep	22,371
Cattle	27,653
Prosimians	170
Marmoset and tamarins	381
Squirrel monkey	25
Cynomolgus monkey	7,619
Rhesus monkey	320
Vervets (Chlorocebus spp.)	16
Baboons	30
Other species of Old World Monkeys (Cercopithecoidea)	22
Other mammals	5,944
Domestic fowl	481,812
Other birds	101,034
Reptiles	1,648
Rana	4,238
Xenopus	15,816
Other amphibians	7,543
Zebra fish	461,521
Other fish	2,304,216
Cephalopods	4,268
Total	**10,572,305**

Table 7: Numbers of animals used for the first time by species

IV.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 IV.1.2.2.).

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

In 2018, almost 89% of the animals used for scientific purposes for the first time were born in the Union at registered breeders[12] and fewer than 3% were born outside of the Union (either in the rest of Europe or outside of Europe). Category 'animals born in the Union but not at a registered breeder' includes animals from, for example, farms, and studies carried out using wild animals, especially wild fish (Figure 8).

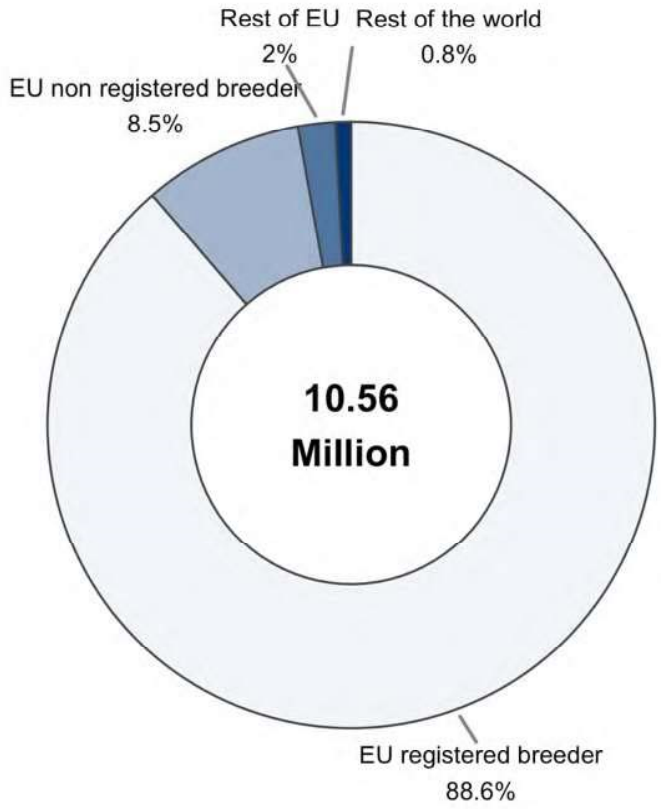


Figure 8: Place of birth of animals other than non-human primates in 2018

[12] This includes animals born at registered breeders in Norway authorised under the conditions of Directive 2010/63/EU.

In 2018, the proportion of animals born in the Union at a registered breeder decreased slightly (-1%) while animals born in the Union but not at a registered breeder (+1%) or in the rest of Europe (+1%) increased. Animals born in the rest of the world remained stable.

	2018
Animals born in the EU at a registered breeder	88,5% (9,363,757)
Animals born in the EU but not at a registered breeder	8,5% (902,879)
Animals born in rest of Europe	2% (209,801)
Animals born in rest of world	1% (87,405)
Total	**100% (10,563,722)**

Table 8: 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 9 shows all the animal species listed in Annex I, except non-human primates.

In 2018, amongst the species listed in Annex I, rodents, rabbits and zebra fish were, for the vast majority, born at Union registered breeders (Figure 9). Dogs (46%), cats (38%) and to a lesser extent frogs (29%) had a higher proportion of animals born in the Union but at a non-registered breeder (Part B – Table 2). The most common reason for using dogs and cats that came from non-registered breeders in the Union 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.

22% of dogs, 15% of cats, 14% of hamsters (Syrian), and 9% of frogs were imported from the rest of the world (Part B – Table 2).

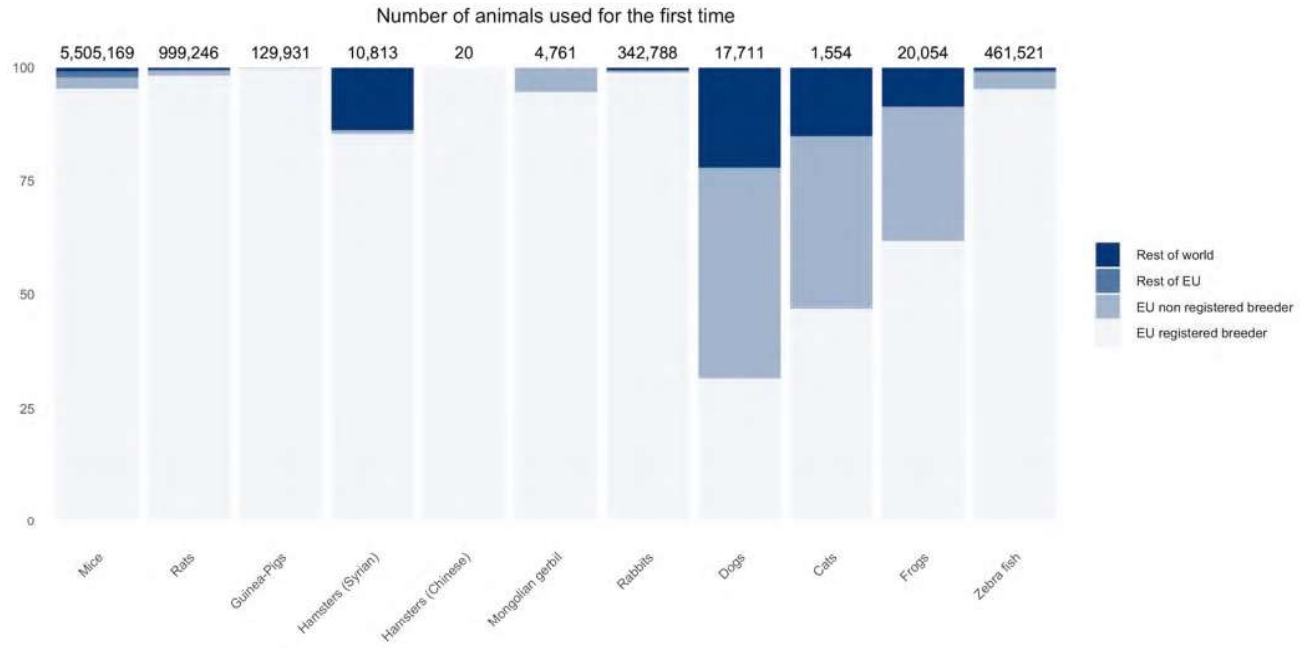


Figure 9: Place of birth of animals other than non-human primates listed in Annex I in 2018

IV.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 Union.

IV.1.2.2.1. Non-human primates - Source

In 2018, the three main sources of non-human primates were Africa, Asia and Union registered breeders representing more than 99% of non-human primates used for scientific purposes (Figure 10).

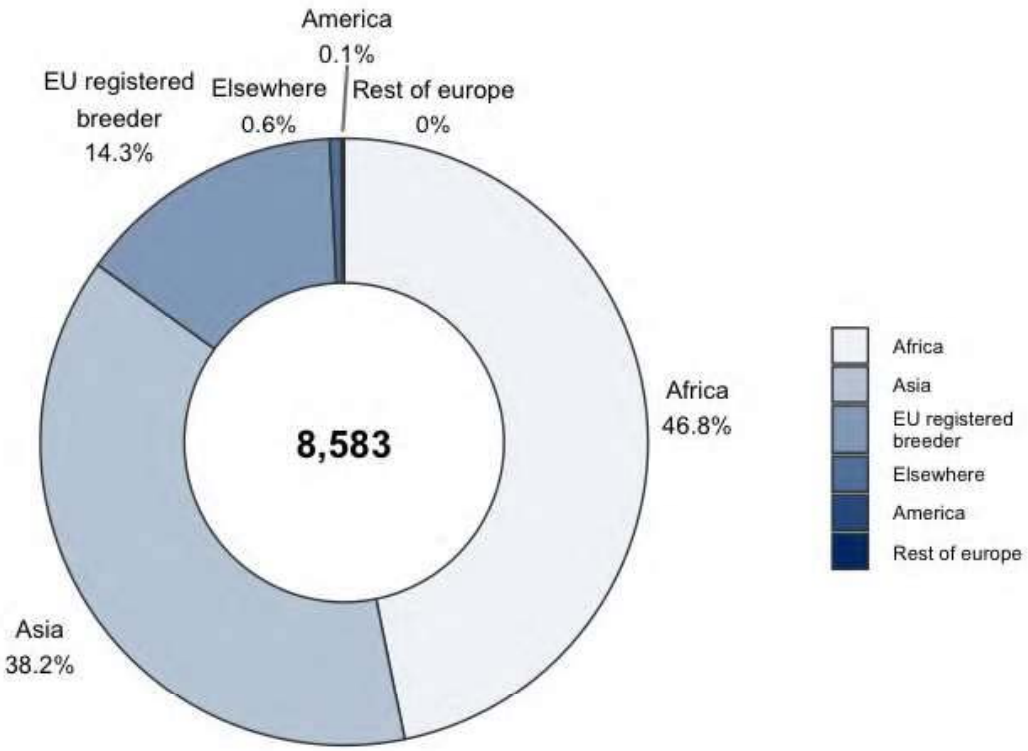


Figure 10: Source of non-human primates in 2018

In 2018, cynomolgus monkeys represented 89% of non-human primates used for the first time. These were sourced almost entirely from outside of the Union (Table 9). In contrast, other species of non-human primates were mainly sourced from Union registered breeders with the exception of Vervet (*Chlorocebus spp*), and "Other species of old world monkeys" (*Cercopithecoidea*).

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total
Prosimians	100% (170)	0% (0)	0% (0)	0% (0)	0% (0)	100% (170)
Marmoset and tamarins	100% (381)	0% (0)	0% (0)	0% (0)	0% (0)	100% (381)
Squirrel monkey	100% (25)	0% (0)	0% (0)	0% (0)	0% (0)	100% (25)
Cynomolgus monkey	4% (323)	42% (3,229)	0% (0)	53% (4,013)	1% (54)	100% (7,619)
Rhesus monkey	92% (296)	8% (24)	0% (0)	0% (0)	0% (0)	100% (320)
Vervets (Chlorocebus spp.)	0% (0)	0% (0)	75% (12)	25% (4)	0% (0)	100% (16)
Baboons	100% (30)	0% (0)	0% (0)	0% (0)	0% (0)	100% (30)
Other species of Old World Monkeys (Cercopithecoidea)	0% (0)	100% (22)	0% (0)	0% (0)	0% (0)	100% (22)
Total	**14% (1,225)**	**38% (3,275)**	**0% (12)**	**47% (4,017)**	**1% (54)**	**100% (8,583)**

Table 9: Source of non-human primates by species in 2018

IV.1.2.2.2. Non-human primates - Generation

With regard to the generation of non-human primates being bred in captivity in 2018, the majority of non-human primates were sourced either from self-sustaining colonies (29%) or as second or higher generation purpose-bred (56%). No non-human primates were sourced from the wild (Table 10) in 2018.

	2015	2016	2017	2018
Self-sustaining colony	39% (2,748)	31% (2,271)	30% (2,504)	29% (2,471)
F2 or greater	37% (2,614)	47% (3,435)	53% (4,368)	56% (4,822)
F1	25% (1,773)	21% (1,528)	17% (1,363)	15% (1,290)
F0	0% (1)	0% (5)	0% (0)	0% (0)
Total	**100% (7,136)**	**100% (7,239)**	**100% (8,235)**	**100% (8,583)**

Table 10: Generation of non-human primates in 2018

Compared to 2017, the proportion of non-human primates coming from self-sustaining colonies decreased slightly (-1%). However, in line with the Directive objectives, the proportion of those being second or higher generation purpose-bred continued to increase (+3%) and those being of first-generation purpose-bred decreased (-2%). This is confirmed over the past four years of reporting (Figure 11).

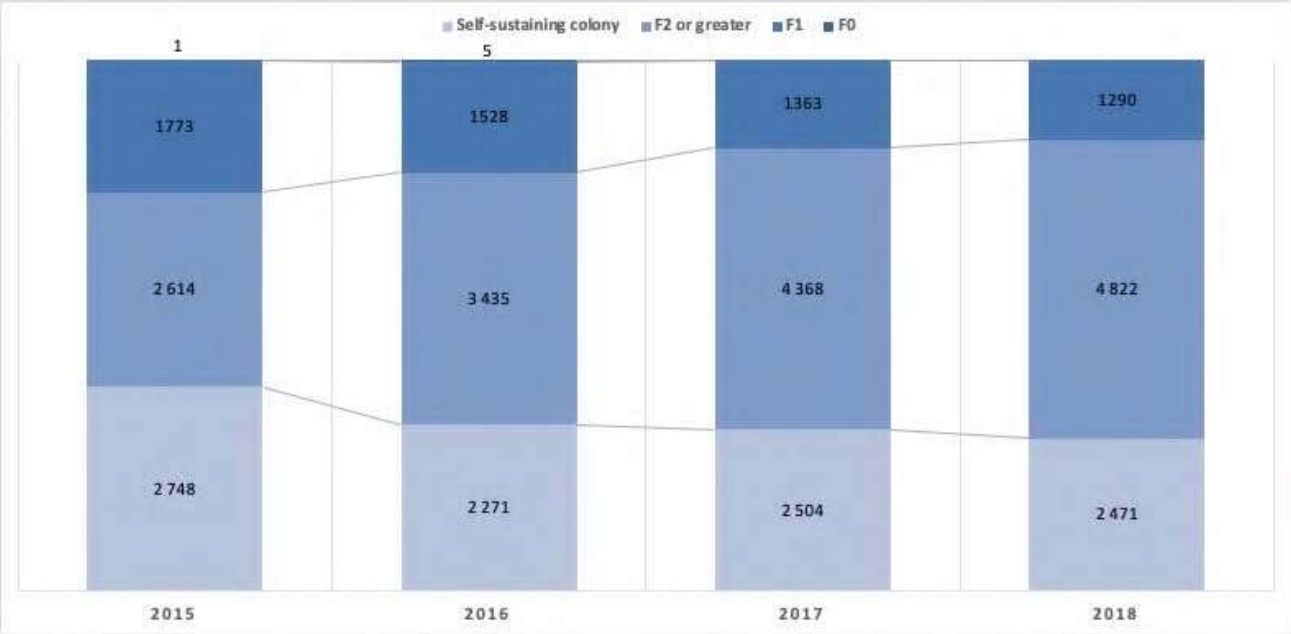


Figure 11: Evolution of the repartition of generation of non-human primates between 2015 and 2018

Looking at different non-human primate species and their generation:

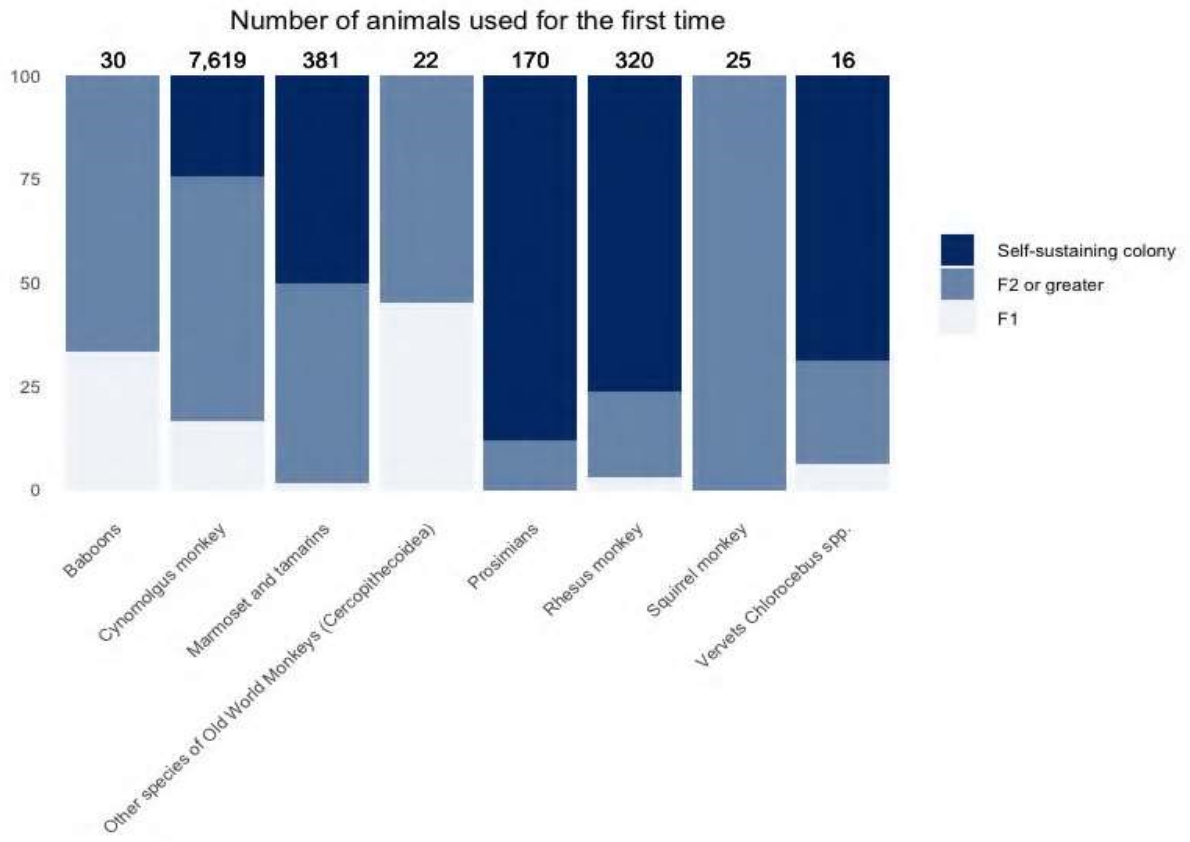


Figure 12: Generation of non-human primates by species in 2018

For non-human primates born at a registered breeder in the Union, only 3% of non-human primates used for the first time were from the first generation, in Africa first generation of animals represented 25% in 2018 and first generation non-human primates from elsewhere represented 31% (Table 11).

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere
F2 or greater	35% (429)	73% (2,395)	33% (4)	49% (1,957)	69% (37)
Self-sustaining colony	62% (754)	20% (653)	58% (7)	26% (1,057)	0% (0)
F1	3% (42)	7% (227)	8% (1)	25% (1,003)	31% (17)
Total	**100% (1,225)**	**100% (3,275)**	**100% (12)**	**100% (4,017)**	**100% (54)**

Table 11: Generation of non-human primates by source in 2018

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

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.

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

In 2018, the total number of all uses (first use and any subsequent reuse) for the purposes of research, testing, routine production and education is 10,8 million. The increase in numbers is mainly the result of the inclusion of data from Norway in 2018 (Table 12).

	2015	2016	2017	2018 (EU-28)	2018 (EU-28 incl. NO)
Total	9,782,570	10,028,498	9,581,741	**9,137,443**	**10,804,854**

Table 12: Total number of uses of animals between 2015 and 2017

Without taking into account the data from Norway, the total number of animal uses in EU-28 decreased, being 9,137,443 uses (-5%) in 2018.

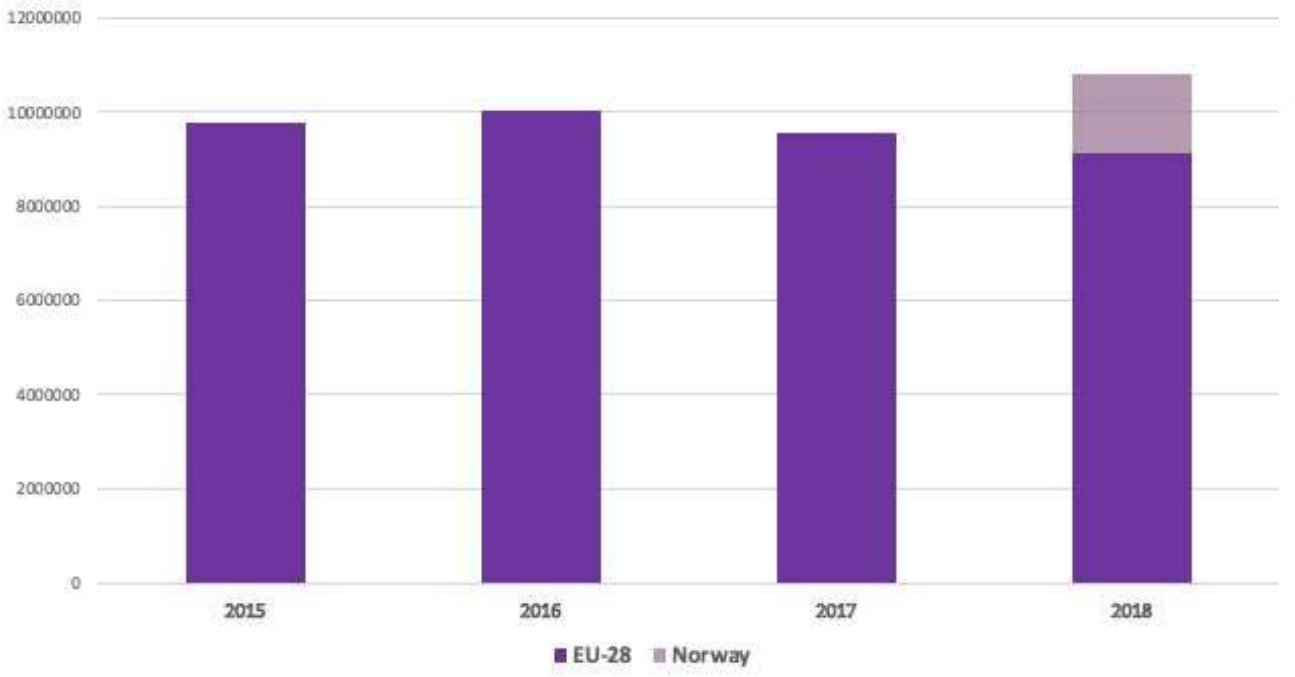


Figure 13: Evolution of total numbers of uses of animals between 2015 and 2018 within EU-28 and Norway

IV.2.1.1. Main categories of scientific purposes

In 2018, 10.8 million uses of animals were reported for scientific purposes in the EU-28 including Norway.

Most uses were conducted for research purposes (74%) with 46% of the uses being carried out for basic research and 28% for translational and applied research purposes. A further 18% of animal uses in procedures were carried out for regulatory use to satisfy legislative requirements, followed by routine production (5%). Compared to 2017, the proportion of animals used for translational and applied research increased (+5%) while the proportion of uses for regulatory requirements decreased (-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 14).

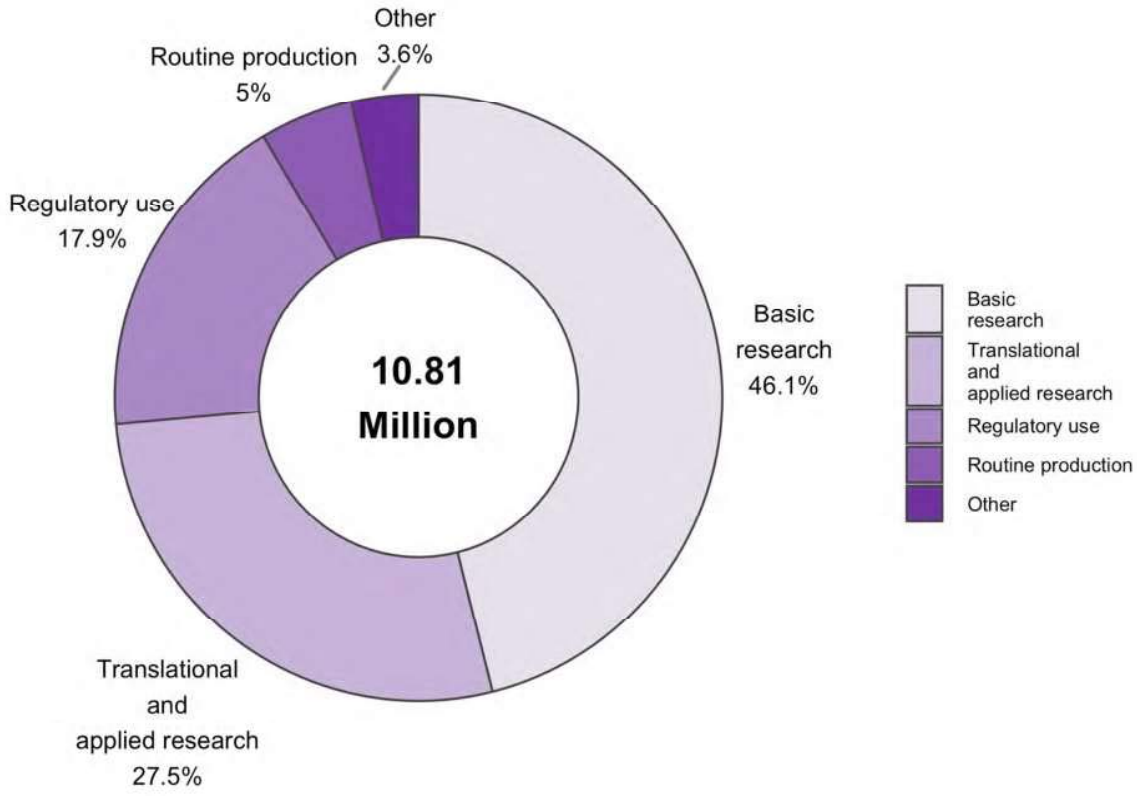


Figure 14: Uses of animals in research and testing in 2018

Compared to 2017, the number of uses for regulatory purposes decreased (-12%) as well as Forensic enquiries (-26%). Routine production (+14%), Higher education for the acquisition maintenance or

improvement of vocational skills (+7%) showed an increase. The addition of the data from Norway in the report led to an increase of numbers of uses in both basic (+ 14%), translational and applied research (+35%), protection of the natural environment in the interest of the health or welfare of human beings or animals (+7%) and preservation of species (+7%) (Table 13).

	2018 (EU-28)	2018 (EU-28 incl. NO)
Basic research	4,125,950	4,978,877
Translational and applied research	2,217,847	2,968,971
Regulatory use	1,908,564	1,935,309
Routine production	529,111	537,094
Higher education or training for the acquisition, maintenance or improvement of vocational skills	165,411	166,437
Protection of the natural environment in the interests of the health or welfare of human beings or animals	115,239	133,097
Preservation of species	75,223	84,720
Forensic enquiries	98	349
Total	**9,137,443**	**10,804,854**

Table 13: Uses of animals by main scientific purposes

IV.2.1.2. Severity of uses

Directive 2010/63/EU requires the reporting of the actual severity experienced by each animal when used for scientific purposes. In 2018, just over half, 51%, of uses, were reported as 'mild' (up to and including), 34% as 'moderate', and 10% as 'severe'. 6% of uses were reported as 'non-recovery'.

The number of uses reported as severe and mild decreased proportionally in 2018 (-1%) while moderate uses increased (+2%) (Table 14).

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.

	2017	2018 (EU)	2018 (EU-28 incl. NO)
Non-recovery	6% (621,054)	6% (534,999)	6% (612,094)
Mild [up to and including]	51% (4,865,721)	49% (4,522,747)	50% (5,469,214)
Moderate	32% (3,071,828)	34% (3,096,460)	34% (3,658,621)
Severe	11% (1,023,138)	11% (983,237)	10% (1,064,925)
Total	**100% (9,581,741)**	**100% (9,137,443)**	**100% (10,804,854)**

Table 14: Severity of uses

In 2018, when looking at high level purposes, most of the uses reported as severe were conducted for regulatory purposes (17% of regulatory uses), while routine production was mostly mild. Uses in

translational and applied research tended to be more severe than those reported in basic research (Figure 15).

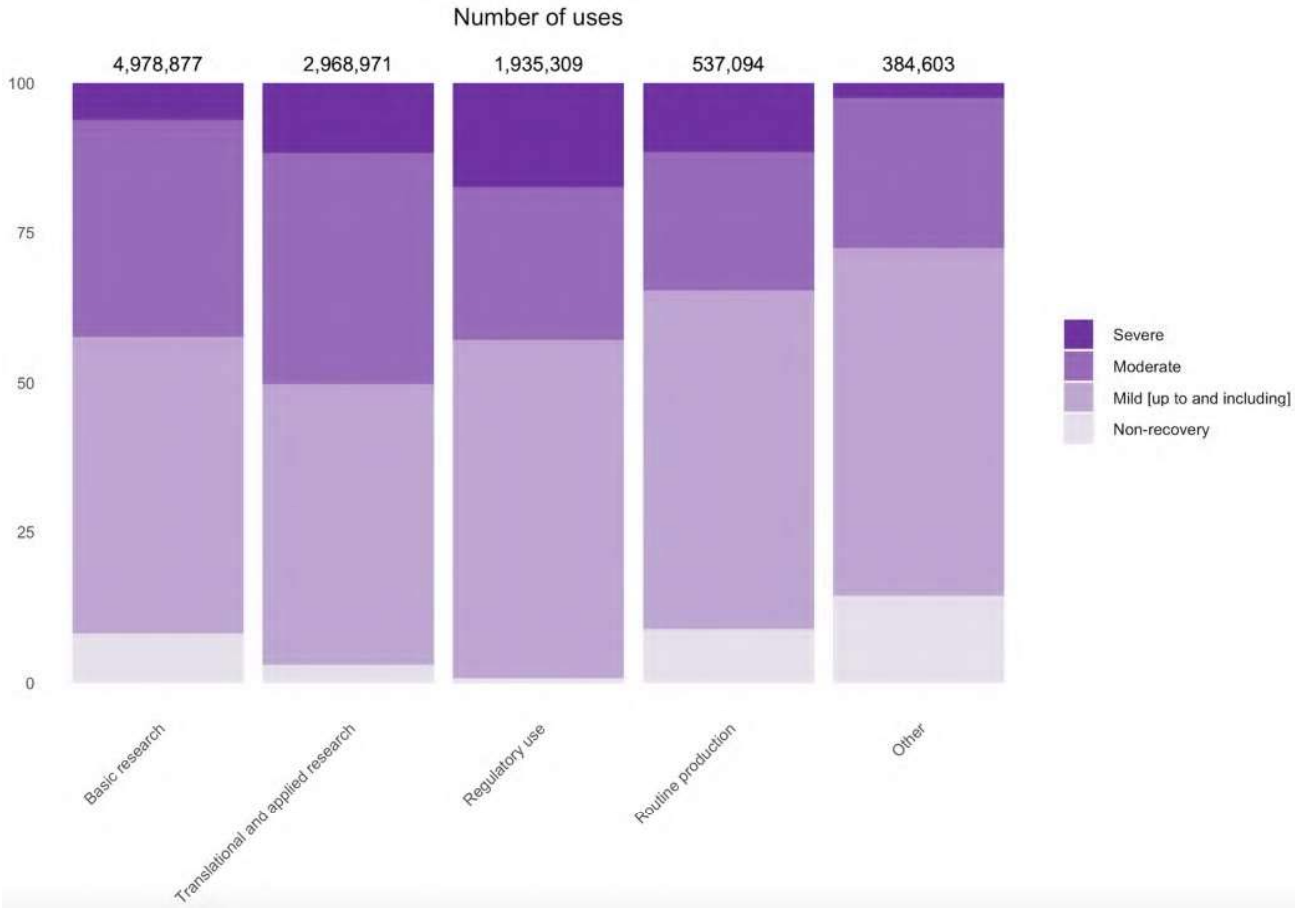


Figure 15: Uses of animals by severity and main categories of scientific purposes in 2018

When analysing all the sub-categories of purposes, batch potency testing resulted in the highest number of severe uses (over 253,000 uses - Figure 19), followed by animal diseases and disorders (124,000 - Figure 18), studies on nervous system (over 90,000 uses - Figure 17) and immune system (over 69,000 uses - Figure 17).

When analysing the proportion of severe uses within a sub-category: the production of monoclonal antibodies was the highest. 94% of all uses for the production of monoclonal antibodies by ascites method were severe – Figure 27), followed by diagnosis of diseases (41% - Figure 18) and acute toxicity studies in the area of ecotoxicity (38% - Figure 24).

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 295,000 uses – Figure 27), followed by preservation of species (0.2% of 84,000 uses – Figure 28), education and training (0.4% of 166,000 uses – Figure 28) and toxicity testing for skin sensitisation (0.5% of 39,000 uses – Figure 21)

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

In 2018, the main species used in basic research were mice (59%), other fish (29%), zebra fish (6%), rats (6%) and domestic fowl (2%). Similar species feature for applied and translational research with proportionally similar uses of mice (51%), other fish (30%) and rat (7%). The increase of the proportion of other fish uses in research is mainly due to the inclusion of data from Norway

For regulatory use, the distribution changes again slightly with mice covering now only less than half (48%), followed by rat (25%), domestic fowl (8%), other fish (5%) and rabbits (5%). Similar numbers compared with 2017.

Routine production has a relatively different pattern compared with the other purpose groups, with rabbits accounting for less than half (44%, decreasing by -6%), followed by domestic fowl (27%), mice (14%) 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. Rabbits, farmed species and birds are mostly used in routine production and finally guinea-pigs, non-human primates and rats for regulatory purposes (Figure 16).

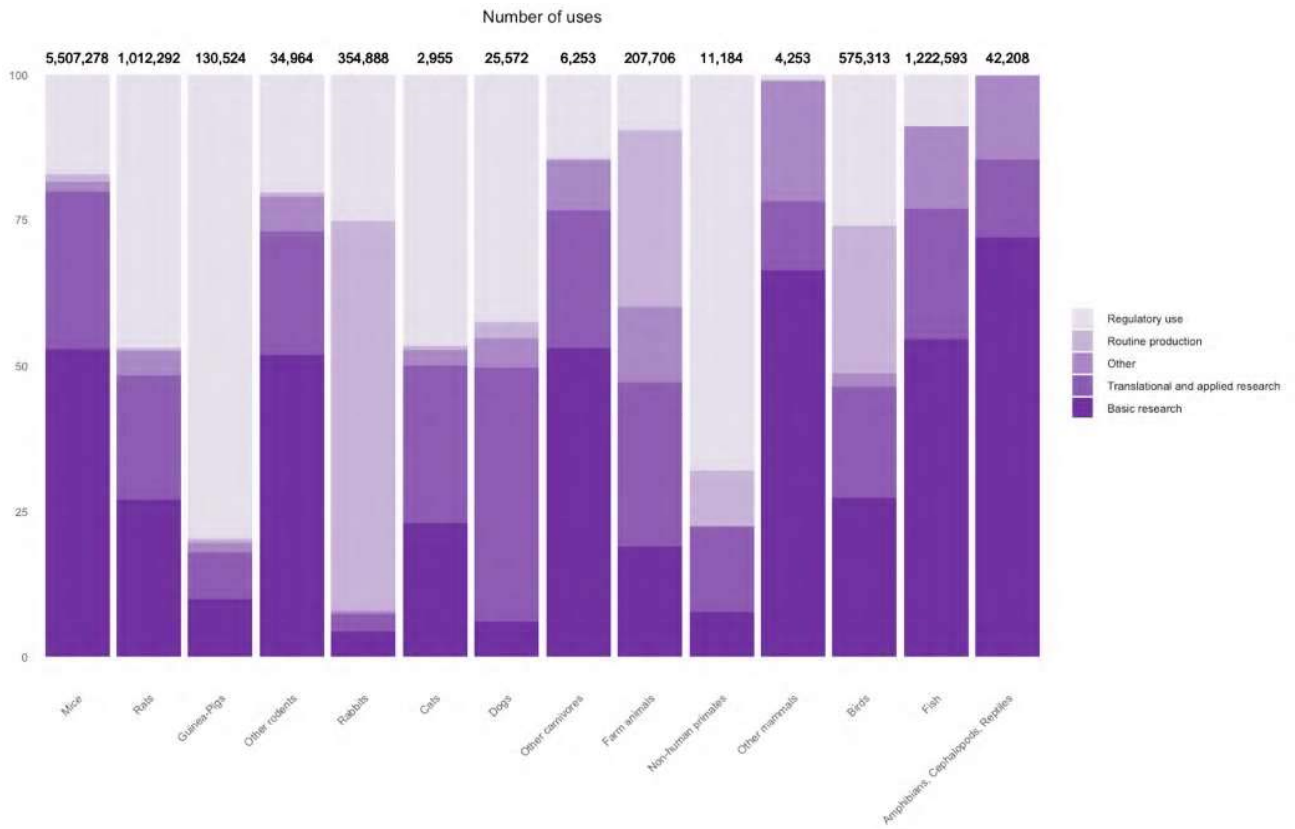


Figure 16: Uses of animals grouped by main classes of species and the main scientific purpose categories in 2018

Looking at the details of the uses of non-human primates, 68 % are to satisfy legislative requirements for medicinal products for human use (of these 71% are on studies for repeated dose toxicity and 10%

for kinetics). In the areas of basic and applied research, non-human primates are mainly used for studying human infectious disorders (5% of all non-human primate uses), non-regulatory toxicology and ecotoxicology (4%), other toxicity/safety testing (4%) and nervous system (3%). Routine production, of mostly blood based products represents 8% of non-human primate uses. Some uses of non-human primates were still reported for the purposes of education and training prohibited under the Directive. These concerned projects authorised under the previous Directive and which had extended over the transitional period. Member State in question gave reassurance that such authorisations are no longer granted. The actual reported severities of uses of non-human primates are lower than the Union averages for all species. In 2018, 57% were of mild severity. Only 2.8% of uses were assessed as severe.

IV.2.2. Detailed information on use purposes

IV.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.

IV.2.2.1.1 Basic research

Basic research was the main area for which animals were used with more than 4.98 million uses in 2018.

The four main domains of basic research using most animals are ethology / animal behaviour / animal biology, nervous system, immune system, that all together account for more than half of the uses in basic research (Figure 17).

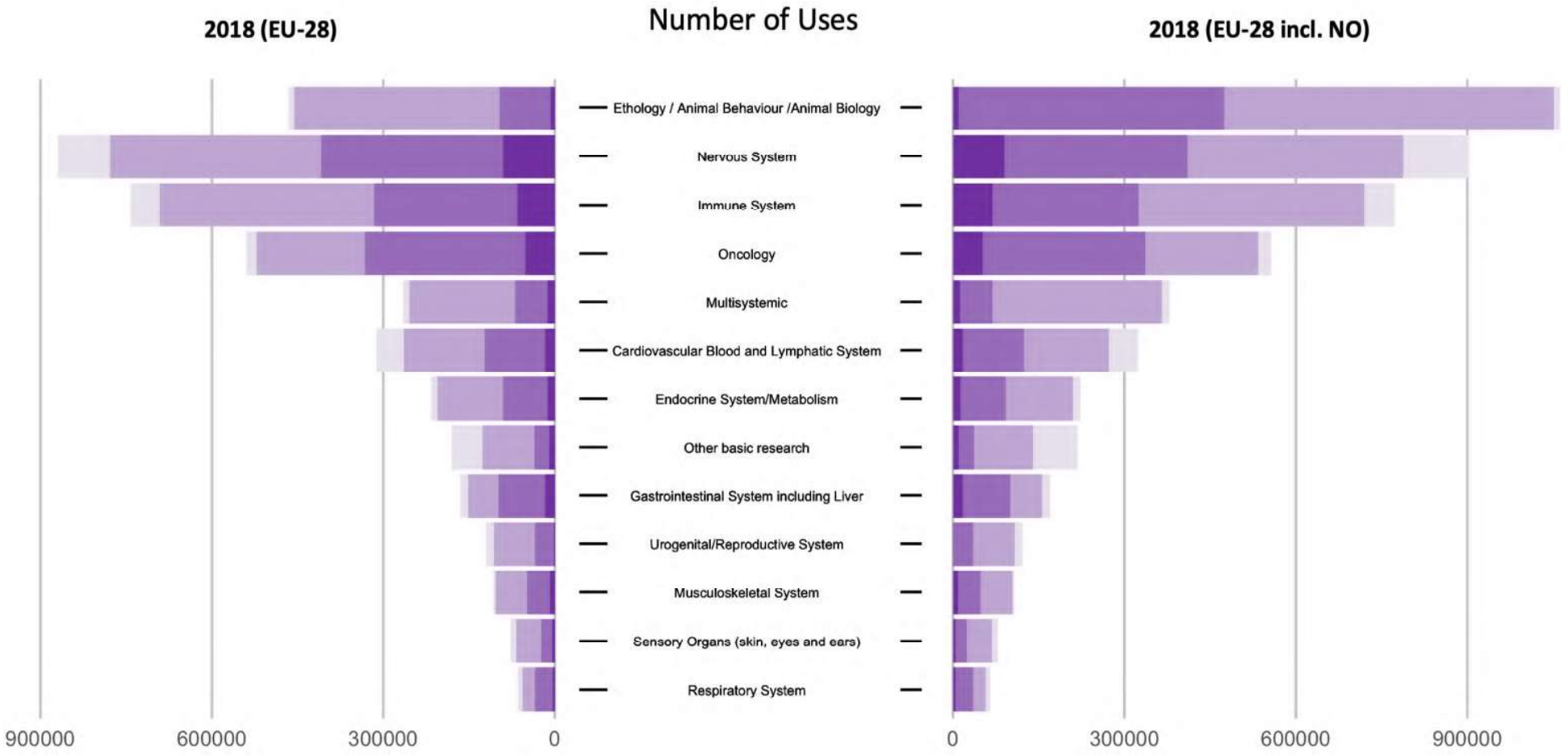


Figure 17: Basic research related uses by type of research and severity in 2018

In 2018, the inclusion of data from Norway changed the repartition of uses of animals in the different domains of basic research. Ethology / animal behaviour / animal biology became now the main domain (+133%), multisystemic research also saw an increase (+76%).

In other domains gastrointestinal system including liver (+31%), urogenital/ reproductive system (+28%), musculoskeletal system (+19%) and sensory organs (+19%) showed an increase not imputable to the Norway's data.

During the same period, the sub-categories respiratory system (-11%) oncology (-9%) and nervous system (-7%) saw some decreases in terms of uses of animals (Table 15). Also, it is worth noting that sub-category other basic research decreased significantly (-42%), which would indicate more accurate reporting in the respective pre-fixed sub-categories.

In 2018, in the area of basic research, proportionally highest severities were reported in following sub-categories: nervous system (10%), gastrointestinal system including lever (10%), immune system (9%), oncology (9%) and musculoskeletal system (8%).

Proportionally lowest severities were reported for urogenital/reproductive system, ethology/ animal behaviour/animal biology, sensory organs and multisystemic (Figure 17).

"Other basic research" includes for example collection of blood, plasma and serum, and studies on nutrition and developmental biology. It is important to note in this context that from 2021 data onward, the uses under developmental biology will be reported separately.[13]

	2018 (EU-28)	2018(EU-28 incl. NO)
Ethology / Animal Behaviour /Animal Biology	465,380	**1,061,647**
Nervous System	869,605	**901,510**
Immune System	742,296	**773,265**
Oncology	539,612	**556,952**
Multisystemic	265,065	**378,560**
Cardiovascular Blood and Lymphatic System	312,042	**323,605**
Endocrine System/Metabolism	216,397	**222,907**
Other basic research	180,287	**217,833**
Gastrointestinal System including Liver	164,925	**169,928**
Urogenital/Reproductive System	120,965	**122,136**
Musculoskeletal System	107,091	**107,272**
Sensory Organs (skin, eyes and ears)	77,336	**77,806**
Respiratory System	64,949	**65,456**
Total	**4,125,950**	**4,978,577**

Table 15: Basic research related uses by type of research

[13] Commission Implementing Decision 2020/569/EU, Annex III

IV.2.2.1.2. Translational and applied research

Translational and applied research accounted for about 2.97 million uses of animals in 2018.

The four main areas of translational and applied research were animal diseases and disorders, human cancer, human nervous and mental disorders and human infectious disorders. The inclusion of data from Norway brought animal diseases and disorder to first place (+340%), and significantly increased uses for animal welfare (+129%).

Proportionally lowest severities were reported for plant diseases, animal welfare, human endocrine/ metabolism disorders (Figure 18).

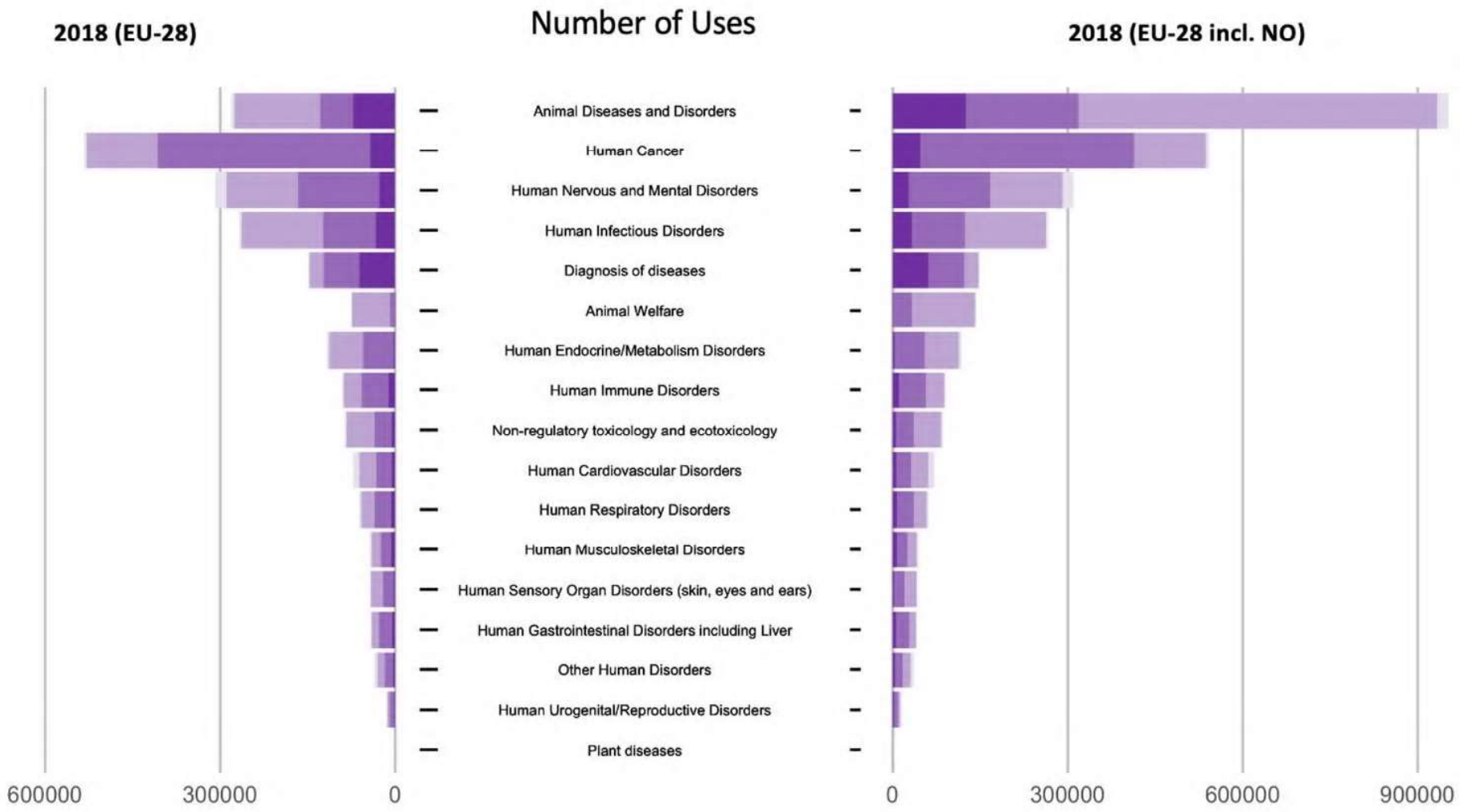


Figure 18: Translational and applied research related uses by type of research and severity in 2018

Human immune disorders (+21%), human endocrine/metabolism disorders (+17%) and human musculoskeletal disorders (+14%) showed an increase compared to 2017, while human sensory organ disorders (skin, eyes and ears) (-20%), human gastrointestinal disorders including liver (-15%), non-regulatory toxicology and ecotoxicology (-10%) had a decrease of uses.

In 2018, in the area of translational and applied research, proportionally highest severities were reported in following sub-categories: diagnosis of diseases (41%, -13% compared to 2017), animal diseases disorders (13%, -11% compared the 2017), human immune disorders (11%, -11% compared to 2017), human musculoskeletal disorders (11%, -5%) and other human disorders (11%, -4%).

	2018 (EU-28)	2018 (EU-28 incl. NO)
Animal Diseases and Disorders	281,034	**952,531**
Human Cancer	533,321	**542,081**
Human Nervous and Mental Disorders	308,317	**310,302**
Human Infectious Disorders	266,734	**267,206**
Diagnosis of diseases	148,234	**148,273**
Animal Welfare	75,442	**142,725**
Human Endocrine/Metabolism Disorders	117,485	**117,835**
Human Immune Disorders	90,635	**90,961**
Non-regulatory toxicology and ecotoxicology	86,443	**86,461**
Human Cardiovascular Disorders	71,609	**71,847**
Human Respiratory Disorders	61,579	**61,579**
Human Musculoskeletal Disorders	43,838	**43,838**
Human Sensory Organ Disorders (skin, eyes and ears)	42,286	**42,286**
Human Gastrointestinal Disorders including Liver	41,168	**41,203**
Other Human Disorders	35,107	**35,228**
Human Urogenital/Reproductive Disorders	14,577	**14,577**
Plant diseases	38	**38**
Total	**2,217,847**	**2,968,971**

Table 16: Translational and applied research related uses by type of research

"Other Human Disorders" includes areas such as haemophilia and pharmacokinetics.

IV.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.

Compared to 2017, the total number of uses for regulatory purposes decreased (-12%) in 2018 despite the data from Norway.

In 2018, regulatory uses accounted for 1.94 million uses. 56% of these uses were related to quality control (including batch safety and potency testing), 38% related to toxicity and other safety testing including pharmacology and the remainder (6%) were for other efficacy and tolerance testing (Table 17).

	2018
Quality control (incl batch safety and potency testing)	1,079,062
Toxicity and other safety testing including pharmacology	731,522
Other efficacy and tolerance testing	124,725
Total	**1,935,309**

Table 17: Regulatory uses by main types of uses

IV.2.2.2.1. Details of the regulatory use purposes

IV.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 of a 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 1.08 million uses in 2018. A large majority of these uses were related to batch potency-testing purposes (80%, as in 2017). The inclusions of data from Norway did not have a significant impact.

With more than 253,000 severe uses, batch potency testing was the most severe type of procedure, representing more than 24% (1% less compared to 2017) of all severe uses in Union (Figure 19). Pyrogenicity testing is the lease sever with less than 1% of severe uses.

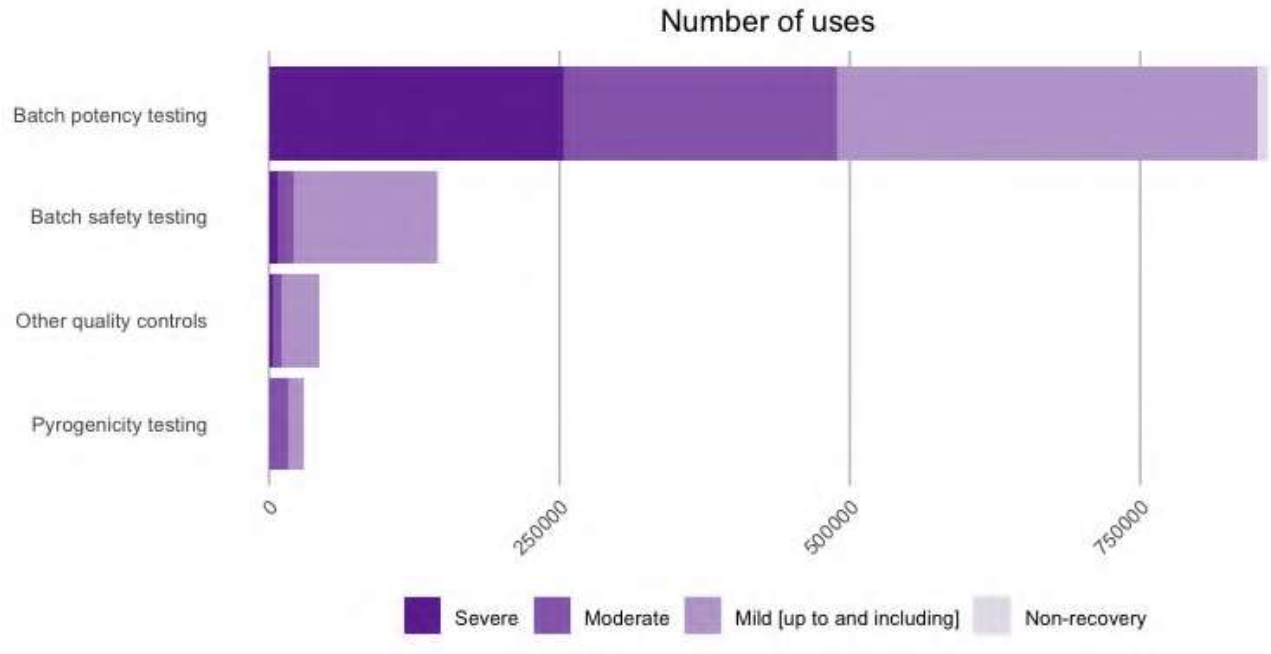


Figure 19: Quality control related uses by type of use and severity in 2018

In 2018, quality control related uses decreased (-5%) with a decrease for other quality control (-33%), for batch potency testing (-4%) and for pyrogenicity testing (-13%) (Table 18). Batch safety testing increased (+4%)

"Other quality controls" are related for example for cell lines characterisation.

	2018
Batch potency testing	859,797
Batch safety testing	145,769
Other quality controls	43,043
Pyrogenicity testing	30,453
Total	**1,079,062**

Table 18: Quality control related uses by type of use

Between 2015 and 2018, pyrogenicity testing decreased steadily (-35%) (Figure 20).

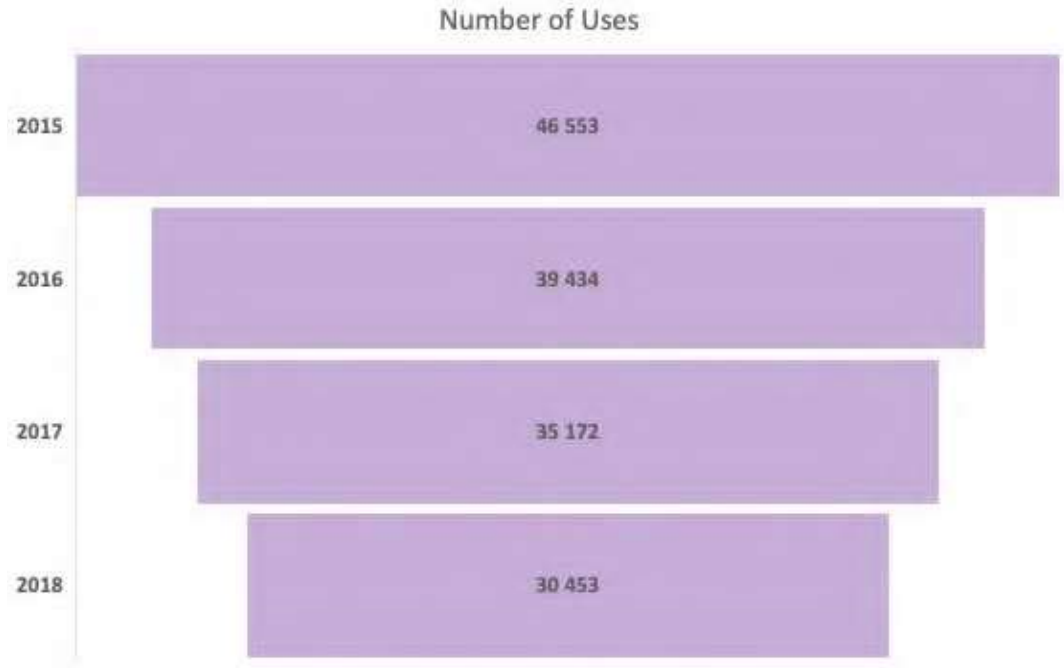


Figure 20: Evolution of total numbers of uses of animals for pyrogenicity testing between 2015 and 2018

IV.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 731,000 uses of animals in 2018, which corresponds to 7% of all uses of animals.

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

In 2018, proportionally highest severities were reported in the following sub-categories: ecotoxicity (25%, +4%), safety testing in the food and feed area (19%, -5% compared to 2017), acute and sub-acute toxicity (19%, +1%) and neurotoxicity (18%, -5%).

Proportionally lowest severities were reported for skin sensitisation, kinetics, carcinogenicity, genotoxicity, and reproductive toxicity (Figure 21).

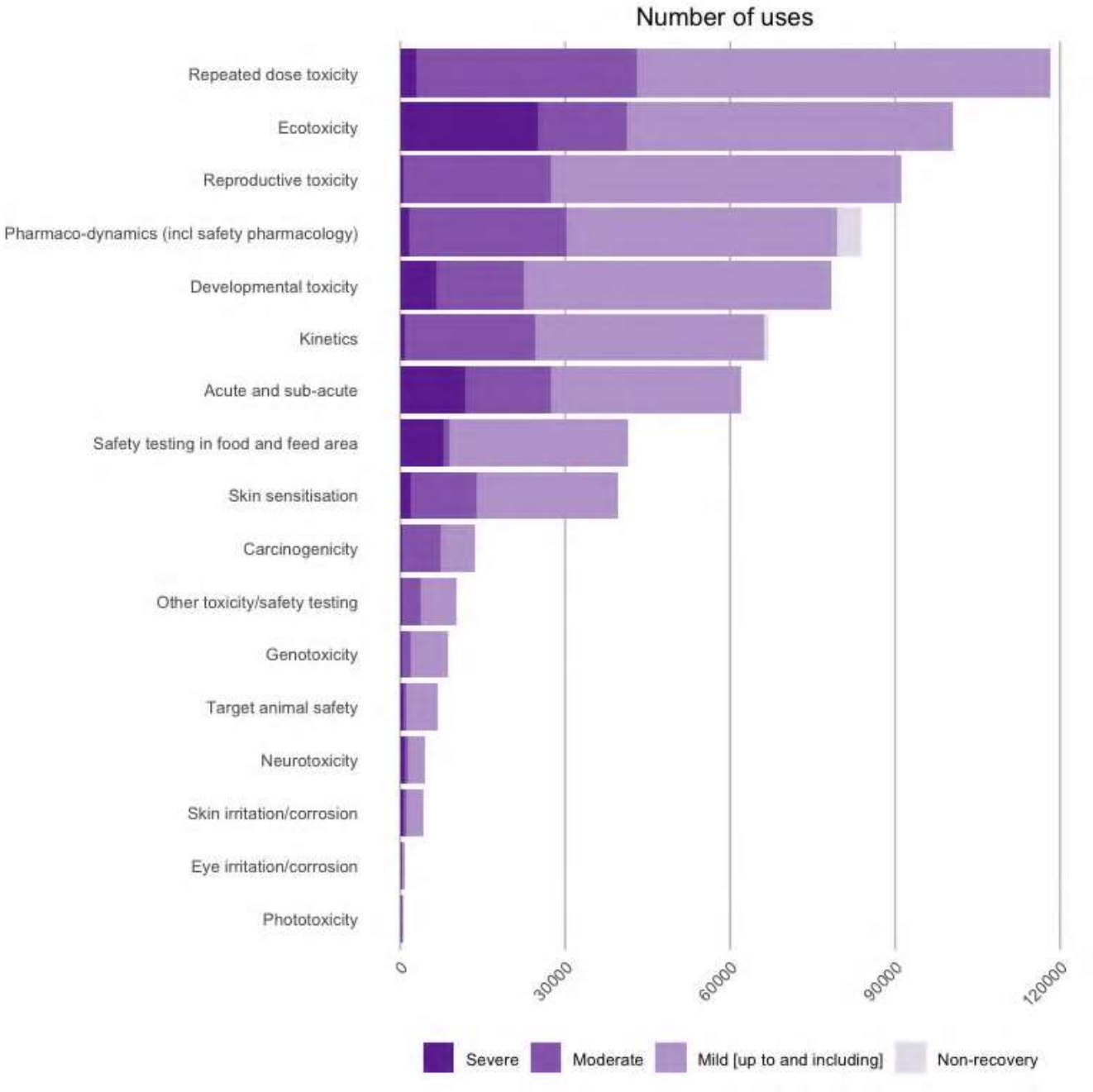


Figure 21: Toxicity and other safety testing including pharmacology by type of use and severity in 2018

In 2018 (Table 19), the total number of uses for toxicity and other safety testing including pharmacology decreased (-13%) despite the data from Norway.

Neurotoxicity related uses saw a significant increase (+63%).

A significant decrease in the number of uses was observed in 2018 compared to 2017 for the following areas: reproductive toxicity (-35%), acute and sub-acute toxicity (-26%), target animal safety (-22%), developmental toxicity (-20%), skin sensitisation (-16%), genotoxicity (-16%) and pharmaco-dynamics (-16%) (Table 19).

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

	2018
Repeated dose toxicity	118,202
Ecotoxicity	100,552
Reproductive toxicity	91,174
Pharmaco-dynamics (incl safety pharmacology)	83,819
Developmental toxicity	78,421
Kinetics	66,929
Acute and sub-acute	61,949
Safety testing in food and feed area	41,497
Skin sensitisation	39,646
Carcinogenicity	13,582
Other toxicity/safety testing	10,233
Genotoxicity	8,675
Target animal safety	6,802
Neurotoxicity	4,521
Skin irritation/corrosion	4,121
Eye irritation/corrosion	880
Phototoxicity	519
Total	**731,522**

Table 19: Toxicity and other safety testing including pharmacology by type of use

Acute and sub and sub-acute testing methods uses

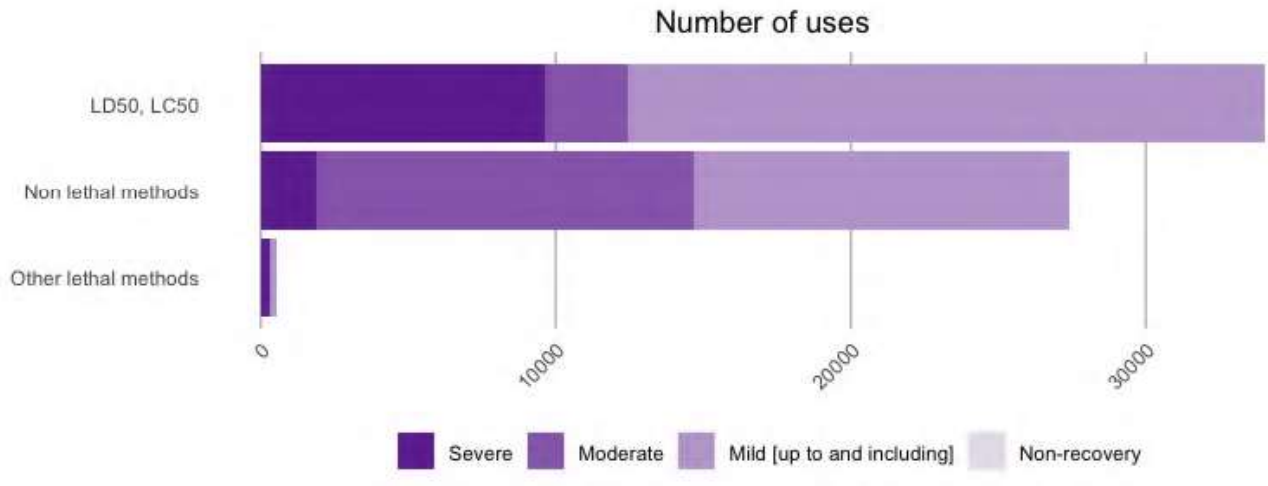


Figure 22: Acute and sub-acute uses testing methods by type of uses and severity in 2018

	2018
LD50, LC50	34,017
Non lethal methods	27,410
Other lethal methods	522
Total	**61,949**

Table 20: Acute and sub-acute uses testing methods by type of use

Repeated dose toxicity uses

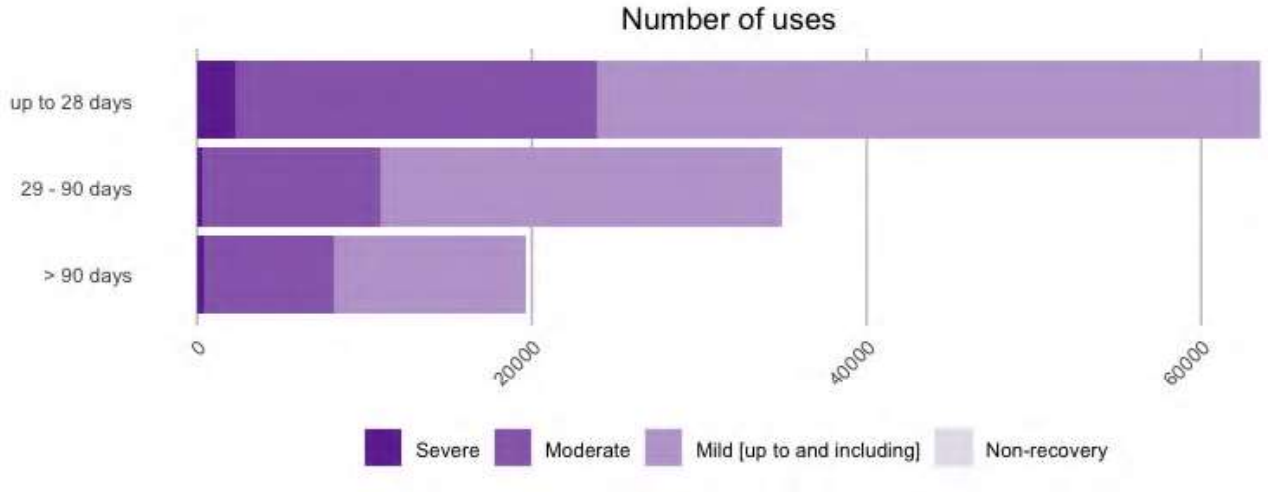


Figure 23: Repeated dose toxicity by type of uses and severity in 2018

	2018
up to 28 days	63,593
29 - 90 days	35,001
> 90 days	19,608
Total	**118,202**

Table 21: Repeated dose toxicity by type of uses and severity in 2018

Ecotoxicity

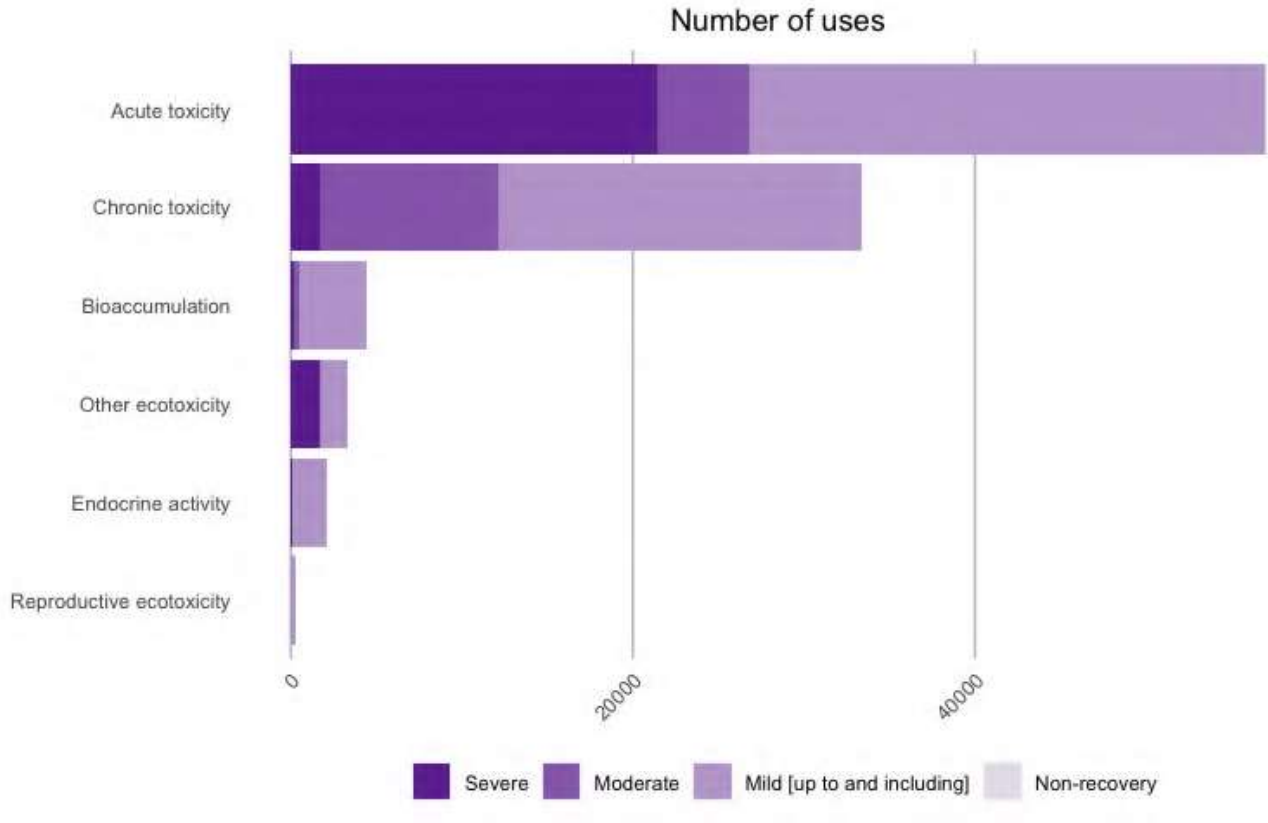


Figure 24: Ecotoxicity by type of uses and severity in 2018

	2018
Acute toxicity	57,009
Chronic toxicity	33,392
Bioaccumulation	4,466
Other ecotoxicity	3,342
Endocrine activity	2,103
Reproductive ecotoxicity	240
Total	**100,552**

Table 21: Ecotoxicity by type of use

IV.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 (immunogenicity) of human and veterinary vaccines and dose ranging studies. They represented little over 124,000 uses in 2018, a decrease (-41%) despite of the addition of the data from Norway. This could be partly explained by an exceptional increase in 2017 (+29% compared to 2016).

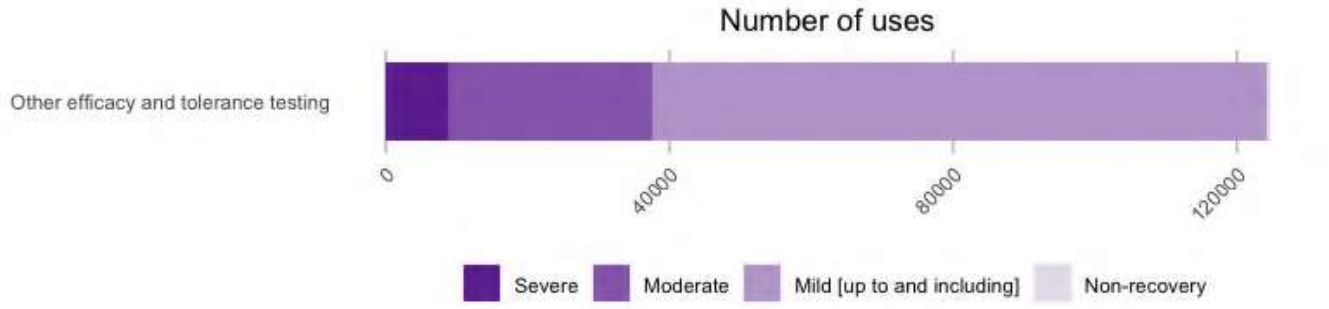


Figure 25: Other efficacy and tolerance testing by type of use and severity in 2018

	2018
Other efficacy and tolerance testing	**124,725**

Table 22: Other efficacy and tolerance testing

IV.2.2.2.2. Legislative aspects of regulatory uses

In 2018, 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 (64%, +3% compared to 2017), veterinary medicinal products (16%) and industrial chemicals (8%, -3% compared to 2017) (Table 23).

In 2018, feed legislation (-82%), biocides (-49%) and industrial chemicals legislation uses significantly decreased (-30%), the uses to satisfy legislative requirements for plant protection products (-18%), for medical devices (-9%), for medical products for human use (-7%) and for veterinary uses (-6%) decreased.

Analysing the considerable reduction in uses to satisfy feed legislation, it can be noted that there was a substantial increase in this category between 2016 and 2017 (+60,000 uses). It can, therefore, be assumed that the decrease between 2017 and 2018 is most likely due to a large fish larvae (70,000) study performed and completed in 2017.

"Other legislation" uses was the only category to increase (+108%) (Table 23). This requires further investigation to understand the reasons and to ensure that "other" category is only used in cases where none of the pre-fixed categories is appropriate. Over 40% of this category seems to be related to testing for persistent organic pollutants and testing for the purposes of waste water legislation.

	2018
Legislation on medicinal products for human use	1,236,276
Legislation on medicinal products for veterinary use and their residues	304,726
Industrial chemicals legislation	161,712
Plant protection product legislation	61,961
Other legislation	53,800
Medical devices legislation	53,283
Food legislation including food contact material	44,260
Feed legislation including legislation for the safety of target animals, workers and environment	17,181
Biocides legislation	2,110

Total	**1,935,309**

Table 23: Regulatory uses by type of legislation

In 2018, the majority of regulatory uses were performed to satisfy regulatory requirements originating from the Union (95%). Non-Union requirements accounted for 4% and national requirements for 2% (Table 2.14).

The sub-category on legislation satisfying Union requirements also includes any requirements for which international harmonisation has been achieved, such as for testing to OECD, ICH[14] and VICH[15] standards. Harmonisation of testing requirements at a global level is of utmost importance when aiming to avoid unnecessary duplication of testing.

	2018
Legislation satisfying EU requirements	95% (1,832,044)
Legislation satisfying Non-EU requirements only	4% (69,424)
Legislation satisfying national requirements only [within EU]	2% (33,841)
Total	**100% (1,935,309)**

Table 24: 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 legislation focuses more specifically on toxicity testing. Feed legislation is mainly related to other efficacy testing.

	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	856,892	317,645	61,739
Legislation on medicinal products for veterinary use and their residues	218,168	39,081	47,477
Medical devices legislation	3,740	48,520	1,023
Industrial chemicals legislation	50	160,920	742
Plant protection product legislation	0	61,598	363
Biocides legislation	0	1,580	530
Food legislation including food contact material	93	44,127	40
Feed legislation including	18	4,503	12,660

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

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

legislation for the safety of target animals, workers and environment			
Other legislation	101	53,548	151
Total	**1,079,062**	**731,522**	**124,725**

Table 25: Regulatory use by type of legislation in 2018

In terms of severity levels, in 2018, for the legislative context, 17% of total uses in the area of regulatory testing were reported as severe, 26% as moderate, 56% mild (and up to mild) and 1% as non-recovery (Figure 26).

Even if the total numbers of uses are not the most significant in the area of food legislation and biocides, the proportion of severe uses is relatively high. This category included still in 2018, for example, the use of mouse bioassay for the purposes of shellfish toxin testing. In the area of 'Other' legislation, 30% of procedures were reported as severe concerning mainly waste water toxicity studies on fish.

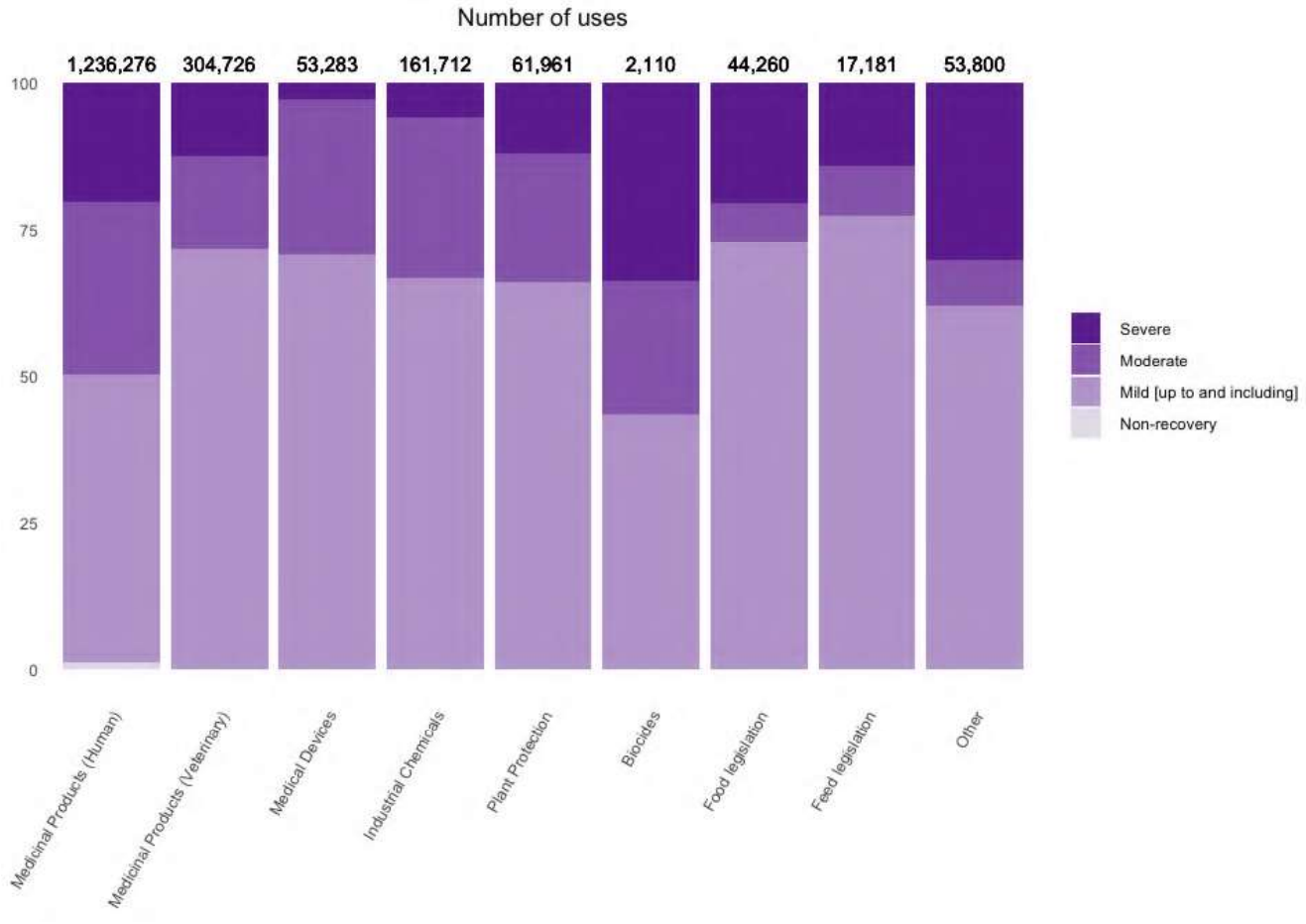


Figure 26: Regulatory use by type of legislation and severity in 2018

IV.2.2.3. Routine production uses

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

In 2018, there were about 537,000 routine production uses, which represented 5% of all uses of animals in the Union. 55% of routine uses were related to the production of blood-based products and 10% for monoclonal antibodies production by mouse ascites method (Figure 27).

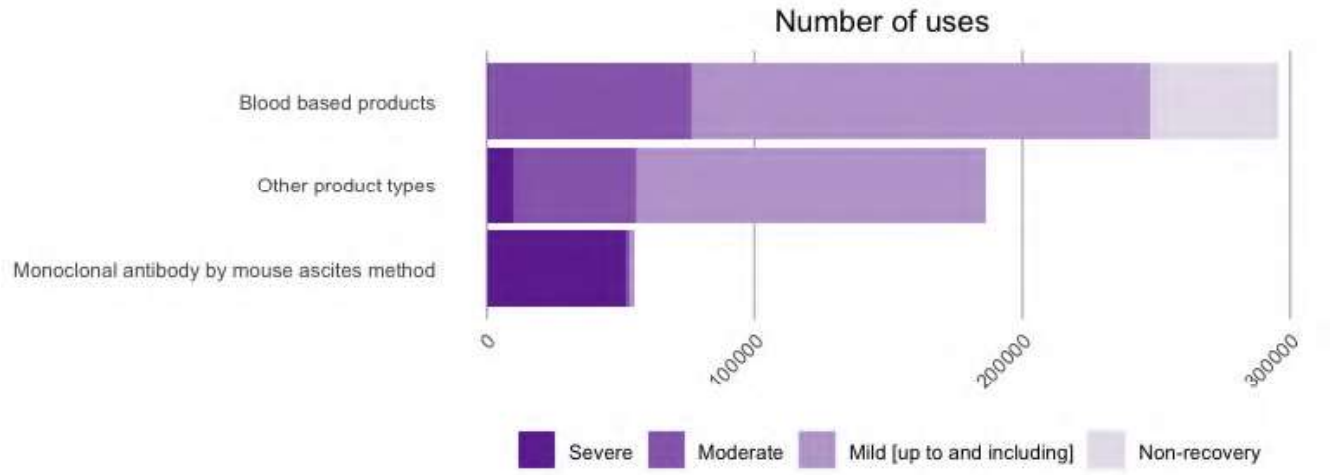


Figure 27: Routine production uses by product type and severity in 2018

While blood based products involved only mild and moderate levels of severity, monoclonal antibody production by mouse ascites method involved mostly severe uses (94%) (Figure 27).

	2018
Blood based products	295,483
Other product types	186,670
Monoclonal antibody by mouse ascites method	54,941
Total	**537,094**

Table 26: Routine production uses by product type

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

Monoclonal antibody production by mouse ascites method showed an increase of 22% between 2017 and 2018. Over 53,000 uses of the 55,000 were carried out in one Member State. In total, only six Member States reported the use of mouse ascites method for the production of monoclonal antibodies. In comparison to 2017, also the level of reported actual severity increased from 70% to 94%. This is of additional concern, when refined end-points exist to avoid reaching the highest severities.

IV.2.2.4. Other types of uses

The last four categories of uses reported as part of the Directive covered a little over 384,000 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 more than 166,000 uses in 2018, 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 and training has the largest proportion of non-recovery uses (32%). Forensic inquiry uses are limited to just a few hundred. (Figure 28).

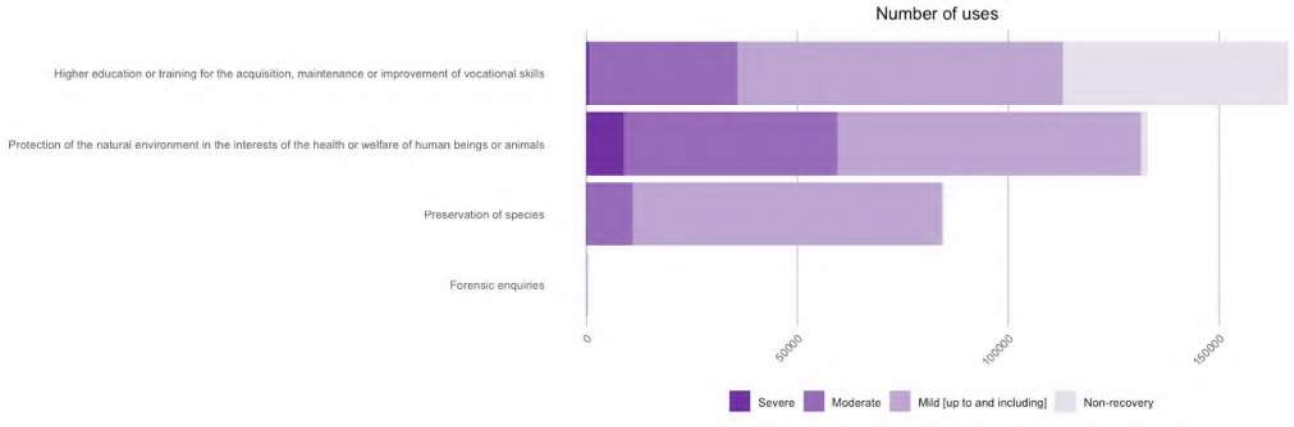


Figure 28: Other types of uses in 2018 including their severity

In 2018, there was an increase in the number of uses for the preservation of species (+7%) and protection of the natural environment (+7%), mainly due to the data from Norway (Table 27).

	2018
Higher education or training for the acquisition, maintenance or improvement of vocational skills	166,437
Protection of the natural environment in the interests of the health or welfare of human beings or animals	133,097
Preservation of species	84,720
Forensic enquiries	349
Total	**384,603**

Table 27: Other types of uses

IV.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.

IV.2.3.1. Reuses

In line with the principle of the Three Rs[16], 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 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

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

be reused following a severe procedure only in exceptional circumstances and after a veterinary examination of that animal.

In 2018, the proportion of reuses remained stable at 2% despite the addition of the data from Norway (Table 28)

	2018
No	98% (10,572,305)
Yes	2% (232,549)
Total	**100% (10,804,854)**

Table 28: Reuses of animals used for research, testing, routine production and educational purposes

IV.2.3.2.1. Animal species reused

In absolute numbers, the main species reused for scientific purposes in 2018 were mice, other fish, sheep, rats, zebra fish, rabbits, horses, donkeys and cross-breeds.

In proportion, large mammals are more often reused such as horses, donkeys and cross-breeds (87%), sheep (70%), cats (47%), dogs (31%) and non-human primates.

Reptiles (59%) and xenopus (28%) amongst amphibians were also often reused (Table 29). The high level of reuse of reptiles may have been a reporting error. However, it was not possible to confirm and correct this in time for the publication of the report.

	Total number of uses	Number of reuses	Proportion of reuses
Mice	5,562,916	57,747	1%
Rats	1,017,398	18,152	2%
Guinea-Pigs	130,902	971	1%
Hamsters (Syrian)	10,934	121	1%
Mongolian gerbil	4,862	101	2%
Other rodents	21,399	1,026	5%
Rabbits	354,466	11,778	3%
Cats	2,959	1,405	47%
Dogs	25,717	8,006	31%
Ferrets	1,567	60	4%
Other carnivores	4,890	315	6%
Horses, donkeys and cross-breeds	13,346	11,634	87%
Pigs	87,769	3,772	4%
Goats	2,427	926	38%
Sheep	74,080	51,709	70%
Cattle	35,294	7,641	22%
Prosimians	222	52	23%
Marmoset and tamarins	584	203	35%
Cynomolgus monkey	9,741	2,122	22%
Rhesus monkey	504	184	37%
Vervets (Chlorocebus spp.)	30	14	47%
Baboons	49	19	39%

Other species of Old World Monkeys (Cercopithecoidea)	29	7	24%
Other mammals	6,236	292	5%
Domestic fowl	487,074	5,262	1%
Other birds	103,092	2,058	2%
Reptiles	4,026	2,378	59%
Xenopus	22,051	6,235	28%
Other amphibians	7,817	274	4%
Zebra fish	475,508	13,987	3%
Other fish	2,328,418	24,082	1%
Cephalopods	4,284	16	**0%**

Table 29: Reuses by type of species in 2018

IV.2.3.2.2. Reuse by purposes of procedures

In 2018, 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 re-uses	Proportion
Basic research	4,978,877	84,161	2%
Translational and applied research	2,968,971	32,113	1%
Regulatory use	1,935,309	35,845	2%
Routine production	537,094	62,572	12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	166,437	16,252	10%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	133,097	902	1%
Preservation of species	84,720	704	1%
Forensic enquiries	349	0	0%

Table 30: Reuses by purposes in 2018

IV.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 2018, most of the reuses, the actual reported severities were mild (78%) or moderate (17%) (Figure 29).

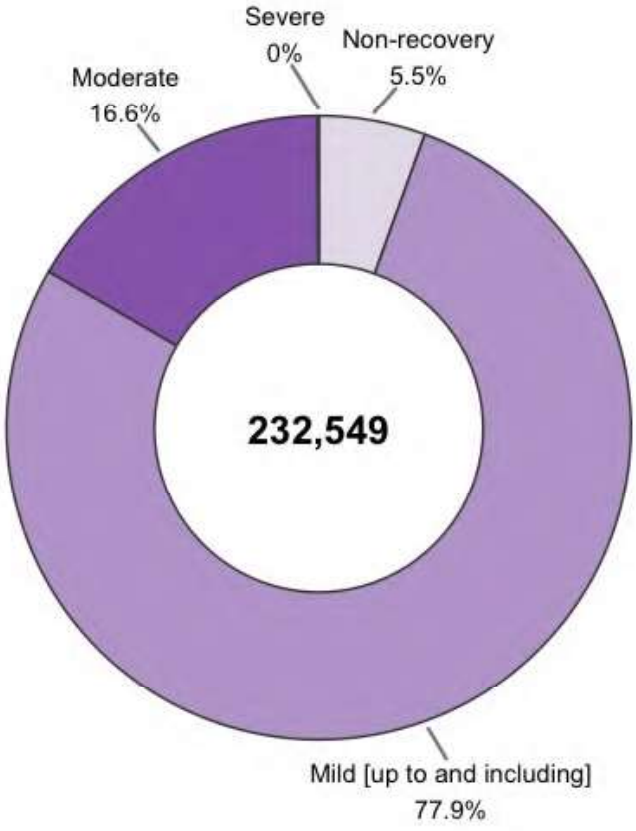


Figure 29: Reuses by severity in 2018

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, with a decrease compared to 2017 (-75%).

These 114 cases should be investigated by the authorities 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.

	2018
Non-recovery	6% (12,840)
Mild [up to and including]	78% (181,043)
Moderate	17% (38,552)
Severe	<1% (114)
Total	**100% (232,549)**

Table 31: Severity classification of reuse procedures

In 2018, the number of reuses remained stable in total with an increase of Mild reuses (+26%).

IV.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.

IV.2.3.2.1. Type of genetic alteration

In 2018, 2.53 million uses for the purposes of research were carried out on animals that were genetically altered. Of these, 16% were of a harmful phenotypic alteration.

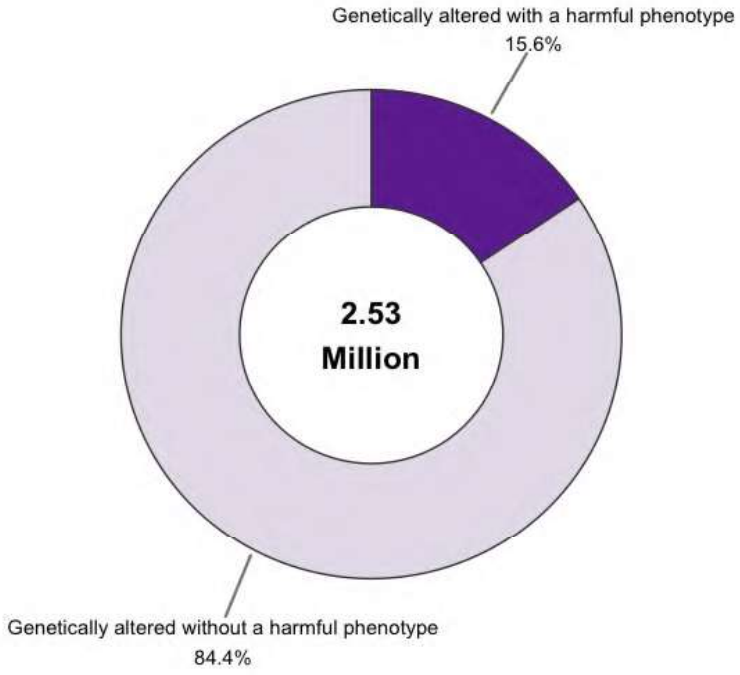


Figure 30: Uses of animals by type of genetic alteration in 2018

In 2018, the proportion of the uses of genetically altered animals for scientific purposes decreased slightly. The percentage of the uses of such animals with a harmful phenotype decreased from 5% to 4%, and the uses of such animals without a harmful phenotype decreased from 23% to 20%.

	2018
Genetically altered with a harmful phenotype	4% (393,735)
Genetically altered without a harmful phenotype	20% (2,136,525)
Not genetically altered	77% (8,274,594)
Total	**100% (10,804,854)**

Table 32: Genetic status of animals used

IV.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 account for the most animals being genetically altered, in proportion, 60% of zebra fish was genetically altered, followed by mice (39%), while only 3% of rats were genetically altered and used in procedures for purposes of research, testing, routine production in 2018 (Table 33).

	Total number of uses	Uses of genetically altered animals	Proportion
Zebra fish	475,508	284,676	60%
Mice	5,562,916	2,174,481	39%
Xenopus	22,051	4,439	20%
Other amphibians	7,817	786	10%
Rabbits	354,566	25,718	7%
Rats	1,017,398	34,304	3%
Hamsters (Syrian)	10,934	271	2%
Pigs	87,769	472	1%
Dogs	25,717	96	<1%
Other fish	2,328,418	4,712	<1%
Domestic fowl	487,074	300	<1%
Other rodents	21,399	5	<1%

Table 33: Genetically altered animals by species in 2018

This situation is mainly explained by the fact that genetically altered animals are used almost exclusively for research purposes. In 2018, basic research accounted for 74% of uses of genetically altered animals and translational and applied research for 22% (Table 34).

	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total
Basic research	62% (3,100,172)	33% (1,618,863)	5% (259,842)	**100% (4,979,377)**
Translational and applied research	81% (2,404,007)	15% (436,803)	4% (128,161)	**100% (2,968,834)**
Regulatory use	98% (1,899,735)	2% (33,298)	0% (2,276)	**100% (1,935,309)**

Routine production	95% (511,148)	5% (25,804)	0% (142)	**100% (537,271)**
Higher education or training for the acquisition, maintenance or improvement of vocational skills	89% (148,435)	10% (15,834)	1% (2,168)	**100% (166,437)**
Preservation of species	93% (78,370)	6% (5,210)	1% (1,140)	**100% (84,720)**
Protection of the natural environment in the interests of the health or welfare of human beings or animals	99% (132,418)	1% (679)	0% (0)	**100% (133,097)**
Forensic enquiries	89% (309)	10% (34)	2% (6)	**100% (349)**

Table 34: Genetic status of animals by use purposes in 2018

IV.3. Numbers and uses of animals for the creation and maintenance of genetically altered animals in the Union

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 Union.

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

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

In 2018, 1.52 million animals were used for the provision of genetically altered animals for the purposes of scientific research.

This included 588,062 animals used for the first time for the creation of new genetically altered animal lines (Table 35), which represents a decrease of 7% from 2017.

932,729 animals were used for the first time for the maintenance of colonies of established genetically altered animal lines (Table 3.8). In comparison to 2017, this represents an increase of 45%, however, being more in line with the number reported in 2015. It is important to note in this context that the reporting requirements for the maintenance of colonies of established genetically altered animal lines are particularly complex. This is likely to be the greatest single contributing factor for such significant year to year fluctuations. The Commission and Member States are working to provide more guidance to the users. More information is provided under section IV.3.3 below.

IV.3.2. All uses of animals for the creation of new genetically altered animal lines

The creation of a new genetically altered animal line is reported under the research purpose category for which the line is being created. 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 IV.4).

Counting all uses, the main species that were used for the creation of new genetically altered animal lines were mice and zebra fish, representing 75% and 20%, respectively. Other species, although in small numbers, include other species of fish, rats, xenopus, domestic fowl, rabbits, and pigs.

In 2018, the creation of new genetic lines decreased by 10% (Table 35).

	2018
Mice	444,109
Zebra fish	118,535
Other fish	16,274
Rats	6,227
Xenopus	1,328
Domestic fowl	560
Rabbits	324
Pigs	269
Sheep	167
Other amphibians	100
Hamsters (Syrian)	89
Other mammals	70
Marmoset and tamarins	10
Total	**588,062**

Table 35: Uses of animals for the creation of new genetically altered animal lines by species

IV.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 line 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 85% were of a non-harmful phenotype.

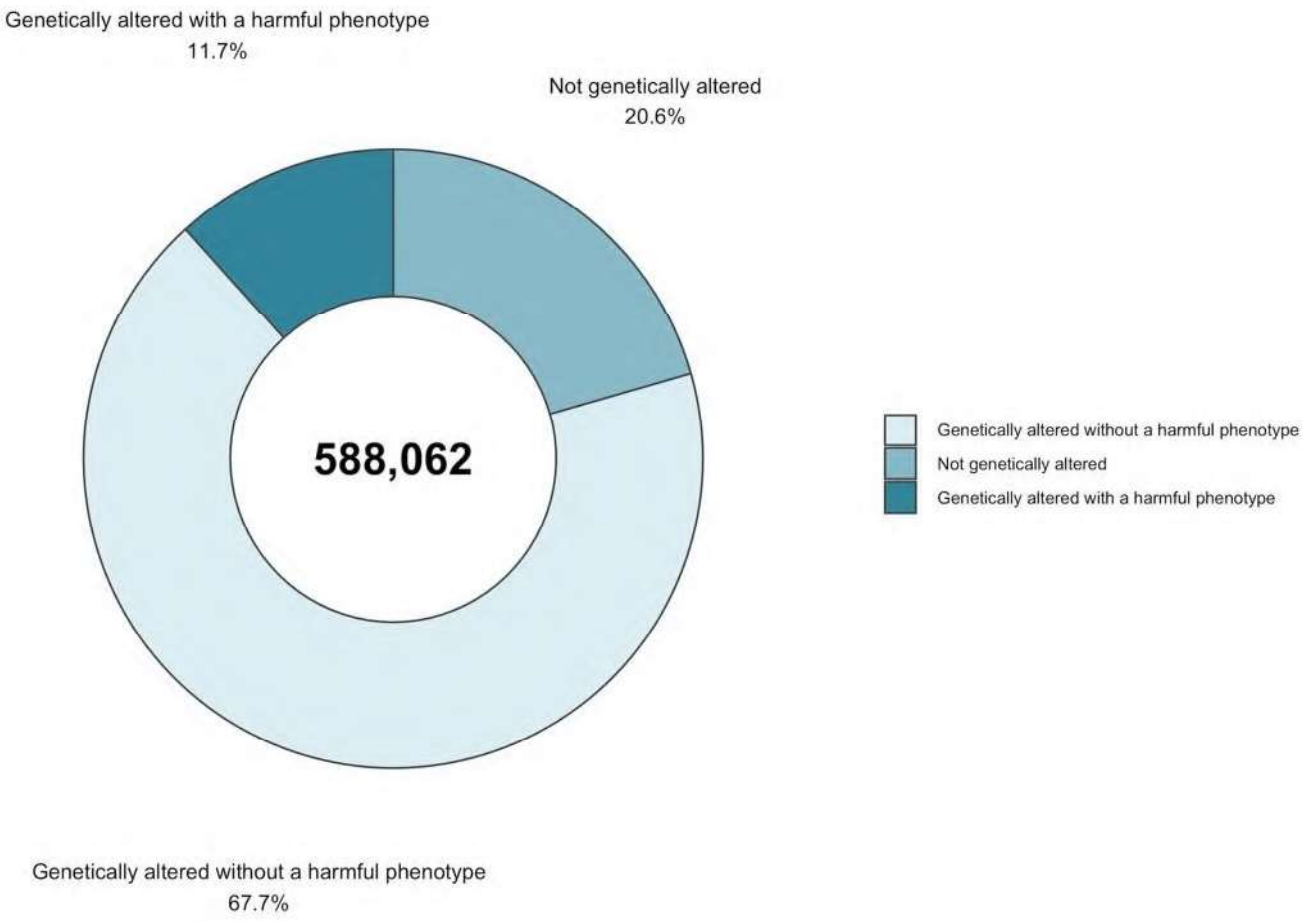


Figure 31: Creation of new genetically altered animal lines: genetic types of animal used in 2018

	2018
Not genetically altered	20% (120,912)
Genetically altered without a harmful phenotype	68% (398,284)
Genetically altered with a harmful phenotype	12% (68,866)
Total	**100% (588,062)**

Table 36: Creation of new genetically altered animal lines: genetic types of animal used

IV.3.2.2. Creation of new genetically altered animal lines by scientific purposes

The creation of new genetic lines is only carried out for research purposes. In 2018, 588,062 uses (first and any subsequent reuses) were reported for the purposes of creating new genetically altered animal lines.

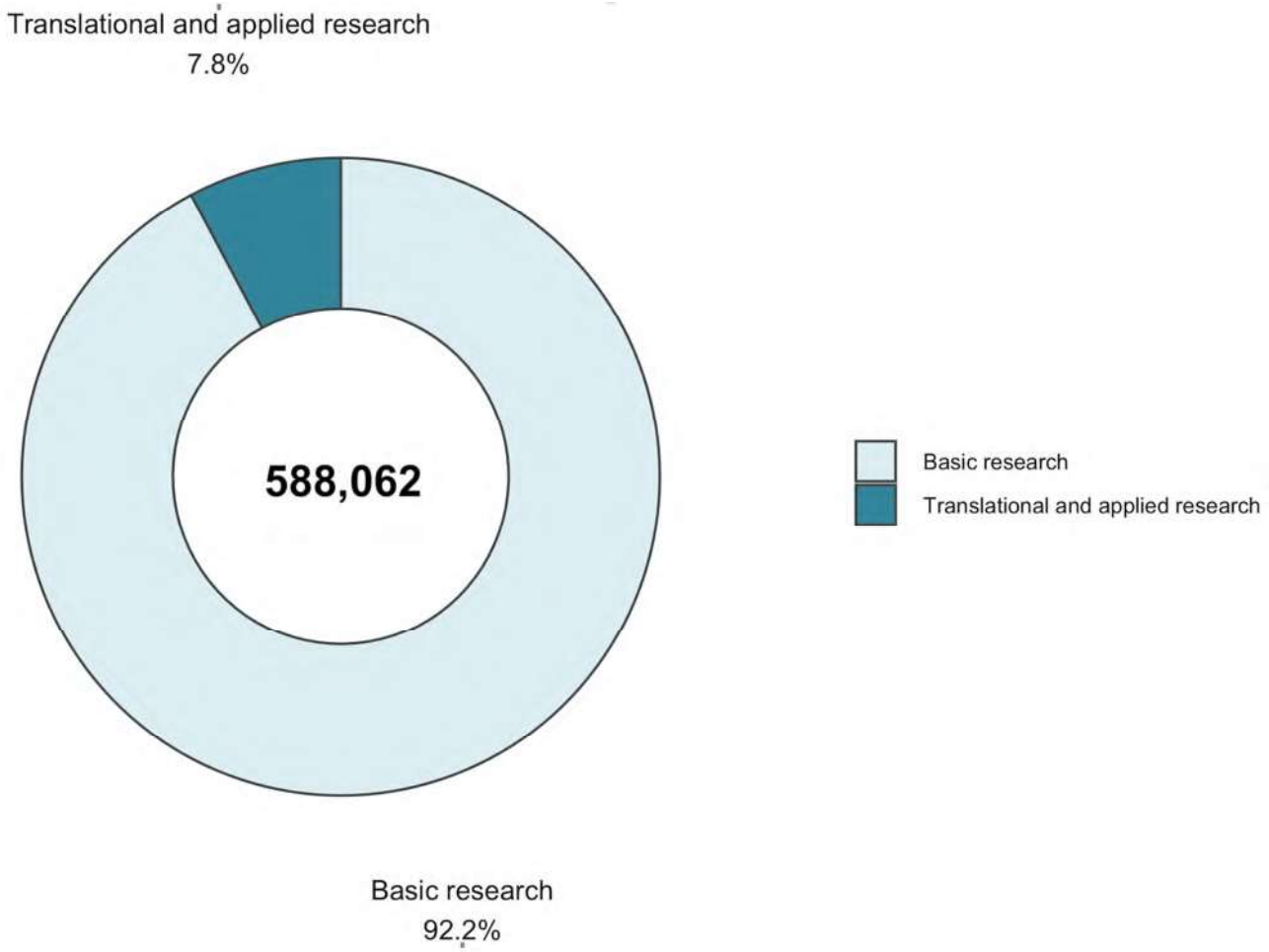


Figure 32: Creation of new genetically altered animal lines: uses for research purposes in 2018

92% 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 2018, for basic research purposes, 19% concerned multisystemic research (where more than one body system is the primary interest of the research, such as in some infectious diseases), 15% oncology, 15% nervous system and 9% cardiovascular, blood and lymphatic system (Table 37).

The most important sub-category under translational and applied research for which new genetically altered animal lines were created was human endocrine / metabolism disorders (2%). 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 37 combines all research purposes both from basic, and translational and applied research.

	2018
Multisystemic	110,902
Oncology	89,677
Nervous System	89,039
Immune System	63,352
Cardiovascular Blood and Lymphatic System	53,762
Other basic research	39,249
Urogenital/Reproductive System	29,658
Endocrine System/Metabolism	18,666
Sensory Organs (skin, eyes and ears)	16,708
Musculoskeletal System	14,804
Gastrointestinal System including Liver	12,947
Human Endocrine/Metabolism Disorders	10,550
Animal Diseases and Disorders	9,150
Human Cancer	9,038
Human Infectious Disorders	3,698
Human Nervous and Mental Disorders	3,528
Human Gastrointestinal Disorders including Liver	3,224
Ethology / Animal Behaviour /Animal Biology	2,826
Human Cardiovascular Disorders	2,673
Other Human Disorders	973
Respiratory System	794
Human Sensory Organ Disorders (skin, eyes and ears)	783
Human Respiratory Disorders	608
Human Immune Disorders	464
Human Urogenital/Reproductive Disorders	400
Human Musculoskeletal Disorders	332
Animal Welfare	223
Non-regulatory toxicology and ecotoxicology	34
Total	**588,062**

Table 37: Uses of animals for the creation of new genetically altered animal lines by type of research

IV.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.

	2018
Non-recovery	5% (28,918)

Mild [up to and including]	74% (437,915)
Moderate	19% (113,576)
Severe	1% (7,653)
Total	**100% (588,062)**

Table 38: Uses of animals for the creation of new genetically altered animal lines by severities

IV.3.2.4. Reuses

In 2018, the number of re-uses for the creation of new genetic lines fell below 1%.

	2018
Yes	1% (4,015)
No	99% (588,062)
Total	**100% (592,077)**

Table 39: Reuse of animals used for the creation of new genetically altered animal lines

Species reused for the creation of new genetic lines are mainly mice and zebra fish.

	Yes	**No**
Mice	1% (2,546)	99% (444,109)
Rats	0% (4)	100% (6,227)
Hamsters (Syrian)	0% (0)	100% (89)
Rabbits	0% (0)	100% (324)
Ferrets	100% (4)	0% (0)
Pigs	1% (4)	99% (269)
Sheep	0% (0)	100% (167)
Marmoset and tamarins	0% (0)	100% (10)
Other mammals	0% (0)	100% (70)
Domestic fowl	0% (0)	100% (560)
Xenopus	0% (0)	100% (1,328)
Other amphibians	0% (0)	100% (100)
Zebra fish	1% (1,457)	99% (118,535)
Other fish	0% (0)	100% (16,274)
Total	**1% (4,015)**	**99% (588,062)**

Table 40: Reuses by species for the creation of new genetically altered animal lines in 2018

IV.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 continue to be detected. The Commission continues to work with Member States to improve the situation.

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

In 2018, 933,328 uses were reported under the maintenance of colonies of established genetically altered animal lines. Amongst these uses, 85% were genetically altered without a harmful phenotype, 12% with a harmful phenotype and 3% without genetic alteration (Figure 33). 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.

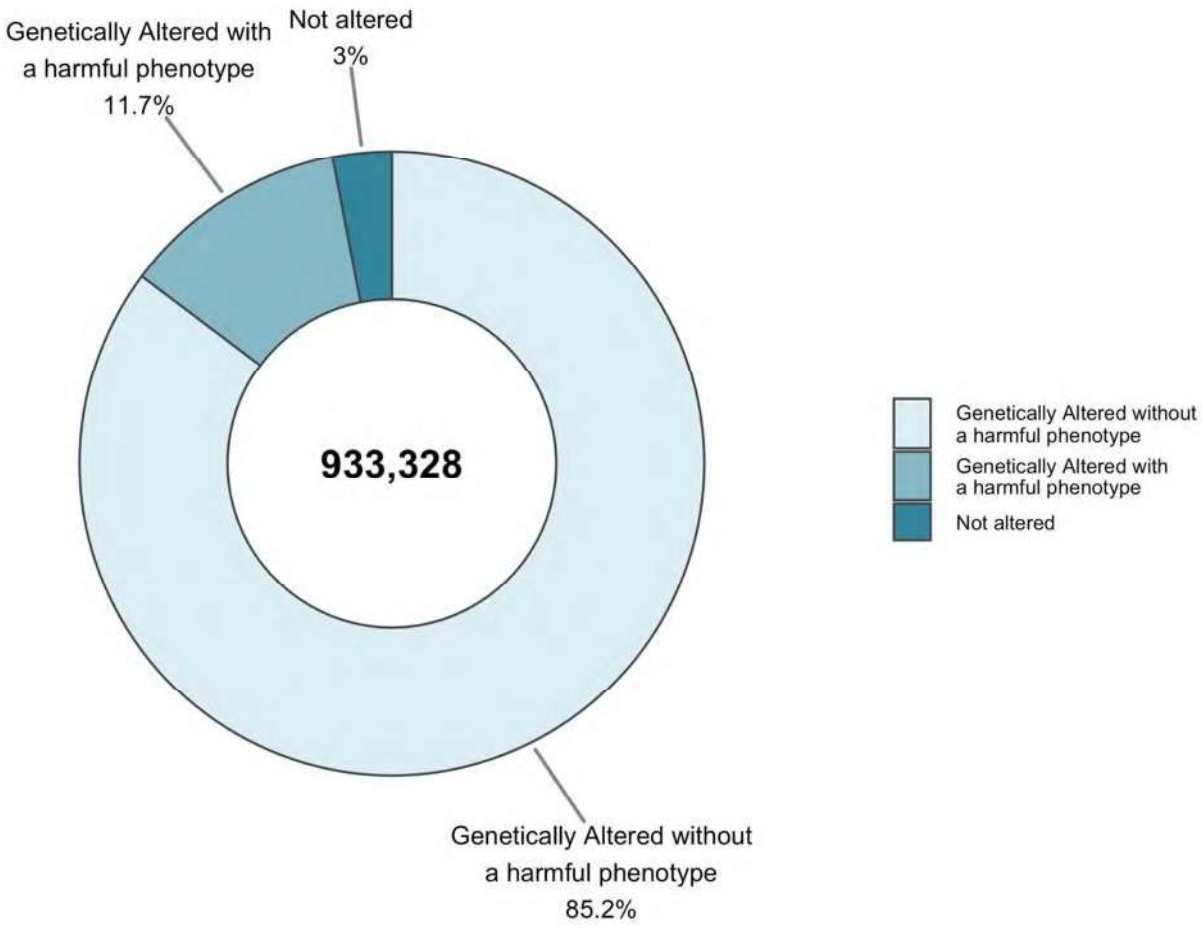


Figure 33: Genetic status of animals used for the maintenance of colonies of established genetically altered animal lines in 2018

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

In 2018, in 86% of the uses the severities remained at mild (and up to mild) level (Table 41). Drawing from the previous figure 33 in which it was stated that 85% 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'.

	2018
Non-recovery	0% (1,333)
Mild [up to and including]	86% (802,654)
Moderate	8% (77,085)
Severe	6% (52,256)
Total	**100% (933,328)**

Table 41: Uses of animals for the maintenance of colonies of genetically altered animal lines by severity in 2018

IV.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.

	2018
Mice	826,298
Rats	6,596
Dogs	5
Sheep	6
Domestic fowl	497
Xenopus	391
Zebra fish	98,082
Other fish	1,453
Total	**933,328**

Table 42: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species

IV.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 category 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 is summarised in the above table.

<u>Creation</u>

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".

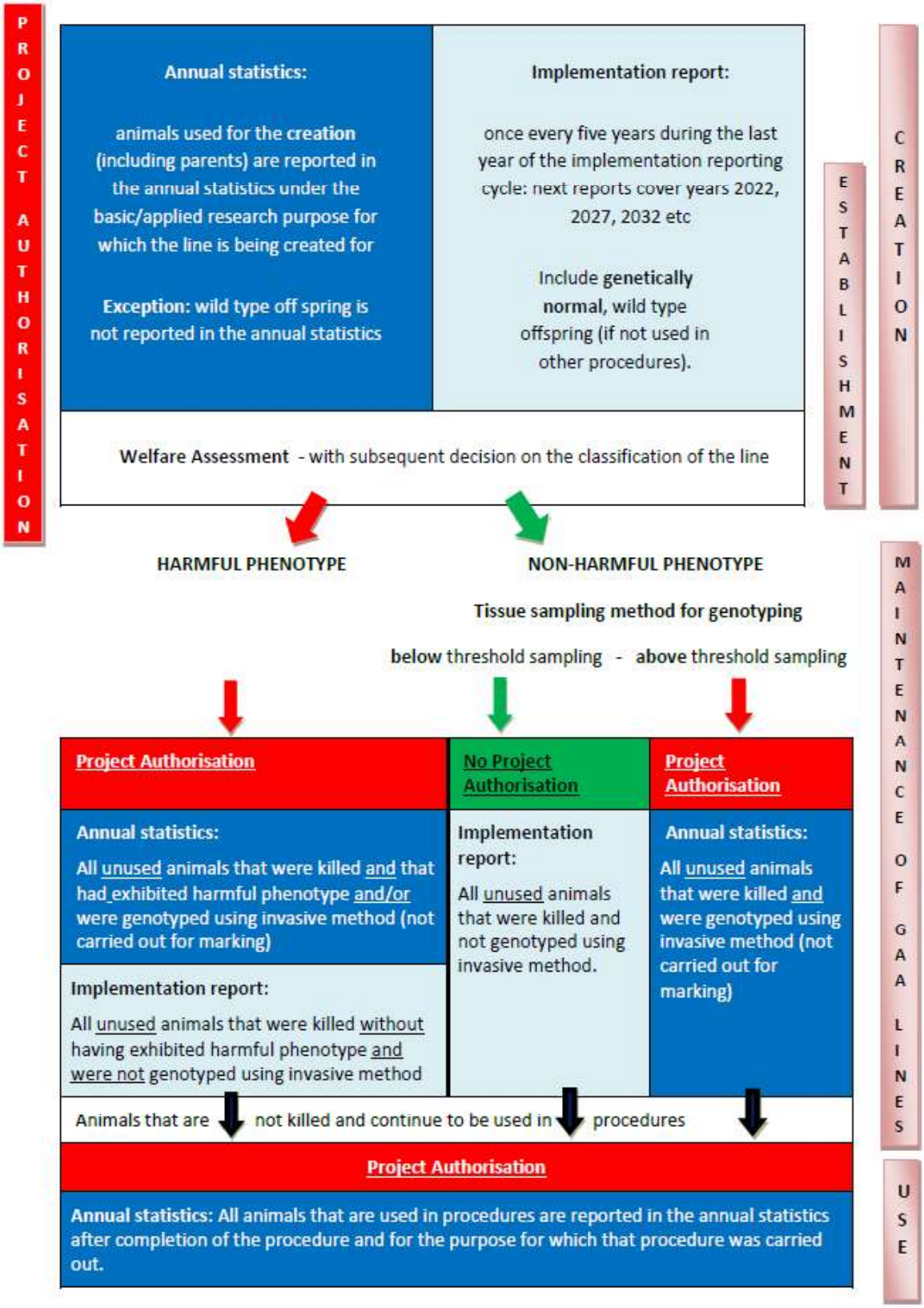
The welfare assessment determines if the newly established line is expected to have an *intended harmful phenotype (characteristic/trait)* i.e. an effect of genetic alteration that impacts negatively on an animal’s health or welfare, such as muscle weakness, diabetes, tumour development.

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 animals used in the manufacturing process of products such as 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 for delivering theoretical knowledge within a higher education programme and also for the acquisition, maintenance or improvement of vocational skills.

Forensic enquiries

Studies to assist the investigation of forensic enquiries.

PART B: Union DATA TABLES IN 2018

V. Detailed Union tables 2018

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

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

Table 1: Numbers of animals used for the first time by species (2018)

		Number of animals	%
Mammals			
	Rodents		
	Mice	5,505,169	**52.1**
	Rats	999,246	**9.5**
	Guinea-Pigs	129,931	**1.2**
	Hamsters (Syrian)	10,813	**0.1**
	Hamsters (Chinese)	20	**0**
	Mongolian gerbil	4,761	**0**
	Other rodents	20,373	**0.2**
	Rabbits		
	Rabbits	342,788	**3.2**
	Carnivores		
	Cats	1,554	**0**
	Dogs	17,711	**0.2**
	Ferrets	1,507	**0**
	Other carnivores	4,575	**0**
	Farm animals		
	Horses, donkeys and cross-breeds	1,712	**0**
	Pigs	83,997	**0.8**
	Goats	1,501	**0**
	Sheep	22,371	**0.2**
	Cattle	27,653	**0.3**
	Non-human primates		
	Prosimians	170	**0**
	Marmoset and tamarins	381	**0**
	Squirrel monkey	25	**0**
	Cynomolgus monkey	7,619	**0.1**
	Rhesus monkey	320	**0**
	Vervets (Chlorocebus spp.)	16	**0**
	Baboons	30	**0**
	Other species of old world monkeys (Cercopithecoidea)	22	**0**
	Other mammals		
	Other mammals	5,944	**0.1**
Birds			
	Domestic fowl	481,812	**4.6**
	Other birds	101,034	**1**
Reptiles			
	Reptiles	1,648	**0**
Amphibians			
	Rana	4,238	**0**
	Xenopus	15,816	**0.1**
	Other amphibians	7,543	**0.1**
Fish			
	Zebra fish	461,521	**4.4**
	Other fish	2,304,216	**21.8**
Cephalopods			
	Cephalopods	4,268	**0**
Totals			
	Total	**10,572,305**	**100**
	%	**100**	

Table 2: Place of birth by species (other than non-human primates) (2018)

	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	5,251,430	137,470	70,652	45,617	**5,505,169**	**52.1**
Rats	982,070	10,185	2,654	4,337	**999,246**	**9.5**
Guinea-Pigs	129,654	277	0	0	**129,931**	**1.2**
Hamsters (Syrian)	9,215	84	0	1,514	**10,813**	**0.1**
Hamsters (Chinese)	20	0	0	0	**20**	**0**
Mongolian gerbil	4,509	252	0	0	**4,761**	**0**
Other rodents	7,958	11,783	528	104	**20,373**	**0.2**
Rabbits						
Rabbits	338,861	1,750	83	2,094	**342,788**	**3.2**
Carnivores						
Cats	728	589	0	237	**1,554**	**0**
Dogs	5,593	8,180	24	3,914	**17,711**	**0.2**
Ferrets	1,361	66	0	80	**1,507**	**0**
Other carnivores	431	3,961	183	0	**4,575**	**0**
Farm animals						
Horses, donkeys and cross-breeds	429	1,274	9	0	**1,712**	**0**
Pigs	41,129	42,585	271	12	**83,997**	**0.8**
Goats	555	938	8	0	**1,501**	**0**
Sheep	10,468	11,308	595	0	**22,371**	**0.2**
Cattle	13,600	13,837	216	0	**27,653**	**0.3**
Other mammals						
Other mammals	1,138	3,410	124	1,272	**5,944**	**0.1**
Birds						
Domestic fowl	370,093	111,719	0	0	**481,812**	**4.6**
Other birds	42,071	55,245	1,833	1,885	**101,034**	**1**
Reptiles						
Reptiles	277	1,138	3	230	**1,648**	**0**
Amphibians						
Rana	1,683	2,555	0	0	**4,238**	**0**
Xenopus	10,701	3,323	10	1,782	**15,816**	**0.1**
Other amphibians	3,118	4,210	150	65	**7,543**	**0.1**
Fish						
Zebra fish	439,890	17,146	1,721	2,764	**461,521**	**4.4**
Other fish	1,694,132	457,849	130,737	21,498	**2,304,216**	**21.8**
Cephalopods						
Cephalopods	2,643	1,625	0	0	**4,268**	**0**
Totals						
Total	**9,363,757**	**902,759**	**209,801**	**87,405**	**10,563,722**	**100**
%	**88.6**	**8.5**	**2**	**0.8**	**100**	

Table 3: Source of non-human primates by species (2018)

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total	%
Non-human primates							
New World Monkeys							
Prosimians	170	0	0	0	0	**170**	**2**
Marmoset and tamarins	381	0	0	0	0	**381**	**4.4**
Squirrel monkey	25	0	0	0	0	**25**	**0.3**
Old World Monkeys							
Cynomolgus monkey	323	3,229	0	4,013	54	**7,619**	**88.8**
Rhesus monkey	296	24	0	0	0	**320**	**3.7**
Vervets (Chlorocebus spp.)	0	0	12	4	0	**16**	**0.2**
Baboons	30	0	0	0	0	**30**	**0.3**
Other species of old world monkeys (Cercopithecoidea)	0	22	0	0	0	**22**	**0.3**
Totals							
Total	**1,225**	**3,275**	**12**	**4,017**	**54**	**8,583**	**100**
%	**14.3**	**38.2**	**0.1**	**46.8**	**0.6**	**100**	

Table 4: Generation of non-human primates by species (2018)

	F1	F2 or greater	Self-sustaining colony	Total	%
Non-human primates					
New World Monkeys					
Prosimians	0	20	150	**170**	**2**
Marmoset and tamarins	6	184	191	**381**	**4.4**
Squirrel monkey	0	25	0	**25**	**0.3**
Old World Monkeys					
Cynomolgus monkey	1,253	4,491	1,875	**7,619**	**88.8**
Rhesus monkey	10	66	244	**320**	**3.7**
Vervets (Chlorocebus spp.)	1	4	11	**16**	**0.2**
Baboons	10	20	0	**30**	**0.3**
Other species of old world monkeys (Cercopithecoidea)	10	12	0	**22**	**0.3**
Totals					
Total	**1,290**	**4,822**	**2,471**	**8,583**	**100**
%	**15**	**56.2**	**28.8**	**100**	

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

Table 5: Uses of animals by species, main categories of scientific purposes and severities (2018)

	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	264,085	45,717	3,038	16,807	0	50	15,046	0	**344,743**	**6.2**
	Mild	1,304,715	483,165	455,339	3,570	4,872	6,594	45,007	223	**2,303,485**	**41.4**
Mice	Moderate	1,154,251	782,838	221,324	2,500	218	99	20,598	0	**2,181,828**	**39.2**
	Severe	225,224	201,802	252,755	52,644	20	7	408	0	**732,860**	**13.2**
	Total	**2,948,275**	**1,513,522**	**932,456**	**75,521**	**5,110**	**6,750**	**81,059**	**223**	**5,562,916**	**100.0**
	Non-recovery	46,246	16,862	4,854	4,370	14	0	23,471	0	**95,817**	**9.4**
	Mild	87,170	85,706	307,612	941	55	0	12,462	34	**493,980**	**48.6**
Rats	Moderate	110,554	95,822	153,687	0	115	0	5,252	0	**365,430**	**35.9**
	Severe	34,174	18,549	9,196	108	113	0	31	0	**62,171**	**6.1**
	Total	**278,144**	**216,939**	**475,349**	**5,419**	**297**	**0**	**41,216**	**34**	**1,017,398**	**100.0**
	Non-recovery	10,095	1,081	249	197	0	0	328	0	**11,950**	**9.1**
	Mild	1,179	4,855	50,171	590	392	0	1,112	0	**58,299**	**44.5**
Guinea-Pigs	Moderate	1,637	2,398	38,298	8	0	0	778	0	**43,119**	**32.9**
	Severe	6	2,030	15,496	0	0	0	2	0	**17,534**	**13.4**
	Total	**12,917**	**10,364**	**104,214**	**795**	**392**	**0**	**2,220**	**0**	**130,902**	**100.0**
	Non-recovery	123	116	0	0	0	0	14	0	**253**	**2.3**
	Mild	317	1,361	3,789	0	0	0	64	0	**5,531**	**50.6**
Hamsters (Syrian)	Moderate	349	1,830	480	0	0	0	9	0	**2,668**	**24.4**
	Severe	151	704	1,517	110	0	0	0	0	**2,482**	**22.7**
	Total	**940**	**4,011**	**5,786**	**110**	**0**	**0**	**87**	**0**	**10,934**	**100.0**
	Non-recovery	0	0	0	0	0	0	0	0	**0**	**0.0**
	Mild	0	20	0	0	0	0	0	0	**20**	**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**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	**100.0**
	Non-recovery	445	0	0	0	0	0	55	0	**500**	**10.3**
	Mild	539	799	145	78	0	0	69	0	**1,630**	**33.5**
Mongolian gerbil	Moderate	1,293	1,161	28	22	0	0	32	0	**2,536**	**52.2**
	Severe	12	20	164	0	0	0	0	0	**196**	**4.0**
	Total	**2,289**	**1,980**	**337**	**100**	**0**	**0**	**156**	**0**	**4,862**	**100.0**
	Non-recovery	556	84	0	0	363	0	20	0	**1,023**	**4.8**
	Mild	13,797	413	911	0	98	140	392	0	**15,751**	**73.6**
Other rodents	Moderate	2,755	357	0	0	193	638	0	0	**3,943**	**18.4**
	Severe	14	527	31	0	110	0	0	0	**682**	**3.2**
	Total	**17,122**	**1,381**	**942**	**0**	**764**	**778**	**412**	**0**	**21,399**	**100.0**
	Non-recovery	1,076	1,156	7,197	25,014	0	0	723	0	**35,166**	**9.9**
	Mild	6,780	3,050	55,478	125,827	3	0	713	0	**191,851**	**54.1**
Rabbits	Moderate	5,365	6,691	25,125	79,759	0	0	57	0	**116,997**	**33.0**
	Severe	1,575	581	2,044	6,350	0	0	2	0	**10,552**	**3.0**
	Total	**14,796**	**11,478**	**89,844**	**236,950**	**3**	**0**	**1,495**	**0**	**354,566**	**100.0**
	Non-recovery	28	0	0	0	0	0	0	0	**28**	**0.9**
	Mild	607	781	809	19	8	0	75	0	**2,299**	**77.7**
Cats	Moderate	32	24	545	0	0	0	1	0	**602**	**20.3**
	Severe	5	0	25	0	0	0	0	0	**30**	**1.0**
	Total	**672**	**805**	**1,379**	**19**	**8**	**0**	**76**	**0**	**2,959**	**100.0**
	Non-recovery	6	110	96	12	0	0	148	0	**372**	**1.4**
	Mild	1,294	10,453	7,075	677	211	0	939	0	**20,649**	**80.3**
Dogs	Moderate	275	566	3,555	17	0	0	77	0	**4,490**	**17.5**
	Severe	0	46	154	1	0	0	5	0	**206**	**0.8**
	Total	**1,575**	**11,175**	**10,880**	**707**	**211**	**0**	**1,169**	**0**	**25,717**	**100.0**
	Non-recovery	150	0	0	2	0	0	8	0	**160**	**10.2**
	Mild	81	265	176	13	0	0	41	0	**576**	**36.8**
Ferrets	Moderate	73	492	227	0	0	0	3	0	**795**	**50.7**
	Severe	3	33	0	0	0	0	0	0	**36**	**2.3**
	Total	**307**	**790**	**403**	**15**	**0**	**0**	**52**	**0**	**1,567**	**100.0**
	Non-recovery	0	0	0	0	0	10	0	0	**10**	**0.2**
	Mild	3,025	545	145	0	167	18	20	0	**3,920**	**80.2**
Other carnivores	Moderate	104	144	353	0	40	291	0	0	**932**	**19.1**
	Severe	0	0	0	0	27	1	0	0	**28**	**0.6**
	Total	**3,129**	**689**	**498**	**0**	**234**	**320**	**20**	**0**	**4,890**	**100.0**
	Non-recovery	0	14	0	0	0	0	56	0	**70**	**0.5**
	Mild	1,719	1,165	249	9,506	0	13	398	0	**13,050**	**97.8**
Horses, donkeys and cross-breeds	Moderate	37	84	6	36	0	0	51	0	**214**	**1.6**
	Severe	4	2	0	6	0	0	0	0	**12**	**0.1**
	Total	**1,760**	**1,265**	**255**	**9,548**	**0**	**13**	**505**	**0**	**13,346**	**100.0**
Pigs	Non-recovery	1,769	3,052	357	27	0	0	9,936	0	**15,141**	**17.3**

	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	%
	Mild	11,824	23,518	9,339	879	1,534	88	1,666	0	**48,848**	**55.7**
	Moderate	5,866	9,420	4,094	42	14	0	1,872	0	**21,308**	**24.3**
	Severe	699	1,324	328	0	120	0	1	0	**2,472**	**2.8**
	Total	**20,158**	**37,314**	**14,118**	**948**	**1,668**	**88**	**13,475**	**0**	**87,769**	**100.0**
	Non-recovery	87	1	0	0	0	0	7	0	**95**	**3.9**
	Mild	495	812	66	113	0	0	111	0	**1,597**	**65.8**
Goats	Moderate	429	237	14	2	0	0	34	0	**716**	**29.5**
	Severe	2	15	2	0	0	0	0	0	**19**	**0.8**
	Total	**1,013**	**1,065**	**82**	**115**	**0**	**0**	**152**	**0**	**2,427**	**100.0**
	Non-recovery	197	318	0	0	0	0	647	0	**1,162**	**1.6**
	Mild	8,004	5,583	1,185	51,973	379	0	853	76	**68,053**	**91.9**
Sheep	Moderate	1,419	2,183	145	46	8	0	161	0	**3,962**	**5.3**
	Severe	188	694	13	0	8	0	0	0	**903**	**1.2**
	Total	**9,808**	**8,778**	**1,343**	**52,019**	**395**	**0**	**1,661**	**76**	**74,080**	**100.0**
	Non-recovery	7	8	0	0	0	0	4	0	**19**	**0.1**
	Mild	10,438	9,481	3,565	474	2,343	0	3,757	16	**30,074**	**85.2**
Cattle	Moderate	418	1,461	394	7	72	0	2,615	0	**4,967**	**14.1**
	Severe	3	90	133	0	4	0	4	0	**234**	**0.7**
	Total	**10,866**	**11,040**	**4,092**	**481**	**2,419**	**0**	**6,380**	**16**	**35,294**	**100.0**
	Non-recovery	0	0	0	0	0	0	0	0	**0**	**0.0**
	Mild	83	0	0	0	0	0	0	0	**83**	**37.4**
Prosimians	Moderate	129	0	0	0	0	0	0	0	**129**	**58.1**
	Severe	10	0	0	0	0	0	0	0	**10**	**4.5**
	Total	**222**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**222**	**100.0**
	Non-recovery	25	10	0	0	0	0	0	0	**35**	**6.0**
	Mild	102	18	7	112	0	0	0	0	**239**	**40.9**
Marmoset and tamarins	Moderate	62	98	150	0	0	0	0	0	**310**	**53.1**
	Severe	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**189**	**126**	**157**	**112**	**0**	**0**	**0**	**0**	**584**	**100.0**
	Non-recovery	0	0	0	0	0	0	0	0	**0**	**0.0**
	Mild	0	20	0	0	0	0	0	0	**20**	**80.0**
Squirrel monkey	Moderate	0	4	0	0	0	0	0	0	**4**	**16.0**
	Severe	0	1	0	0	0	0	0	0	**1**	**4.0**
	Total	**0**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**25**	**100.0**
	Non-recovery	2	24	7	0	0	0	2	0	**35**	**0.4**
	Mild	141	701	3,948	945	0	0	7	0	**5,742**	**58.9**
Cynomolgus monkey	Moderate	87	325	3,258	0	0	0	6	0	**3,676**	**37.7**
	Severe	8	56	224	0	0	0	0	0	**288**	**3.0**
	Total	**238**	**1,106**	**7,437**	**945**	**0**	**0**	**15**	**0**	**9,741**	**100.0**
	Non-recovery	15	3	0	0	0	0	0	0	**18**	**3.6**
	Mild	78	117	0	15	0	0	0	0	**210**	**41.7**
Rhesus monkey	Moderate	103	166	0	0	0	0	0	0	**269**	**53.4**
	Severe	5	2	0	0	0	0	0	0	**7**	**1.4**
	Total	**201**	**288**	**0**	**15**	**0**	**0**	**0**	**0**	**504**	**100.0**
	Non-recovery	0	0	0	7	0	0	0	0	**7**	**23.3**
	Mild	0	14	0	5	0	0	0	0	**19**	**63.3**
Vervets (Chlorocebus spp.)	Moderate	0	4	0	0	0	0	0	0	**4**	**13.3**
	Severe	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**18**	**0**	**12**	**0**	**0**	**0**	**0**	**30**	**100.0**
	Non-recovery	0	2	0	0	0	0	0	0	**2**	**4.1**
	Mild	17	7	0	0	0	0	0	0	**24**	**49.0**
Baboons	Moderate	10	3	0	0	0	0	0	0	**13**	**26.5**
	Severe	0	10	0	0	0	0	0	0	**10**	**20.4**
	Total	**27**	**22**	**0**	**0**	**0**	**0**	**0**	**0**	**49**	**100.0**
	Non-recovery	0	0	0	0	0	0	0	0	**0**	**0.0**
Other species of old world monkeys (Cercopithecoidea)	Mild	0	7	0	12	0	0	0	0	**19**	**65.5**
	Moderate	0	10	0	0	0	0	0	0	**10**	**34.5**
	Severe	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**17**	**0**	**12**	**0**	**0**	**0**	**0**	**29**	**100.0**
	Non-recovery	65	0	0	0	0	4	0	0	**69**	**1.1**
	Mild	3,495	432	0	3	484	159	270	0	**4,843**	**77.7**
Other mammals	Moderate	1,077	57	34	8	13	71	0	0	**1,260**	**20.2**
	Severe	4	59	0	1	0	0	0	0	**64**	**1.0**
	Total	**4,641**	**548**	**34**	**12**	**497**	**234**	**270**	**0**	**6,236**	**100.0**
	Non-recovery	1,637	733	38	1,444	0	0	131	0	**3,983**	**0.8**
	Mild	52,310	81,168	115,317	105,580	3,242	88	1,930	0	**359,635**	**73.8**
Domestic fowl	Moderate	51,317	18,134	25,519	15,067	636	0	1,259	0	**111,932**	**23.0**
	Severe	240	4,620	6,316	110	0	0	238	0	**11,524**	**2.4**
	Total	**105,504**	**104,655**	**147,190**	**122,201**	**3,878**	**88**	**3,558**	**0**	**487,074**	**100.0**
	Non-recovery	2,464	49	0	0	0	0	122	0	**2,635**	**2.6**
Other birds	Mild	45,446	10,666	2,334	1,032	2,421	3,802	374	0	**66,075**	**64.1**
	Moderate	8,282	763	367	22,461	558	1,056	239	0	**33,726**	**32.7**

	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	%
	Severe	29	300	312	0	0	0	15	0	**656**	**0.6**
	Total	**56,221**	**11,778**	**3,013**	**23,493**	**2,979**	**4,858**	**750**	**0**	**103,092**	**100.0**
	Non-recovery	2	18	0	0	0	0	0	0	**20**	**0.5**
	Mild	2,804	60	5	0	0	553	91	0	**3,513**	**87.3**
Reptiles	Moderate	379	114	0	0	0	0	0	0	**493**	**12.2**
	Severe	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**3,185**	**192**	**5**	**0**	**0**	**553**	**91**	**0**	**4,026**	**100.0**
	Non-recovery	400	0	0	0	0	0	1,114	0	**1,514**	**35.7**
	Mild	1,619	169	0	0	19	0	240	0	**2,047**	**48.3**
Rana	Moderate	0	0	0	0	0	0	0	0	**0**	**0.0**
	Severe	675	0	2	0	0	0	0	0	**677**	**16.0**
	Total	**2,694**	**169**	**2**	**0**	**19**	**0**	**1,354**	**0**	**4,238**	**100.0**
	Non-recovery	438	0	0	0	0	72	40	0	**550**	**2.5**
	Mild	13,990	2,995	60	0	237	0	112	0	**17,394**	**78.9**
Xenopus	Moderate	2,436	360	0	0	900	0	56	0	**3,752**	**17.0**
	Severe	355	0	0	0	0	0	0	0	**355**	**1.6**
	Total	**17,219**	**3,355**	**60**	**0**	**1,137**	**72**	**208**	**0**	**22,051**	**100.0**
	Non-recovery	102	0	0	0	0	0	403	0	**505**	**6.5**
	Mild	1,086	317	0	0	206	791	449	0	**2,849**	**36.4**
Other amphibians	Moderate	469	0	0	0	0	30	42	0	**541**	**6.9**
	Severe	3,922	0	0	0	0	0	0	0	**3,922**	**50.2**
	Total	**5,579**	**317**	**0**	**0**	**206**	**821**	**894**	**0**	**7,817**	**100.0**
	Non-recovery	27,521	28	7	0	0	0	430	0	**27,986**	**5.9**
	Mild	243,962	83,158	18,104	0	5,292	0	1,614	0	**352,130**	**74.1**
Zebra fish	Moderate	28,253	29,488	10,758	0	120	0	1,623	0	**70,242**	**14.8**
	Severe	13,343	3,443	8,364	0	0	0	0	0	**25,150**	**5.3**
	Total	**313,079**	**116,117**	**37,233**	**0**	**5,412**	**0**	**3,667**	**0**	**475,508**	**100.0**
	Non-recovery	45,561	18,579	0	0	1,265	309	908	0	**66,622**	**2.9**
	Mild	646,278	576,351	53,567	1,162	50,100	61,112	3,557	0	**1,392,127**	**59.8**
Other fish	Moderate	422,685	189,632	5,188	3,653	47,659	8,600	336	0	**677,753**	**29.1**
	Severe	29,881	111,205	39,445	2,730	8,411	124	0	0	**191,796**	**8.2**
	Total	**1,144,405**	**895,767**	**98,200**	**7,545**	**107,435**	**70,145**	**4,801**	**0**	**2,328,298**	**100.0**
	Non-recovery	1,600	0	0	0	0	0	4	0	**1,604**	**37.4**
	Mild	63	1,855	0	0	24	0	690	0	**2,632**	**61.4**
Cephalopods	Moderate	0	0	0	0	0	0	0	0	**0**	**0.0**
	Severe	39	0	0	0	9	0	0	0	**48**	**1.1**
	Total	**1,702**	**1,855**	**0**	**0**	**33**	**0**	**694**	**0**	**4,284**	**100.0**
	Non-recovery	**404,702**	**87,965**	**15,843**	**47,880**	**1,642**	**445**	**53,617**	**0**	**612,094**	**5.7**
	Mild	**2,463,458**	**1,390,027**	**1,089,396**	**303,526**	**72,087**	**73,358**	**77,013**	**349**	**5,469,214**	**50.6**
All Species	**Moderate**	**1,800,146**	**1,144,866**	**493,549**	**123,628**	**50,546**	**10,785**	**35,101**	**0**	**3,658,621**	**33.9**
	Severe	**310,571**	**346,113**	**336,521**	**62,060**	**8,822**	**132**	**706**	**0**	**1,064,925**	**9.9**
	Total	**4,978,877**	**2,968,971**	**1,935,309**	**537,094**	**133,097**	**84,720**	**166,437**	**349**	**10,804,854**	**100.0**

Table 6: Uses of animals in all sub-categories of research and testing by severities (2018)

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Basic research						
Oncology	22,152	198,194	284,429	52,177	**556,952**	**5.2**
Cardiovascular Blood and Lymphatic System	50,950	148,988	106,794	16,873	**323,605**	**3**
Nervous System	113,611	376,951	320,660	90,288	**901,510**	**8.3**
Respiratory System	8,571	22,009	30,989	3,887	**65,456**	**0.6**
Gastrointestinal System including Liver	14,284	55,649	83,151	16,844	**169,928**	**1.6**
Musculoskeletal System	3,660	55,345	39,392	8,875	**107,272**	**1**
Immune System	53,287	395,042	255,400	69,536	**773,265**	**7.2**
Urogenital/Reproductive System	14,487	72,710	33,260	1,679	**122,136**	**1.1**
Sensory Organs (skin, eyes and ears)	10,100	43,663	19,391	4,652	**77,806**	**0.7**
Endocrine System/Metabolism	12,570	118,614	78,943	12,780	**222,907**	**2.1**
Multisystemic	12,654	296,372	56,774	12,760	**378,560**	**3.5**
Ethology / Animal Behaviour /Animal Biology	10,691	577,024	463,719	10,213	**1,061,647**	**9.8**
Other basic research	77,685	102,897	27,244	10,007	**217,833**	**2**
Translational and applied research						
Human Cancer	5,115	123,120	366,258	47,588	**542,081**	**5**
Human Infectious Disorders	4,321	139,384	90,980	32,521	**267,206**	**2.5**
Human Cardiovascular Disorders	10,692	29,385	25,805	5,965	**71,847**	**0.7**
Human Nervous and Mental Disorders	19,409	124,059	139,660	27,174	**310,302**	**2.9**
Human Respiratory Disorders	3,561	22,470	28,548	7,000	**61,579**	**0.6**
Human Gastrointestinal Disorders including Liver	1,219	12,088	23,138	4,758	**41,203**	**0.4**
Human Musculoskeletal Disorders	3,054	15,781	17,957	7,046	**43,838**	**0.4**
Human Immune Disorders	2,503	31,081	46,697	10,680	**90,961**	**0.8**
Human Urogenital/Reproductive Disorders	1,563	4,621	6,512	1,881	**14,577**	**0.1**
Human Sensory Organ Disorders (skin, eyes and ears)	1,317	20,532	18,129	2,308	**42,286**	**0.4**
Human Endocrine/Metabolism Disorders	4,669	58,296	51,987	2,883	**117,835**	**1.1**
Other Human Disorders	5,026	13,296	12,945	3,961	**35,228**	**0.3**
Animal Diseases and Disorders	18,853	615,854	193,085	124,739	**952,531**	**8.8**
Animal Welfare	1,586	108,349	31,739	1,051	**142,725**	**1.3**
Diagnosis of diseases	1,737	23,802	61,620	61,114	**148,273**	**1.4**
Plant diseases	0	24	14	0	**38**	**0**
Non-regulatory toxicology and ecotoxicology	3,340	47,885	29,792	5,444	**86,461**	**0.8**
Regulatory use						
Quality control (incl batch safety and potency testing)						
Batch safety testing	792	124,485	12,678	7,814	**145,769**	**1.3**
Pyrogenicity testing	104	13,762	16,317	270	**30,453**	**0.3**
Batch potency testing	8,913	362,083	235,037	253,764	**859,797**	**8**
Other quality controls	0	32,653	6,996	3,394	**43,043**	**0.4**
Toxicity and other safety testing including pharmacology						
Acute and sub-acute toxicity testing methods						
LD50, LC50	0	21,547	2,829	9,641	**34,017**	**0.3**
Other lethal methods	0	201	12	309	**522**	**0**
Non lethal methods	0	12,753	12,767	1,890	**27,410**	**0.3**
Skin irritation/corrosion	0	2,932	611	578	**4,121**	**0**
Skin sensitisation	0	25,722	12,133	1,791	**39,646**	**0.4**
Eye irritation/corrosion	0	486	251	143	**880**	**0**
Repeated dose toxicity						
up to 28 days	50	39,633	21,595	2,315	**63,593**	**0.6**
29 - 90 days	0	24,026	10,634	341	**35,001**	**0.3**
> 90 days	0	11,495	7,736	377	**19,608**	**0.2**
Carcinogenicity	40	6,236	6,850	456	**13,582**	**0.1**
Genotoxicity	117	6,633	1,652	273	**8,675**	**0.1**
Reproductive toxicity	0	63,670	27,024	480	**91,174**	**0.8**
Developmental toxicity	1	55,974	15,745	6,701	**78,421**	**0.7**
Neurotoxicity	0	3,160	554	807	**4,521**	**0**
Kinetics	740	41,649	23,586	954	**66,929**	**0.6**
Pharmaco-dynamics (incl safety pharmacology)	4,463	49,018	28,787	1,551	**83,819**	**0.8**
Phototoxicity	0	294	167	58	**519**	**0**
Ecotoxicity						
Acute toxicity	60	30,174	5,362	21,413	**57,009**	**0.5**
Chronic toxicity	0	21,221	10,501	1,670	**33,392**	**0.3**
Reproductive ecotoxicity	0	225	15	0	**240**	**0**
Endocrine activity	0	2,040	0	63	**2,103**	**0**
Bioaccumulation	0	3,951	315	200	**4,466**	**0**
Other ecotoxicity	0	1,667	14	1,661	**3,342**	**0**
Safety testing in food and feed area	0	32,621	1,035	7,841	**41,497**	**0.4**
Target animal safety	0	5,771	368	663	**6,802**	**0.1**
Other toxicity/safety testing	54	6,582	3,329	268	**10,233**	**0.1**
Other efficacy and tolerance testing						
Other efficacy and tolerance testing	509	86,732	28,649	8,835	**124,725**	**1.2**

		Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Routine production							
	Blood based products	47,773	171,191	76,181	338	**295,483**	**2.7**
	Monoclonal antibody by mouse ascites method	0	1,842	1,599	51,500	**54,941**	**0.5**
	Other product types	107	130,493	45,848	10,222	**186,670**	**1.7**
Other							
	Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,642	72,087	50,546	8,822	**133,097**	**1.2**
	Preservation of species	445	73,358	10,785	132	**84,720**	**0.8**
	Higher education or training for the acquisition, maintenance or improvement of vocational skills	53,617	77,013	35,101	706	**166,437**	**1.5**
	Forensic enquiries	0	349	0	0	**349**	**0**
Total		**612,094**	**5,469,214**	**3,658,621**	**1,064,925**	**10,804,854**	**100**
%		**5.7**	**50.6**	**33.9**	**9.9**	**100**	

Table 7: Basic research related uses by species and type of research (2018)

	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	522,054	253,677	640,431	56,662	107,515	80,269	677,839	94,995	55,199	170,662	182,436	14,785	91,751	**2,948,275**	**59.2**
Rats	4,701	31,242	133,989	6,334	14,705	4,660	9,889	5,700	5,569	20,857	10,557	12,262	17,679	**278,144**	**5.6**
Guinea-Pigs	33	225	84	850	73	0	285	31	1,287	200	109	74	9,666	**12,917**	**0.3**
Hamsters (Syrian)	25	18	119	0	56	2	408	49	0	190	0	16	57	**940**	**0**
Mongolian gerbil	0	0	1,009	0	64	0	237	0	498	0	264	2	215	**2,289**	**0**
Other rodents	81	0	123	0	0	5	508	109	157	10	4,302	11,364	463	**17,122**	**0.3**
Rabbits															
Rabbits	191	1,634	225	484	1,006	463	547	496	587	380	870	4,141	3,772	**14,796**	**0.3**
Carnivores															
Cats	0	0	63	0	178	56	47	0	0	44	206	0	78	**672**	**0**
Dogs	292	37	20	24	171	251	41	50	6	57	220	186	220	**1,575**	**0**
Ferrets	0	0	189	55	0	0	33	0	0	0	30	0	0	**307**	**0**
Other carnivores	0	10	0	0	0	0	0	0	0	0	0	3,119	0	**3,129**	**0.1**
Farm animals															
Horses, donkeys and cross-breeds	4	66	80	17	0	109	462	336	20	566	49	51	0	**1,760**	**0**
Pigs	118	1,873	689	549	3,541	319	685	621	136	763	3,080	6,461	1,323	**20,158**	**0.4**
Goats	0	0	0	0	102	0	51	10	0	242	0	464	144	**1,013**	**0**
Sheep	5	399	216	8	454	1,134	3,359	953	35	492	127	2,217	409	**9,808**	**0.2**
Cattle	0	31	3	95	505	0	1,913	1,316	0	3,217	1,448	2,187	151	**10,866**	**0.2**
Non-human primates															
Prosimians	0	0	93	0	0	0	0	0	0	66	0	63	0	**222**	**0**
Marmoset and tamarins	0	0	75	0	0	0	0	10	0	12	41	51	0	**189**	**0**
Cynomolgus monkey	0	0	50	0	0	0	38	41	4	31	60	0	14	**238**	**0**
Rhesus monkey	0	56	114	0	0	0	19	0	2	0	2	0	8	**201**	**0**
Baboons	0	0	0	0	0	0	0	0	0	0	0	27	0	**27**	**0**
Other mammals															
Other mammals	0	14	117	0	0	8	19	30	6	13	66	4,230	138	**4,641**	**0.1**
Birds															
Domestic fowl	4	233	4,513	0	23,809	2	3,690	11	205	2,388	1,646	61,813	7,190	**105,504**	**2.1**
Other birds	0	803	655	0	254	55	105	55	27	867	61	51,808	1,531	**56,221**	**1.1**
Reptiles															
Reptiles	0	136	124	17	0	6	0	0	5	0	0	2,897	0	**3,185**	**0.1**
Amphibians															
Rana	0	0	400	0	0	0	0	0	9	800	0	1,485	0	**2,694**	**0.1**
Xenopus	987	162	3,332	5	0	282	14	1,289	56	3,017	1,213	2,145	4,717	**17,219**	**0.3**
Other amphibians	0	126	284	0	0	1,118	0	0	91	64	280	3,616	0	**5,579**	**0.1**
Fish															
Zebra fish	28,085	30,692	112,501	0	5,710	17,910	16,374	4,977	12,381	11,200	33,213	19,691	20,345	**313,079**	**6.3**
Other fish	372	2,171	1,996	356	11,785	588	56,702	10,057	1,526	6,769	138,280	855,841	57,962	**1,144,405**	**23**
Cephalopods															
Cephalopods	0	0	16	0	0	35	0	1,000	0	0	0	651	0	**1,702**	**0**
Totals															
Total	**556,952**	**323,605**	**901,510**	**65,456**	**169,928**	**107,272**	**773,265**	**122,136**	**77,806**	**222,907**	**378,560**	**1,061,647**	**217,833**	**4,978,877**	**100**
%	**11.2**	**6.5**	**18.1**	**1.3**	**3.4**	**2.2**	**15.5**	**2.5**	**1.6**	**4.5**	**7.6**	**21.3**	**4.4**	**100**	

Table 8.1: Translational and applied research related uses by species and type of research (Part 1) (2018)

		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	524,600	210,896	44,708	198,445	46,720	27,949	26,170	86,795	8,933
	Rats	6,988	3,603	19,573	82,843	9,809	11,935	10,080	3,393	4,786
	Guinea-Pigs	0	1,717	589	147	3,250	23	104	189	92
	Hamsters (Syrian)	192	1,344	607	271	0	41	0	0	0
	Hamsters (Chinese)	20	0	0	0	0	0	0	0	0
	Mongolian gerbil	0	1,464	0	0	0	0	0	0	0
	Other rodents	0	507	0	0	37	0	511	0	0
	Rabbits									
	Rabbits	2,549	890	529	275	808	63	1,069	339	113
	Carnivores									
	Cats	0	0	0	0	0	0	0	0	0
	Dogs	45	23	157	136	56	10	56	14	16
	Ferrets	0	645	0	0	0	0	0	0	0
	Other carnivores	0	0	0	0	0	0	0	0	0
	Farm animals									
	Horses, donkeys and cross-breeds	0	2	0	0	0	0	0	0	0
	Pigs	168	323	2,750	402	696	872	424	76	402
	Goats	0	77	26	0	0	0	37	0	2
	Sheep	26	635	906	91	80	0	486	3	52
	Cattle	27	97	6	0	0	1	0	0	5
	Non-human primates									
	Marmoset and tamarins	0	68	0	3	0	0	0	33	0
	Squirrel monkey	0	25	0	0	0	0	0	0	0
	Cynomolgus monkey	24	215	30	131	62	9	3	59	8
	Rhesus monkey	3	252	4	19	0	0	0	0	3
	Vervets (Chlorocebus spp.)	0	18	0	0	0	0	0	0	0
	Baboons	0	9	10	3	0	0	0	0	0
	Other species of old world monkeys (Cercopithecoidea)	0	7	0	0	0	0	0	0	0
	Other mammals									
	Other mammals	74	28	0	0	16	0	0	0	0
Birds										
	Domestic fowl	0	211	0	0	45	300	0	54	0
	Other birds	0	335	0	0	0	0	0	6	0
Reptiles										
	Reptiles	0	0	0	30	0	0	0	0	0
Amphibians										
	Rana	0	0	0	0	0	0	0	0	0
	Xenopus	527	0	0	25	0	0	0	0	0
	Other amphibians	0	0	0	0	0	0	0	0	0
Fish										
	Zebra fish	2,176	43,710	1,880	27,481	0	0	4,898	0	165
	Other fish	4,662	105	72	0	0	0	0	0	0
Cephalopods										
	Cephalopods	0	0	0	0	0	0	0	0	0
Totals										
	Total	**542,081**	**267,206**	**71,847**	**310,302**	**61,579**	**41,203**	**43,838**	**90,961**	**14,577**
	%	**18.3**	**9**	**2.4**	**10.5**	**2.1**	**1.4**	**1.5**	**3.1**	**0.5**

Table 8.2: Translational and applied research related uses by species and type of research (Part 2) (2018)

	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	29,252	84,792	26,764	40,497	2,427	135,773	0	18,801	**1,513,522**	**51**
Rats	7,700	27,397	7,713	1,299	304	4,097	0	15,419	**216,939**	**7.3**
Guinea-Pigs	310	60	42	2,809	18	411	0	603	**10,364**	**0.3**
Hamsters (Syrian)	20	580	0	914	0	0	0	42	**4,011**	**0.1**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	**20**	**0**
Mongolian gerbil	44	0	0	472	0	0	0	0	**1,980**	**0.1**
Other rodents	2	0	0	160	0	101	0	63	**1,381**	**0**
Rabbits										
Rabbits	888	256	310	1,567	302	886	38	596	**11,478**	**0.4**
Carnivores										
Cats	16	0	0	754	32	3	0	0	**805**	**0**
Dogs	35	98	20	8,154	129	84	0	2,142	**11,175**	**0.4**
Ferrets	0	0	0	62	0	83	0	0	**790**	**0**
Other carnivores	0	0	0	175	514	0	0	0	**689**	**0**
Farm animals										
Horses, donkeys and cross-breeds	0	0	0	1,120	128	15	0	0	**1,265**	**0**
Pigs	222	2,115	203	21,765	5,967	695	0	234	**37,314**	**1.3**
Goats	0	0	0	820	22	81	0	0	**1,065**	**0**
Sheep	0	48	44	4,063	734	1,599	0	11	**8,778**	**0.3**
Cattle	0	216	0	8,712	1,859	117	0	0	**11,040**	**0.4**
Non-human primates										
Marmoset and tamarins	22	0	0	0	0	0	0	0	**126**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	**25**	**0**
Cynomolgus monkey	38	48	84	0	0	0	0	395	**1,106**	**0**
Rhesus monkey	0	0	7	0	0	0	0	0	**288**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	**18**	**0**
Baboons	0	0	0	0	0	0	0	0	**22**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	10	0	0	0	0	0	**17**	**0**
Other mammals										
Other mammals	0	8	0	229	109	84	0	0	**548**	**0**
Birds										
Domestic fowl	0	87	5	69,190	32,225	2,100	0	438	**104,655**	**3.5**
Other birds	0	0	1	9,723	918	282	0	513	**11,778**	**0.4**
Reptiles										
Reptiles	0	0	0	44	118	0	0	0	**192**	**0**
Amphibians										
Rana	0	0	0	2	0	0	0	167	**169**	**0**
Xenopus	0	28	0	0	0	0	0	2,775	**3,355**	**0.1**
Other amphibians	0	0	9	308	0	0	0	0	**317**	**0**
Fish										
Zebra fish	3,729	2,090	16	1,067	2,262	482	0	26,161	**116,117**	**3.9**
Other fish	0	12	0	776,961	94,657	1,380	0	17,918	**895,767**	**30.2**
Cephalopods										
Cephalopods	8	0	0	1,664	0	0	0	183	**1,855**	**0.1**
Totals										
Total	**42,286**	**117,835**	**35,228**	**952,531**	**142,725**	**148,273**	**38**	**86,461**	**2,968,971**	**100**
%	**1.4**	**4**	**1.2**	**32.1**	**4.8**	**5**	**0**	**2.9**	**100**	

Table 9: Regulatory uses by species and type of use (2018)

	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	72,609	0	548,414	33,776	222,800	54,857	**932,456**	**48.2**
Rats	3,038	0	159,456	1,237	306,532	5,086	**475,349**	**24.6**
Guinea-Pigs	15,832	0	57,081	1,076	29,168	1,057	**104,214**	**5.4**
Hamsters (Syrian)	12	0	4,286	473	570	445	**5,786**	**0.3**
Hamsters (Chinese)	0	0	0	0	0	0	**0**	**0**
Mongolian gerbil	0	0	192	0	125	20	**337**	**0**
Other rodents	60	0	0	0	842	40	**942**	**0**
Rabbits								
Rabbits	2,006	30,453	18,488	1,221	34,096	3,580	**89,844**	**4.6**
Carnivores								
Cats	196	0	20	71	631	461	**1,379**	**0.1**
Dogs	583	0	0	27	9,089	1,181	**10,880**	**0.6**
Ferrets	108	0	180	0	0	115	**403**	**0**
Other carnivores	182	0	270	0	0	46	**498**	**0**
Farm animals								
Horses, donkeys and cross-breeds	0	0	1	0	167	87	**255**	**0**
Pigs	2,982	0	1,477	260	4,561	4,838	**14,118**	**0.7**
Goats	0	0	1	0	81	0	**82**	**0**
Sheep	146	0	456	18	477	246	**1,343**	**0.1**
Cattle	432	0	1,253	0	1,293	1,114	**4,092**	**0.2**
Non-human primates								
Prosimians	0	0	0	0	0	0	**0**	**0**
Marmoset and tamarins	0	0	0	0	157	0	**157**	**0**
Squirrel monkey	0	0	0	0	0	0	**0**	**0**
Cynomolgus monkey	50	0	0	0	7,229	158	**7,437**	**0.4**
Rhesus monkey	0	0	0	0	0	0	**0**	**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	34	0	**34**	**0**
Birds								
Domestic fowl	43,225	0	44,645	3,259	9,535	46,526	**147,190**	**7.6**
Other birds	792	0	350	0	720	1,151	**3,013**	**0.2**
Reptiles								
Reptiles	0	0	0	0	5	0	**5**	**0**
Amphibians								
Rana	0	0	0	2	0	0	**2**	**0**
Xenopus	0	0	0	0	60	0	**60**	**0**
Other amphibians	0	0	0	0	0	0	**0**	**0**
Fish								
Zebra fish	0	0	0	42	37,191	0	**37,233**	**1.9**
Other fish	3,516	0	23,227	1,581	66,159	3,717	**98,200**	**5.1**
Cephalopods								
Cephalopods	0	0	0	0	0	0	**0**	**0**
Totals								
Total	**145,769**	**30,453**	**859,797**	**43,043**	**731,522**	**124,725**	**1,935,309**	**100**
%	**7.5**	**1.6**	**44.4**	**2.2**	**37.8**	**6.4**	**100**	

Table 10.1: Toxicity and other safety testing including pharmacology by species and type of use (Part 1) (2018)

	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	Reproductive toxicity	Developmental toxicity	Safety testing in food and feed area
Mammals														
Rodents														
Mice	21,313	164	12,237	346	11,982	0	15,967	5,027	2,216	5,481	3,247	1,247	3,097	37,446
Rats	4,131	358	12,759	121	0	0	39,945	24,613	13,782	8,101	5,427	85,806	52,379	104
Guinea-Pigs	126	0	774	0	27,528	0	0	0	15	0	0	0	0	0
Hamsters (Syrian)	0	0	267	85	7	6	0	161	0	0	0	0	0	0
Mongolian gerbil	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
Rabbits														
Rabbits	0	0	538	3,528	99	874	2,002	1,782	306	0	0	3,561	18,186	60
Carnivores														
Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Dogs	0	0	479	0	0	0	2,623	1,527	1,281	0	1	23	88	0
Farm animals														
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pigs	0	0	14	41	30	0	884	320	264	0	0	0	0	414
Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	6
Sheep	0	0	0	0	0	0	0	0	0	0	0	25	0	99
Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	83
Non-human primates														
Marmoset and tamarins	0	0	0	0	0	0	10	32	89	0	0	0	0	0
Cynomolgus monkey	0	0	270	0	0	0	2,162	1,539	1,595	0	0	32	213	0
Other mammals														
Other mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Birds														
Domestic fowl	4,347	0	0	0	0	0	0	0	60	0	0	0	0	3,060
Other birds	209	0	10	0	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	0
Amphibians														
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish														
Zebra fish	1,874	0	62	0	0	0	0	0	0	0	0	0	3,096	0
Other fish	2,017	0	0	0	0	0	0	0	0	0	0	480	1,362	225
Totals														
Total	**34,017**	**522**	**27,410**	**4,121**	**39,646**	**880**	**63,593**	**35,001**	**19,608**	**13,582**	**8,675**	**91,174**	**78,421**	**41,497**
%	**4.7**	**0.1**	**3.7**	**0.6**	**5.4**	**0.1**	**8.7**	**4.8**	**2.7**	**1.9**	**1.2**	**12.5**	**10.7**	**5.7**

Table 10.2: Toxicity and other safety testing including pharmacology by species and type of use (Part 2) (2018)

						EcoToxicity									
		Target animal safety	Neurotoxicity	Kinetics	Pharmaco - dynamics (incl safety pharmacology)	Phototoxicity	Acute toxicity	Chronic toxicity	Reproductive ecotoxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Other toxicity / safety testing	Total	%
Mammals															
	Rodents														
	Mice	1,007	962	38,211	49,632	411	8,063	472	0	0	0	0	4,272	**222,800**	**30.5**
	Rats	0	1,207	21,274	30,698	70	833	920	0	0	0	0	4,004	**306,532**	**41.9**
	Guinea-Pigs	0	0	75	432	38	148	0	0	0	0	0	32	**29,168**	**4**
	Hamsters (Syrian)	4	0	40	0	0	0	0	0	0	0	0	0	**570**	**0.1**
	Mongolian gerbil	0	0	0	125	0	0	0	0	0	0	0	0	**125**	**0**
	Other rodents	842	0	0	0	0	0	0	0	0	0	0	0	**842**	**0.1**
	Rabbits														
	Rabbits	109	0	736	844	0	53	252	0	0	0	0	1,166	**34,096**	**4.7**
	Carnivores														
	Cats	92	0	539	0	0	0	0	0	0	0	0	0	**631**	**0.1**
	Dogs	235	0	1,868	872	0	0	0	0	0	0	0	92	**9,089**	**1.2**
	Farm animals														
	Horses, donkeys and cross-breeds	0	0	144	7	0	0	0	0	0	0	16	0	**167**	**0**
	Pigs	493	0	1,222	777	0	0	0	0	0	22	42	38	**4,561**	**0.6**
	Goats	22	0	53	0	0	0	0	0	0	0	0	0	**81**	**0**
	Sheep	80	0	205	66	0	0	2	0	0	0	0	0	**477**	**0.1**
	Cattle	398	0	620	160	0	0	0	0	0	0	32	0	**1,293**	**0.2**
	Non-human primates														
	Marmoset and tamarins	0	0	26	0	0	0	0	0	0	0	0	0	**157**	**0**
	Cynomolgus monkey	0	0	734	206	0	0	0	0	0	0	3	475	**7,229**	**1**
	Other mammals														
	Other mammals	34	0	0	0	0	0	0	0	0	0	0	0	**34**	**0**
Birds															
	Domestic fowl	1,473	0	561	0	0	0	0	0	0	0	0	34	**9,535**	**1.3**
	Other birds	0	0	75	0	0	268	38	0	0	0	0	120	**720**	**0.1**
Reptiles															
	Reptiles	5	0	0	0	0	0	0	0	0	0	0	0	**5**	**0**
Amphibians															
	Xenopus	0	0	0	0	0	0	0	0	60	0	0	0	**60**	**0**
Fish															
	Zebra fish	0	2,352	0	0	0	15,269	12,110	0	370	399	1,659	0	**37,191**	**5.1**
	Other fish	2,008	0	546	0	0	32,375	19,598	240	1,673	4,045	1,590	0	**66,159**	**9**
Totals															
	Total	**6,802**	**4,521**	**66,929**	**83,819**	**519**	**57,009**	**33,392**	**240**	**2,103**	**4,466**	**3,342**	**10,233**	**731,522**	**100**
	%	**0.9**	**0.6**	**9.1**	**11.5**	**0.1**	**7.8**	**4.6**	**0**	**0.3**	**0.6**	**0.5**	**1.4**	**100**	

Table 11: Regulatory uses by species and type of legislation (2018)

		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	767,056	96,305	17,072	6,029	5,605	789	38,973	62	565	**932,456**	**48.2**
	Rats	303,262	9,611	2,882	112,986	37,801	999	4,843	269	2,696	**475,349**	**24.6**
	Guinea-Pigs	63,607	15,033	24,061	1,269	33	33	0	73	105	**104,214**	**5.4**
	Hamsters (Syrian)	796	4,635	355	0	0	0	0	0	0	**5,786**	**0.3**
	Mongolian gerbil	192	145	0	0	0	0	0	0	0	**337**	**0**
	Other rodents	60	0	0	0	842	20	0	0	20	**942**	**0**
	Rabbits											
	Rabbits	53,582	12,504	6,348	13,341	2,673	269	118	24	985	**89,844**	**4.6**
	Carnivores											
	Cats	10	1,303	0	0	0	0	66	0	0	**1,379**	**0.1**
	Dogs	8,094	2,547	22	36	108	0	43	0	30	**10,880**	**0.6**
	Ferrets	368	35	0	0	0	0	0	0	0	**403**	**0**
	Other carnivores	0	498	0	0	0	0	0	0	0	**498**	**0**
	Farm animals											
	Horses, donkeys and cross-breeds	75	180	0	0	0	0	0	0	0	**255**	**0**
	Pigs	2,955	10,094	205	0	0	0	69	569	226	**14,118**	**0.7**
	Goats	1	64	0	0	17	0	0	0	0	**82**	**0**
	Sheep	25	1,094	114	0	0	0	92	18	0	**1,343**	**0.1**
	Cattle	0	4,038	0	0	10	0	0	44	0	**4,092**	**0.2**
	Non-human primates											
	Marmoset and tamarins	157	0	0	0	0	0	0	0	0	**157**	**0**
	Cynomolgus monkey	7,427	0	0	0	0	0	0	0	10	**7,437**	**0.4**
	Other mammals											
	Other mammals	0	0	0	0	34	0	0	0	0	**34**	**0**
Birds												
	Domestic fowl	1,732	131,877	0	0	138	0	0	13,443	0	**147,190**	**7.6**
	Other birds	0	2,488	0	0	525	0	0	0	0	**3,013**	**0.2**
Reptiles												
	Reptiles	0	0	0	0	5	0	0	0	0	**5**	**0**
Amphibians												
	Rana	2	0	0	0	0	0	0	0	0	**2**	**0**
	Xenopus	0	0	0	0	60	0	0	0	0	**60**	**0**
Fish												
	Zebra fish	3,581	0	1,725	16,176	2,559	0	0	0	13,192	**37,233**	**1.9**
	Other fish	23,300	12,275	499	11,869	11,551	0	56	2,679	35,971	**98,200**	**5.1**
Totals												
	Total	**1,236,282**	**304,726**	**53,283**	**161,706**	**61,961**	**2,110**	**44,260**	**17,181**	**53,800**	**1,935,309**	**100**
	%	**63.9**	**15.7**	**2.8**	**8.4**	**3.2**	**0.1**	**2.3**	**0.9**	**2.8**	**100**	

Table 12: Regulatory uses by species and origin of regulatory requirement (2018)

	Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total	%
Mammals					
Rodents					
Mice	884,091	10,078	38,287	**932,456**	**48.2**
Rats	471,680	752	2,917	**475,349**	**24.6**
Guinea-Pigs	98,013	1,036	5,165	**104,214**	**5.4**
Hamsters (Syrian)	5,328	0	458	**5,786**	**0.3**
Mongolian gerbil	145	192	0	**337**	**0**
Other rodents	922	20	0	**942**	**0**
Rabbits					
Rabbits	77,973	470	11,401	**89,844**	**4.6**
Carnivores					
Cats	1,367	0	12	**1,379**	**0.1**
Dogs	10,798	4	78	**10,880**	**0.6**
Ferrets	403	0	0	**403**	**0**
Other carnivores	498	0	0	**498**	**0**
Farm animals					
Horses, donkeys and cross-breeds	255	0	0	**255**	**0**
Pigs	12,161	21	1,936	**14,118**	**0.7**
Goats	82	0	0	**82**	**0**
Sheep	1,303	0	40	**1,343**	**0.1**
Cattle	4,082	0	10	**4,092**	**0.2**
Non-human primates					
Marmoset and tamarins	157	0	0	**157**	**0**
Cynomolgus monkey	7,370	0	67	**7,437**	**0.4**
Other mammals					
Other mammals	34	0	0	**34**	**0**
Birds					
Domestic fowl	139,610	0	7,580	**147,190**	**7.6**
Other birds	2,954	0	59	**3,013**	**0.2**
Reptiles					
Reptiles	5	0	0	**5**	**0**
Amphibians					
Rana	2	0	0	**2**	**0**
Xenopus	60	0	0	**60**	**0**
Fish					
Zebra fish	36,145	1,014	74	**37,233**	**1.9**
Other fish	76,606	20,254	1,340	**98,200**	**5.1**
Totals					
Total	**1,832,044**	**33,841**	**69,424**	**1,935,309**	**100**
%	**94.7**	**1.7**	**3.6**	**100**	

Table 13: Routine production uses by species and product type (2018)

	Blood based products	Other product types	Monoclonal antibody by mouse ascites method	Total	%
Mammals					
Rodents					
Mice	18,453	2,138	54,930	**75,521**	**14.1**
Rats	5,001	418	0	**5,419**	**1**
Guinea-Pigs	779	16	0	**795**	**0.1**
Hamsters (Syrian)	110	0	0	**110**	**0**
Mongolian gerbil	0	100	0	**100**	**0**
Rabbits	200,600	36,350	0	**236,950**	**44.1**
Rabbits					
Cats	6	13	0	**19**	**0**
Carnivores					
Dogs	623	84	0	**707**	**0.1**
Ferrets	15	0	0	**15**	**0**
Horses, donkeys and cross-breeds	9,548	0	0	**9,548**	**1.8**
Farm animals					
Pigs	348	600	0	**948**	**0.2**
Goats	113	2	0	**115**	**0**
Sheep	51,933	86	0	**52,019**	**9.7**
Cattle	363	118	0	**481**	**0.1**
Marmoset and tamarins	112	0	0	**112**	**0**
Non-human primates					
Cynomolgus monkey	748	197	0	**945**	**0.2**
Rhesus monkey	15	0	0	**15**	**0**
Vervets (Chlorocebus spp.)	5	7	0	**12**	**0**
Other species of old world monkeys (Cercopithecoidea)	12	0	0	**12**	**0**
Other mammals	0	1	11	**12**	**0**
Other mammals					
Domestic fowl	6,471	115,730	0	**122,201**	**22.8**
Birds					
Other birds	228	23,265	0	**23,493**	**4.4**
Other fish	0	7,545	0	**7,545**	**1.4**
Totals					
Total	**295,483**	**186,670**	**54,941**	**537,094**	**100**
%	**55**	**34.8**	**10.2**	**100**	

Table 14: Reuses of animals by species and main categories of scientific purposes in research, testing routine production and education (2018)

	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	20,613	14,405	15,425	506	0	371	6,427	0	57,747	**1.0**
	No	2,927,662	1,499,117	917,031	75,015	5,110	6,379	74,632	223	5,505,169	**99.0**
	Total	**2,948,275**	**1,513,522**	**932,456**	**75,521**	**5,110**	**6,750**	**81,059**	**223**	**5,562,916**	**100.0**
Rats	Yes	7,525	5,687	2,268	341	0	0	2,331	0	18,152	**1.8**
	No	270,619	211,252	473,081	5,078	297	0	38,885	34	999,246	**98.2**
	Total	**278,144**	**216,939**	**475,349**	**5,419**	**297**	**0**	**41,216**	**34**	**1,017,398**	**100.0**
Guinea-Pigs	Yes	0	118	443	205	16	0	189	0	971	**0.7**
	No	12,917	10,246	103,771	590	376	0	2,031	0	129,931	**99.3**
	Total	**12,917**	**10,364**	**104,214**	**795**	**392**	**0**	**2,220**	**0**	**130,902**	**100.0**
Hamsters (Syrian)	Yes	16	101	0	0	0	0	4	0	121	**1.1**
	No	924	3,910	5,786	110	0	0	83	0	10,813	**98.9**
	Total	**940**	**4,011**	**5,786**	**110**	**0**	**0**	**87**	**0**	**10,934**	**100.0**
Hamsters (Chinese)	Yes	0	0	0	0	0	0	0	0	0	**0.0**
	No	0	20	0	0	0	0	0	0	20	**100.0**
	Total	**0**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	**100.0**
Mongolian gerbil	Yes	26	64	0	0	0	0	11	0	101	**2.1**
	No	2,263	1,916	337	100	0	0	145	0	4,761	**97.9**
	Total	**2,289**	**1,980**	**337**	**100**	**0**	**0**	**156**	**0**	**4,862**	**100.0**
Other rodents	Yes	864	2	0	0	0	140	20	0	1,026	**4.8**
	No	16,258	1,379	942	0	764	638	392	0	20,373	**95.2**
	Total	**17,122**	**1,381**	**942**	**0**	**764**	**778**	**412**	**0**	**21,399**	**100.0**
Rabbits	Yes	400	594	9,604	961	0	0	219	0	11,778	**3.3**
	No	14,396	10,884	80,240	235,989	3	0	1,276	0	342,788	**96.7**
	Total	**14,796**	**11,478**	**89,844**	**236,950**	**3**	**0**	**1,495**	**0**	**354,566**	**100.0**
Cats	Yes	486	101	746	6	8	0	58	0	1,405	**47.5**
	No	186	704	633	13	0	0	18	0	1,554	**52.5**
	Total	**672**	**805**	**1,379**	**19**	**8**	**0**	**76**	**0**	**2,959**	**100.0**
Dogs	Yes	648	2,767	3,045	637	36	0	873	0	8,006	**31.1**
	No	927	8,408	7,835	70	175	0	296	0	17,711	**68.9**
	Total	**1,575**	**11,175**	**10,880**	**707**	**211**	**0**	**1,169**	**0**	**25,717**	**100.0**
Ferrets	Yes	3	32	0	0	0	0	25	0	60	**3.8**
	No	304	758	403	15	0	0	27	0	1,507	**96.2**
	Total	**307**	**790**	**403**	**15**	**0**	**0**	**52**	**0**	**1,567**	**100.0**
Other carnivores	Yes	0	270	0	0	8	37	0	0	315	**6.4**
	No	3,129	419	498	0	226	283	20	0	4,575	**93.6**
	Total	**3,129**	**689**	**498**	**0**	**234**	**320**	**20**	**0**	**4,890**	**100.0**
Horses, donkeys and cross-breeds	Yes	1,454	336	2	9,509	0	13	320	0	11,634	**87.2**
	No	306	929	253	39	0	0	185	0	1,712	**12.8**
	Total	**1,760**	**1,265**	**255**	**9,548**	**0**	**13**	**505**	**0**	**13,346**	**100.0**
Pigs	Yes	836	1,433	544	7	0	0	952	0	3,772	**4.3**
	No	19,322	35,881	13,574	941	1,668	88	12,523	0	83,997	**95.7**
	Total	**20,158**	**37,314**	**14,118**	**948**	**1,668**	**88**	**13,475**	**0**	**87,769**	**100.0**
Goats	Yes	691	157	0	26	0	0	52	0	926	**38.2**
	No	322	908	82	89	0	0	100	0	1,501	**61.8**
	Total	**1,013**	**1,065**	**82**	**115**	**0**	**0**	**152**	**0**	**2,427**	**100.0**
Sheep	Yes	1,238	869	182	49,101	11	0	308	0	51,709	**69.8**
	No	8,570	7,909	1,161	2,918	384	0	1,353	76	22,371	**30.2**
	Total	**9,808**	**8,778**	**1,343**	**52,019**	**395**	**0**	**1,661**	**76**	**74,080**	**100.0**
Cattle	Yes	1,776	1,543	321	188	229	0	3,584	0	7,641	**21.6**
	No	9,090	9,497	3,771	293	2,190	0	2,796	16	27,653	**78.4**
	Total	**10,866**	**11,040**	**4,092**	**481**	**2,419**	**0**	**6,380**	**16**	**35,294**	**100.0**
Prosimians	Yes	52	0	0	0	0	0	0	0	52	**23.4**
	No	170	0	0	0	0	0	0	0	170	**76.6**
	Total	**222**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**222**	**100.0**
Marmoset and tamarins	Yes	71	11	19	102	0	0	0	0	203	**34.8**
	No	118	115	138	10	0	0	0	0	381	**65.2**
	Total	**189**	**126**	**157**	**112**	**0**	**0**	**0**	**0**	**584**	**100.0**
Squirrel monkey	Yes	0	0	0	0	0	0	0	0	0	**0.0**

	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	%
	No	0	25	0	0	0	0	0	0	25	**100.0**
	Total	**0**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**25**	**100.0**
Cynomolgus monkey	Yes	71	524	935	577	0	0	15	0	2,122	**21.8**
	No	167	582	6,502	368	0	0	0	0	7,619	**78.2**
	Total	**238**	**1,106**	**7,437**	**945**	**0**	**0**	**15**	**0**	**9,741**	**100.0**
Rhesus monkey	Yes	98	71	0	15	0	0	0	0	184	**36.5**
	No	103	217	0	0	0	0	0	0	320	**63.5**
	Total	**201**	**288**	**0**	**15**	**0**	**0**	**0**	**0**	**504**	**100.0**
Vervets (Chlorocebus spp.)	Yes	0	14	0	0	0	0	0	0	14	**46.7**
	No	0	4	0	12	0	0	0	0	16	**53.3**
	Total	**0**	**18**	**0**	**12**	**0**	**0**	**0**	**0**	**30**	**100.0**
Baboons	Yes	17	2	0	0	0	0	0	0	19	**38.8**
	No	10	20	0	0	0	0	0	0	30	**61.2**
	Total	**27**	**22**	**0**	**0**	**0**	**0**	**0**	**0**	**49**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Yes	0	7	0	0	0	0	0	0	7	**24.1**
	No	0	10	0	12	0	0	0	0	22	**75.9**
	Total	**0**	**17**	**0**	**12**	**0**	**0**	**0**	**0**	**29**	**100.0**
Other mammals	Yes	116	87	0	0	1	88	0	0	292	**4.7**
	No	4,525	461	34	12	496	146	270	0	5,944	**95.3**
	Total	**4,641**	**548**	**34**	**12**	**497**	**234**	**270**	**0**	**6,236**	**100.0**
Domestic fowl	Yes	1,905	743	1,825	232	0	0	557	0	5,262	**1.1**
	No	103,599	103,912	145,365	121,969	3,878	88	3,001	0	481,812	**98.9**
	Total	**105,504**	**104,655**	**147,190**	**122,201**	**3,878**	**88**	**3,558**	**0**	**487,074**	**100.0**
Other birds	Yes	1,252	258	152	159	21	1	215	0	2,058	**2.0**
	No	54,969	11,520	2,861	23,334	2,958	4,857	535	0	101,034	**98.0**
	Total	**56,221**	**11,778**	**3,013**	**23,493**	**2,979**	**4,858**	**750**	**0**	**103,092**	**100.0**
Reptiles	Yes	2,372	0	0	0	0	0	6	0	2,378	**59.1**
	No	813	192	5	0	0	553	85	0	1,648	**40.9**
	Total	**3,185**	**192**	**5**	**0**	**0**	**553**	**91**	**0**	**4,026**	**100.0**
Rana	Yes	0	0	0	0	0	0	0	0	0	**0.0**
	No	2,694	169	2	0	19	0	1,354	0	4,238	**100.0**
	Total	**2,694**	**169**	**2**	**0**	**19**	**0**	**1,354**	**0**	**4,238**	**100.0**
Xenopus	Yes	5,936	208	0	0	12	0	79	0	6,235	**28.3**
	No	11,283	3,147	60	0	1,125	72	129	0	15,816	**71.7**
	Total	**17,219**	**3,355**	**60**	**0**	**1,137**	**72**	**208**	**0**	**22,051**	**100.0**
Other amphibians	Yes	85	9	0	0	180	0	0	0	274	**3.5**
	No	5,494	308	0	0	26	821	894	0	7,543	**96.5**
	Total	**5,579**	**317**	**0**	**0**	**206**	**821**	**894**	**0**	**7,817**	**100.0**
Zebra fish	Yes	13,783	204	0	0	0	0	0	0	13,987	**2.9**
	No	299,296	115,913	37,233	0	5,412	0	3,667	0	461,521	**97.1**
	Total	**313,079**	**116,117**	**37,233**	**0**	**5,412**	**0**	**3,667**	**0**	**475,508**	**100.0**
Other fish	Yes	21,811	1,496	334	0	380	54	7	0	24,082	**1.0**
	No	1,122,594	894,271	97,866	7,545	107,055	70,091	4,794	0	2,304,216	**99.0**
	Total	**1,144,405**	**895,767**	**98,200**	**7,545**	**107,435**	**70,145**	**4,801**	**0**	**2,328,298**	**100.0**
Cephalopods	Yes	16	0	0	0	0	0	0	0	16	**0.4**
	No	1,686	1,855	0	0	33	0	694	0	4,268	**99.6**
	Total	**1,702**	**1,855**	**0**	**0**	**33**	**0**	**694**	**0**	**4,284**	**100.0**
All Species	**Yes**	**84,161**	**32,113**	**35,845**	**62,572**	**902**	**704**	**16,252**	**0**	**232,549**	**2.2**
	No	**4,894,716**	**2,936,858**	**1,899,464**	**474,522**	**132,195**	**84,016**	**150,185**	**349**	**10,572,305**	**97.8**
	Total	**4,978,877**	**2,968,971**	**1,935,309**	**537,094**	**133,097**	**84,720**	**166,437**	**349**	**10,804,854**	**100.0**

Table 15: Genetic status of animals used by species and main categories of scientific purposes (2018)

	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	1,318,049	1,025,245	898,675	75,242	4,962	400	65,645	217	3,388,435	60.9
	Non harmful	1,394,400	374,142	31,995	137	148	5,210	14,861	0	1,820,893	32.7
	Harmful	235,826	114,135	1,786	142	0	1,140	553	6	353,588	6.4
	Total	**2,948,275**	**1,513,522**	**932,456**	**75,521**	**5,110**	**6,750**	**81,059**	**223**	**5,562,916**	**100.0**
Rats	Not altered	256,671	206,231	473,867	5,209	297	0	40,819	0	983,094	96.6
	Non harmful	17,668	7,520	1,302	210	0	0	387	34	27,121	2.7
	Harmful	3,805	3,188	180	0	0	0	10	0	7,183	0.7
	Total	**278,144**	**216,939**	**475,349**	**5,419**	**297**	**0**	**41,216**	**34**	**1,017,398**	**100.0**
Guinea-Pigs	Not altered	12,917	10,364	104,214	795	392	0	2,220	0	130,902	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	**12,917**	**10,364**	**104,214**	**795**	**392**	**0**	**2,220**	**0**	**130,902**	**100.0**
Hamsters (Syrian)	Not altered	940	3,740	5,786	110	0	0	87	0	10,663	97.5
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	271	0	0	0	0	0	0	271	2.5
	Total	**940**	**4,011**	**5,786**	**110**	**0**	**0**	**87**	**0**	**10,934**	**100.0**
Hamsters (Chinese)	Not altered	0	20	0	0	0	0	0	0	20	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**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	**100.0**
Mongolian gerbil	Not altered	2,289	1,980	337	100	0	0	156	0	4,862	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	**2,289**	**1,980**	**337**	**100**	**0**	**0**	**156**	**0**	**4,862**	**100.0**
Other rodents	Not altered	17,117	1,381	942	0	764	778	412	0	21,394	100.0
	Non harmful	5	0	0	0	0	0	0	0	5	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**17,122**	**1,381**	**942**	**0**	**764**	**778**	**412**	**0**	**21,399**	**100.0**
Rabbits	Not altered	14,648	11,363	89,844	211,496	3	0	1,494	0	328,848	92.7
	Non harmful	120	115	0	25,454	0	0	1	0	25,690	7.2
	Harmful	28	0	0	0	0	0	0	0	28	0.0
	Total	**14,796**	**11,478**	**89,844**	**236,950**	**3**	**0**	**1,495**	**0**	**354,566**	**100.0**
Cats	Not altered	672	805	1,379	19	8	0	76	0	2,959	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	**672**	**805**	**1,379**	**19**	**8**	**0**	**76**	**0**	**2,959**	**100.0**
Dogs	Not altered	1,502	11,152	10,880	707	211	0	1,169	0	25,621	99.6
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	73	23	0	0	0	0	0	0	96	0.4
	Total	**1,575**	**11,175**	**10,880**	**707**	**211**	**0**	**1,169**	**0**	**25,717**	**100.0**
Ferrets	Not altered	307	790	403	15	0	0	52	0	1,567	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	**307**	**790**	**403**	**15**	**0**	**0**	**52**	**0**	**1,567**	**100.0**
Other carnivores	Not altered	3,129	689	498	0	234	320	20	0	4,890	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	**3,129**	**689**	**498**	**0**	**234**	**320**	**20**	**0**	**4,890**	**100.0**
Horses, donkeys and cross-breeds	Not altered	1,760	1,265	255	9,548	0	13	505	0	13,346	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	**1,760**	**1,265**	**255**	**9,548**	**0**	**13**	**505**	**0**	**13,346**	**100.0**
Pigs	Not altered	19,963	37,040	14,117	948	1,668	88	13,473	0	87,297	99.5
	Non harmful	170	230	1	0	0	0	0	0	401	0.5
	Harmful	25	44	0	0	0	0	2	0	71	0.1
	Total	**20,158**	**37,314**	**14,118**	**948**	**1,668**	**88**	**13,475**	**0**	**87,769**	**100.0**
Goats	Not altered	1,013	1,065	82	115	0	0	152	0	2,427	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	**1,013**	**1,065**	**82**	**115**	**0**	**0**	**152**	**0**	**2,427**	**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	%
Sheep	Not altered	9,808	8,778	1,343	52,019	395	0	1,661	76	74,080	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	**9,808**	**8,778**	**1,343**	**52,019**	**395**	**0**	**1,661**	**76**	**74,080**	**100.0**
Cattle	Not altered	10,866	11,040	4,092	481	2,419	0	6,380	16	35,294	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	**10,866**	**11,040**	**4,092**	**481**	**2,419**	**0**	**6,380**	**16**	**35,294**	**100.0**
Prosimians	Not altered	222	0	0	0	0	0	0	0	222	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	**222**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**222**	**100.0**
Marmoset and tamarins	Not altered	189	126	157	112	0	0	0	0	584	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	**189**	**126**	**157**	**112**	**0**	**0**	**0**	**0**	**584**	**100.0**
Squirrel monkey	Not altered	0	25	0	0	0	0	0	0	25	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**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**25**	**100.0**
Cynomolgus monkey	Not altered	238	1,106	7,437	945	0	0	15	0	9,741	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	**238**	**1,106**	**7,437**	**945**	**0**	**0**	**15**	**0**	**9,741**	**100.0**
Rhesus monkey	Not altered	201	288	0	15	0	0	0	0	504	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	**201**	**288**	**0**	**15**	**0**	**0**	**0**	**0**	**504**	**100.0**
Vervets (Chlorocebus spp.)	Not altered	0	18	0	12	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**	**18**	**0**	**12**	**0**	**0**	**0**	**0**	**30**	**100.0**
Baboons	Not altered	27	22	0	0	0	0	0	0	49	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	**27**	**22**	**0**	**0**	**0**	**0**	**0**	**0**	**49**	**100.0**
Other species of old world monkeys (Cercopithecoidea)	Not altered	0	17	0	12	0	0	0	0	29	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**	**17**	**0**	**12**	**0**	**0**	**0**	**0**	**29**	**100.0**
Other mammals	Not altered	4,641	548	34	12	497	234	270	0	6,236	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	**4,641**	**548**	**34**	**12**	**497**	**234**	**270**	**0**	**6,236**	**100.0**
Domestic fowl	Not altered	105,207	104,655	147,190	122,198	3,878	88	3,558	0	486,774	99.9
	Non harmful	296	0	0	3	0	0	0	0	299	0.1
	Harmful	1	0	0	0	0	0	0	0	1	0.0
	Total	**105,504**	**104,655**	**147,190**	**122,201**	**3,878**	**88**	**3,558**	**0**	**487,074**	**100.0**
Other birds	Not altered	56,221	11,778	3,013	23,493	2,979	4,858	750	0	103,092	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	**56,221**	**11,778**	**3,013**	**23,493**	**2,979**	**4,858**	**750**	**0**	**103,092**	**100.0**
Reptiles	Not altered	3,185	192	5	0	0	553	91	0	4,026	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	**3,185**	**192**	**5**	**0**	**0**	**553**	**91**	**0**	**4,026**	**100.0**
Rana	Not altered	2,694	169	2	0	19	0	1,354	0	4,238	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	**2,694**	**169**	**2**	**0**	**19**	**0**	**1,354**	**0**	**4,238**	**100.0**
Xenopus	Not altered	13,207	2,948	60	0	1,137	72	188	0	17,612	79.9
	Non harmful	3,652	47	0	0	0	0	20	0	3,719	16.9
	Harmful	360	360	0	0	0	0	0	0	720	3.3
	Total	**17,219**	**3,355**	**60**	**0**	**1,137**	**72**	**208**	**0**	**22,051**	**100.0**
Other amphibians	Not altered	5,010	317	0	0	206	821	677	0	7,031	89.9

	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	%
	Non harmful	569	0	0	0	0	0	217	0	786	10.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	**5,579**	**317**	**0**	**0**	**206**	**821**	**894**	**0**	**7,817**	**100.0**
Zebra fish	Not altered	93,354	53,777	36,923	0	5,062	0	1,716	0	190,832	40.1
	Non harmful	200,094	52,200	0	0	350	0	348	0	252,992	53.2
	Harmful	19,631	10,140	310	0	0	0	1,603	0	31,684	6.7
	Total	**313,079**	**116,117**	**37,233**	**0**	**5,412**	**0**	**3,667**	**0**	**475,508**	**100.0**
Other fish	Not altered	1,142,423	893,218	98,200	7,545	107,254	70,145	4,801	0	2,323,586	99.8
	Non harmful	1,889	2,549	0	0	181	0	0	0	4,619	0.2
	Harmful	93	0	0	0	0	0	0	0	93	0.0
	Total	**1,144,405**	**895,767**	**98,200**	**7,545**	**107,435**	**70,145**	**4,801**	**0**	**2,328,298**	**100.0**
Cephalopods	Not altered	1,702	1,855	0	0	33	0	694	0	4,284	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	**1,702**	**1,855**	**0**	**0**	**33**	**0**	**694**	**0**	**4,284**	**100.0**
All Species	**Harmful**	**259,842**	**128,161**	**2,276**	**142**	**0**	**1,140**	**2,168**	**6**	**393,735**	**3.6**
	Non harmful	**1,618,863**	**436,803**	**33,298**	**25,804**	**679**	**5,210**	**15,834**	**34**	**2,136,525**	**19.8**
	Not altered	**3,100,172**	**2,404,007**	**1,899,735**	**511,148**	**132,418**	**78,370**	**148,435**	**309**	**8,274,594**	**76.6**
	Total	**4,978,877**	**2,968,971**	**1,935,309**	**537,094**	**133,097**	**84,720**	**166,437**	**349**	**10,804,854**	**100.0**

Section 3: Numbers and uses of animals for the creation and maintenance of genetically altered animals in the Union

Table 16: 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	26,514	673	27,187	6.1
	Mild	312,646	15,438	328,084	73.5
	Moderate	71,740	12,525	84,265	18.9
	Severe	6,166	953	7,119	1.6
	Total	**417,066**	**29,589**	**446,655**	**100.0**
Rats	Non-recovery	140	7	147	2.4
	Mild	2,309	78	2,387	38.3
	Moderate	1,871	1,628	3,499	56.2
	Severe	198	0	198	3.2
	Total	**4,518**	**1,713**	**6,231**	**100.0**
Hamsters (Syrian)	Non-recovery	89	0	89	100.0
	Mild	0	0	0	0.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**89**	**0**	**89**	**100.0**
Rabbits	Non-recovery	18	183	201	62.0
	Mild	32	10	42	13.0
	Moderate	16	65	81	25.0
	Severe	0	0	0	0.0
	Total	**66**	**258**	**324**	**100.0**
Ferrets	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**
Pigs	Non-recovery	0	0	0	0.0
	Mild	196	0	196	71.8
	Moderate	19	54	73	26.7
	Severe	4	0	4	1.5
	Total	**219**	**54**	**273**	**100.0**
Sheep	Non-recovery	0	0	0	0.0
	Mild	166	0	166	99.4
	Moderate	1	0	1	0.6
	Severe	0	0	0	0.0
	Total	**167**	**0**	**167**	**100.0**
Marmoset and tamarins	Non-recovery	0	0	0	0.0
	Mild	10	0	10	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**10**	**0**	**10**	**100.0**
Other mammals	Non-recovery	4	0	4	5.7
	Mild	2	0	2	2.9
	Moderate	64	0	64	91.4
	Severe	0	0	0	0.0
	Total	**70**	**0**	**70**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0.0
	Mild	440	17	457	81.6
	Moderate	3	100	103	18.4
	Severe	0	0	0	0.0
	Total	**443**	**117**	**560**	**100.0**
Xenopus	Non-recovery	0	0	0	0.0
	Mild	1,328	0	1,328	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	**1,328**	**0**	**1,328**	**100.0**
Other amphibians	Non-recovery	0	0	0	0.0
	Mild	17	0	17	17.0
	Moderate	83	0	83	83.0
	Severe	0	0	0	0.0

	Severity	Basic research	Translational and applied research	Total	%
	Total	**100**	**0**	**100**	**100.0**
Zebra fish	Non-recovery	2,186	0	2,186	1.8
	Mild	85,849	5,152	91,001	75.8
	Moderate	26,443	37	26,480	22.1
	Severe	325	0	325	0.3
	Total	**114,803**	**5,189**	**119,992**	**100.0**
Other fish	Non-recovery	226	0	226	1.4
	Mild	7,201	8,800	16,001	98.3
	Moderate	40	0	40	0.2
	Severe	7	0	7	0.0
	Total	**7,474**	**8,800**	**16,274**	**100.0**
All Species	**Non-recovery**	**29,177**	**863**	**30,040**	**5.1**
	Mild	**410,196**	**29,495**	**439,691**	**74.3**
	Moderate	**100,284**	**14,409**	**114,693**	**19.4**
	Severe	**6,700**	**953**	**7,653**	**1.3**
	Total	**546,357**	**45,720**	**592,077**	**100.0**

Table 17: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2018)

	Reuse	Basic research	Translational and applied research	Total	%
Mice	Yes	2,508	38	2,546	0.6
	No	414,558	29,551	444,109	99.4
	Total	**417,066**	**29,589**	**446,655**	**100.0**
Rats	Yes	4	0	4	0.1
	No	4,514	1,713	6,227	99.9
	Total	**4,518**	**1,713**	**6,231**	**100.0**
Hamsters (Syrian)	Yes	0	0	0	0.0
	No	89	0	89	100.0
	Total	**89**	**0**	**89**	**100.0**
Rabbits	Yes	0	0	0	0.0
	No	66	258	324	100.0
	Total	**66**	**258**	**324**	**100.0**
Ferrets	Yes	4	0	4	100.0
	No	0	0	0	0.0
	Total	**4**	**0**	**4**	**100.0**
Pigs	Yes	0	4	4	1.5
	No	219	50	269	98.5
	Total	**219**	**54**	**273**	**100.0**
Sheep	Yes	0	0	0	0.0
	No	167	0	167	100.0
	Total	**167**	**0**	**167**	**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	70	0	70	100.0
	Total	**70**	**0**	**70**	**100.0**
Domestic fowl	Yes	0	0	0	0.0
	No	443	117	560	100.0
	Total	**443**	**117**	**560**	**100.0**
Xenopus	Yes	0	0	0	0.0
	No	1,328	0	1,328	100.0
	Total	**1,328**	**0**	**1,328**	**100.0**
Other amphibians	Yes	0	0	0	0.0
	No	100	0	100	100.0
	Total	**100**	**0**	**100**	**100.0**
Zebra fish	Yes	1,457	0	1,457	1.2
	No	113,346	5,189	118,535	98.8
	Total	**114,803**	**5,189**	**119,992**	**100.0**
Other fish	Yes	0	0	0	0.0
	No	7,474	8,800	16,274	100.0
	Total	**7,474**	**8,800**	**16,274**	**100.0**
All Species	**Yes**	**3,973**	**42**	**4,015**	**0.7**
	No	**542,384**	**45,678**	**588,062**	**99.3**
	Total	**546,357**	**45,720**	**592,077**	**100.0**

Table 18: Uses of animals for the creation of new genetically altered animal lines in basic research by species and type of research (2018)

	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	84,856	21,507	58,417	688	12,292	11,054	57,037	22,377	7,736	12,917	96,540	481	31,164	**417,066**	**76.3**
Rats	35	516	1,013	63	0	20	1,224	24	0	0	1,623	0	0	**4,518**	**0.8**
Hamsters (Syrian)	0	0	0	0	0	0	0	89	0	0	0	0	0	**89**	**0**
Rabbits	0	66	0	0	0	0	0	0	0	0	0	0	0	**66**	**0**
Rabbits															
Ferrets	0	0	4	0	0	0	0	0	0	0	0	0	0	**4**	**0**
Farm animals															
Pigs	0	14	0	0	0	0	205	0	0	0	0	0	0	**219**	**0**
Sheep	0	0	124	43	0	0	0	0	0	0	0	0	0	**167**	**0**
Non-human primates															
Marmoset and tamarins	0	0	0	0	0	0	0	0	0	0	10	0	0	**10**	**0**
Other mammals															
Other mammals	0	0	65	0	0	0	0	0	0	0	5	0	0	**70**	**0**
Birds															
Domestic fowl	0	0	0	0	0	0	168	45	0	0	230	0	0	**443**	**0.1**
Amphibians															
Xenopus	0	1,288	0	0	0	0	0	0	0	0	0	0	40	**1,328**	**0.2**
Other amphibians	0	0	0	0	0	0	0	0	0	0	100	0	0	**100**	**0**
Fish															
Zebra fish	5,529	30,227	30,266	0	655	3,678	4,748	4,162	6,492	5,604	13,054	2,345	8,043	**114,803**	**21**
Other fish	0	167	54	0	0	60	91	3,000	2,480	226	1,394	0	2	**7,474**	**1.4**
Totals															
Total	**90,420**	**53,785**	**89,943**	**794**	**12,947**	**14,812**	**63,473**	**29,697**	**16,708**	**18,747**	**112,956**	**2,826**	**39,249**	**546,357**	**100**
%	**16.5**	**9.8**	**16.5**	**0.1**	**2.4**	**2.7**	**11.6**	**5.4**	**3.1**	**3.4**	**20.7**	**0.5**	**7.2**	**100**	

Table 19.1: 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) (2018)

	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	9,013	1,062	867	3,283	585	3,224	332	452
Rats	25	0	0	6	23	0	0	0
Rabbits								
Rabbits	0	0	0	0	0	0	0	10
Farm animals								
Pigs	0	0	35	3	0	0	0	2
Birds								
Domestic fowl	0	0	0	0	0	0	0	0
Fish								
Zebra fish	0	2,636	1,772	238	0	0	0	0
Other fish	0	0	0	0	0	0	0	0
Totals								
Total	**9,038**	**3,698**	**2,674**	**3,530**	**608**	**3,224**	**332**	**464**
%	**19.8**	**8.1**	**5.8**	**7.7**	**1.3**	**7.1**	**0.7**	**1**

Table 19.2: 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) (2018)

	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	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals									
Rodents									
Mice	400	271	8,694	968	269	169	0	**29,589**	**64.7**
Rats	0	0	1,605	0	0	54	0	**1,713**	**3.7**
Rabbits									
Rabbits	0	0	248	0	0	0	0	**258**	**0.6**
Farm animals									
Pigs	0	3	4	7	0	0	0	**54**	**0.1**
Birds									
Domestic fowl	0	0	0	0	117	0	0	**117**	**0.3**
Fish									
Zebra fish	0	509	0	0	0	0	34	**5,189**	**11.3**
Other fish	0	0	0	0	8,800	0	0	**8,800**	**19.2**
Totals									
Total	**400**	**783**	**10,551**	**975**	**9,186**	**223**	**34**	**45,720**	**100**
%	**0.9**	**1.7**	**23.1**	**2.1**	**20.1**	**0.5**	**0.1**	**100**	

Table 20: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, severity and genetic status (2018)

	Severity	Genetically altered with a harmful phenotype	Genetically altered without a harmful phenotype	Not genetically altered	Total	%
Mice	Non-recovery	188	345	8	541	0.1
	Mild	46,467	636,625	20,883	703,975	85.2
	Moderate	29,048	38,441	3,452	70,941	8.6
	Severe	28,139	22,619	83	50,841	6.2
	Total	**103,842**	**698,030**	**24,426**	**826,298**	**100.0**
Rats	Non-recovery	22	0	0	22	0.3
	Mild	1,165	1,532	169	2,866	43.5
	Moderate	892	1,914	0	2,806	42.5
	Severe	709	191	2	902	13.7
	Total	**2,788**	**3,637**	**171**	**6,596**	**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	5	0	5	100.0
	Total	**0**	**5**	**0**	**5**	**100.0**
Sheep	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	0	0	6	6	100.0
	Severe	0	0	0	0	0.0
	Total	**0**	**0**	**6**	**6**	**100.0**
Domestic fowl	Non-recovery	0	0	0	0	0.0
	Mild	21	398	9	428	86.1
	Moderate	65	0	0	65	13.1
	Severe	4	0	0	4	0.8
	Total	**90**	**398**	**9**	**497**	**100.0**
Xenopus	Non-recovery	0	0	0	0	0.0
	Mild	0	353	36	389	99.5
	Moderate	0	0	0	0	0.0
	Severe	0	2	0	2	0.5
	Total	**0**	**355**	**36**	**391**	**100.0**
Zebra fish	Non-recovery	0	2	0	2	0.0
	Mild	2,415	88,301	3,786	94,502	96.3
	Moderate	248	2,828	0	3,076	3.1
	Severe	1	488	13	502	0.5
	Total	**2,664**	**91,619**	**3,799**	**98,082**	**100.0**
Other fish	Non-recovery	0	768	0	768	52.9
	Mild	14	480	0	494	34.0
	Moderate	0	191	0	191	13.1
	Severe	0	0	0	0	0.0
	Total	**14**	**1,439**	**0**	**1,453**	**100.0**
All Species	**Non-recovery**	**210**	**1,115**	**8**	**1,333**	**0.1**
	Mild	**50,082**	**727,689**	**24,883**	**802,654**	**86.0**
	Moderate	**30,253**	**43,374**	**3,458**	**77,085**	**8.3**
	Severe	**28,853**	**23,305**	**98**	**52,256**	**5.6**
	Total	**109,398**	**795,483**	**28,447**	**933,328**	**100.0**

Table 21: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and genetic status (2018)

	Reuse	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	%
Mice	Yes	0	257	287	544	0.1
	No	24,426	697,773	103,555	825,754	99.9
	Total	**24,426**	**698,030**	**103,842**	**826,298**	**100.0**
Rats	Yes	0	0	0	0	0.0
	No	171	3,637	2,788	6,596	100.0
	Total	**171**	**3,637**	**2,788**	**6,596**	**100.0**
Dogs	Yes	0	0	0	0	0.0
	No	0	5	0	5	100.0
	Total	**0**	**5**	**0**	**5**	**100.0**
Sheep	Yes	0	0	0	0	0.0
	No	6	0	0	6	100.0
	Total	**6**	**0**	**0**	**6**	**100.0**
Domestic fowl	Yes	0	0	0	0	0.0
	No	9	398	90	497	100.0
	Total	**9**	**398**	**90**	**497**	**100.0**
Xenopus	Yes	18	37	0	55	14.1
	No	18	318	0	336	85.9
	Total	**36**	**355**	**0**	**391**	**100.0**
Zebra fish	Yes	0	0	0	0	0.0
	No	3,799	91,619	2,664	98,082	100.0
	Total	**3,799**	**91,619**	**2,664**	**98,082**	**100.0**
Other fish	Yes	0	0	0	0	0.0
	No	0	1,439	14	1,453	100.0
	Total	**0**	**1,439**	**14**	**1,453**	**100.0**
All species	**Yes**	**18**	**294**	**287**	**599**	**0.1**
	No	**28,429**	**795,189**	**109,111**	**932,729**	**99.9**
	Total	**28,447**	**795,483**	**109,398**	**933,328**	**100.0**