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PART I

## COMMISSION STAFF WORKING DOCUMENT

Annex to the:

## REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union
\{COM (2007) 675 final $\}$

## TABLE OF CONTENTS

I. INTRODUCTION ..... 3
II. DATA SUBMITTED AND GENERAL ASSESSMENT ..... 4
II.1. Data submitted by the Member States ..... 4
II.2. General assessment ..... 4
II.3. Structure of the Report ..... 6
PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005 ..... 7
III.1. Results of EU Table 1: Species and number of animals ..... 7
III.2. Results of EU Table 1: Origin of animals used ..... 21
III.3. Results of EU Table 2: Purposes of the experiments ..... 25
III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoints. ..... 31
III.5. Results of EU Table 4: Animals used for studies of diseases ..... 35
III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine ..... 41
III.7. Results of EU harmonized Table 6: Origin of regulatory requirements for animals used in toxicological and other safety evaluations ..... 44
III.8. Results of EU Table 7: Animals used in toxicity test for toxicological and other safety evaluations ..... 48
III.9. Results of EU Table 8: Type of toxicity tests carried out for toxicological and other safety evaluations of products ..... 54

## I. INTRODUCTION

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ${ }^{1}$, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The first two statistical reports published in $1994^{2}$ and $1999^{3}$ covering data on experimental animals collected in 1991 and 1996 respectively provided a limited amount of statistical analysis due to the absence of a consistent system of reporting the data on the use of experimental animals in the Member States. In 1997 an agreement was reached between the competent authorities of the Member States and the Commission to submit data for the future reports under a format of eight harmonized tables. The third and the fourth statistical reports published in $2003^{4}$ and $2005^{5}$ covering data collected in 1999 and 2002 were based on these agreed harmonized tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. In spite of the progress made in the content of these two last statistical reports, it ought to be stressed that there were some inconsistencies in the data submitted by the Member States and also that in all cases except the report of 2003, one Member State collected data from another year.

This Fifth Statistical Report covers for the first time data collected by 25 Member States as a result of the accession of 10 new Member States in 2005. It gives an overview of the year 2005 with the exception of one Member State who reported data of 2004.

The Commission Staff Working Document accompanies the "Report from the Commission to the Council and the European Parliament - Fifth Report on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union". The report summarizes the data and conclusions presented in this Staff Working Document.

[^0]
## II. DATA SUBMITTED AND GENERAL ASSESSMENT

## II.1. Data submitted by the Member States

All 25 Member States submitted the data in the agreed EU format.
Regarding the quality of data, in most cases, Member States have applied a quality control check on the set of data submitted for 2005. This exercise was the first for the 10 new Member States (EU 10), and in general the coherence of the data has greatly improved for the other Member States.

The quality check of the data submitted by the Member States is essentially governed by four criteria based on certain relationship between the data in the different tables.

- The first of these relationships is the total number of animals used by species, column 1.2 of EU Table 1, which is broken down into purposes of experiments in EU Table 2. Thus, the totals of the Tables 1 and 2 should be identical.
- The second relationship concerns column 2.6 of EU Table 2 "animals used for toxicological and other safety evaluation" which is broken down into types of products/endpoints, EU Table 3, into Regulatory requirements, EU Table 6, and into types of toxicological tests, EU Table 7. The total at the bottom of column 2.6 must be equal to the total at the bottom of table 3,6 and 7 .
- The third relationship is that the sum of column 2.4 and 2.5 of EU Table 2 must be equal to the total of EU Table 5.
- In the fourth relationship, the total row of EU table 3 "animals used for toxicological and other safety evaluation by types of products" should be equal to the total of table 8 .

For the present report it was generally considered that the quality criteria had sufficiently been respected to allow an analysis at European level of all eight EU tables.

## II.2. General assessment

Each Member State is requested, pursuant to Articles 13 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. The data covers the year 2005 with the exception of France who reported on the year 2004. Malta has reported no animal use in 2005.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes ${ }^{6}$ allows the use of animals in experiments for education and training, but where the purposes of such experiments are not covered by the Directive i.e. they are not experimental or scientific in the sense of the Directive, Member States will according to the Resolution apply national provisions which are no less severe than those of the Directive. Therefore, a number of Member States have also included animals covered by the Resolution in the report.

[^1]The first part of this report aims at providing a comprehensive overview on the numbers of animals used for various experimental purposes in the Community in 2005. The analysis will look at the purposes of the use of animals. Some of these purposes will be broken down further into more precise parameters. It will also look at the different legislative requirements regarding the use of experimental animals and also the type of testing carried out on the different species of animals. For the first time the analysis will cover all eight tables submitted by the Member States in 2005.

Because 10 new Member States are reporting data for the first time it will not be possible to draw conclusions on the evolution of the use of animals for experimental purposed in the EU by comparing data with those of the previous reports. However, some comparisons in trends will be attempted and significant changes in use will be highlighted in the report.

The number of animals used in the 10 new Member States (EU 10) represents $8,6 \%$ of the total number of animals used in the 25 Member States (EU 25). Therefore, when any of the categories reported in the different areas show a significant increase or decrease beyond the $8,6 \%$, this will be highlighted in the report

In addition, in the first chapter of this report, Table 1bis with the data of EU 15 and Table 1 tris with the data of EU 10 have been prepared to see the effects of the new Member States on the EU statistics. Furthermore, an attempt will be made to compare the results of the total number of animals used in 2005 within the "old" EU 15 with those submitted for the pervious reports.

The second part of this report provides the individual data from the Member States together with their respective comments and interpretations.

In the EU, the total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States amounts to 12,1 million (with data from France of 2004).

As in previous reports rodents together with rabbits represent almost $78 \%$ of the total number of animals used in the EU. Mice are by far the most commonly used species covering $53 \%$ of the total use, followed by rats with $19 \%$.

The second most used group of animals was, as in previous years, cold-blooded animals representing $15 \%$. The third biggest group of animals was birds with a little over $5 \%$ of the total use.

As in 2002, no Great Apes were used in experiments in the EU in 2005.

## II.3. Structure of the Report

The report is divided into two parts:
A A global compilation and overview for the European Union of the statistical data of the Member States for 2005.

A consolidated table has been computed on the basis of the data submitted by the Member States for each EU Table and is presented at the end of each chapter. Each table is illustrated by a graphical presentation to give a more readable overview of the EU situation.

Similarly to what happened in 2002, the complete data for 2005 include statistics from the year 2004 in France. Therefore, the totals used in this report are a mixture of years. Comparisons were nevertheless made on this basis since no other data were available.

The reader is invited to take note that the numbering of tables and graphical presentation in Part A of the report are linked to the numbers of the EU Tables and not to the numbering of the chapters of the report.

B The data submitted by each Member State with a summary of the Member State's comments.

## PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005

## III.1. Results of EU Table 1: Species and number of animals

Two types of information can be drawn from the data submitted by the Member States in EU Table 1. The first is relating to the total number of animals used subdivided into 25 species by the Member States. The second is relating to the place of origin of the animals used for experimental or other scientific purposes.

## III.1.1. The data on the total number of animals used in the $M S$

Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by 25 Member States. Since the previous report of 2002, Table 1.1 includes the data on the number of animals used also in the 10 new Member States.

Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used in 2005 (France reporting for 2004) in the 25 Member States (EU 25) amounts to 12.1 million animals. It is important to note that the number of animals used in the 10 new Member States (EU 10) represents 8,6\% of the total number of animals in the EU 25 . This proportion will be used as the basis to highlight any changes in trends which significantly deviate from it.

## III.1.2. Treatment and interpretation of the data of Table 1.1

In order to present an overall evaluation and subsequently a graphical analysis, animals were grouped in classes. The result of this exercise is presented in Table 1.2 at the end of this chapter. Table 1.2 is illustrated by Figure 1.1.

Figure 1.1
Percentages of animals used by classes by the reporting Member States


Rodents together with rabbits represent $77,5 \%$ of the total number of animals used. Within the rodents class, mice ( $53 \%$ ) and rats ( $19 \%$ ) are by far the most used species.

The second most used group is represented by cold-blooded animals with $15 \%$.
Birds is the next highest animal group being used for experimental purposes with 5,4\%
The Artio and Perissodactyla group including horses, donkeys and crossbreeds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represent only $1,1 \%$ of the total number of animals used in the Member States.

Carnivores represent $0,3 \%$ of the total number of animals used and non-human primates represent $0,1 \%$ of the animals used in 2005.

## III.1.3. Comparison with the data of the previous reports

In this chapter, and the following chapters dealing with comparisons, the reader is invited to take note of the fact that in 1996, in 2002 and 2005 one Member State (France) has reported data respectively for 1997, for 2001 and 2004. Nevertheless, assuming that fluctuations in the annual numbers of animals used per species in a country are limited, it is possible to make semi-quantitative estimates of the observed trends by comparing changes in proportions of use, expressed in percent.

Comparison between proportions of classes of animals used in 1996, 1999
2002 and 2005

| Class of species | $1996\left(^{*}\right)$ | 1999 | 2002 (**) $^{2005(* * *)}$ |  |
| :--- | :---: | :---: | :---: | :---: |
| $\%$ Rodents-rabbits | 81,3 | 86,9 | 78,0 | 77,5 |
| \% Cold-blooded <br> animals | 12,9 | 6,6 | 15,4 | 15, |


| \% Birds |  | 4,7 | 5 | 5,4 |
| :--- | :--- | :---: | :---: | :---: |
| \% Artio Perissodactyla |  | 1,2 | 1,2 | 1,1 |

(*) 14 Member States reporting for 1996, one for 1997
(**) 14 Member States reporting for 2002, one for 2001
(***) 24 Member States reporting for 2005, one for 2004
In overall, the percentages of rodents and rabbits show some fluctuation around $80 \%$. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 10 to $15 \%$ but a much lower use of $6,6 \%$ was observed in 1999.

Birds representing the third largest percentage of animal used, varies between 4 to $5 \%$. The group of artio and perissodactyla fluctuates around $1 \%$.

The inclusion of the data of the new Member States (EU 10) should in principle increase the actual numbers of animals of each species with the magnitude of around $8,6 \%$. However, the use of some species has decreased compared to the 2002 report. This is illustrated in Table 1.0 below.

Three other columns were included in Table 1.0 to show the change between 2002 and 2005 among EU 15, and to further analyse the changes in total numbers. More substantial overall changes have been highlighted and in particular any changes among EU 15 contrary to the overall change.

Table 1.0 : Changes in species number and proportion between 2002 and 2005

| Species | Anima 1 numb ers in EU 25 2005 | $\begin{gathered} \hline \text { Anima } \\ \text { I } \\ \text { numb } \\ \text { ers } \\ \text { in EU } \\ 15 \\ 2002 \end{gathered}$ | $\begin{gathered} \hline \text { Chan } \\ \text { ge } \\ \text { since } \\ 2002 \end{gathered}$ | $\begin{gathered} \text { \%ch } \\ \text { an } \\ \text { ge } \\ \text { sinc } \\ \text { e. } \\ 2002 \end{gathered}$ | Animal numbe rs in EU 15 2005 | $\begin{gathered} \hline \text { Chang } \\ \text { e } \\ \text { since } \\ 2002 \\ \text { in EU } \\ 15 \end{gathered}$ | $\begin{gathered} \hline \% \mathrm{ch} \\ \text { ang } \\ \text { e } \\ \text { sinc } \\ \text { e } \\ 200 \\ 2 \\ \text { in } \\ \text { EU } \\ 15 \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a Mice (Mus musculus) | $\begin{array}{r} 64303 \\ \hline 46 \end{array}$ | $\begin{array}{r} 54597 \\ 29 \end{array}$ | $\begin{array}{r} \hline 9706 \\ \hline \end{array}$ | 17,8 | $\begin{array}{r} \hline 60388 \\ \hline 46 \\ \hline \end{array}$ | $\begin{array}{r} \hline 57911 \\ \hline \end{array}$ | 10,6 |
| 1.b Rats (Rattus norvegicus) | $\begin{array}{r} 23360 \\ 32 \end{array}$ | $\begin{array}{r} 23113 \\ 44 \end{array}$ | $\begin{array}{r} 2468 \\ 8 \end{array}$ | 1,1 | $\begin{array}{r} 21304 \\ 46 \end{array}$ | $18089$ $8$ | -7,8 |
| 1.c Guinea-Pigs (Cavia porcellus) | $\begin{array}{r} 25730 \\ \hline \end{array}$ | $\begin{array}{r} 22633 \\ 9 \end{array}$ | $\begin{array}{r} 3096 \\ 8 \\ \hline \end{array}$ | 13,7 | $\begin{array}{r} 23318 \\ 0 \\ \hline \end{array}$ | 6841 | 3,0 |
| 1.d Hamsters (Mesocricetus ) | 31535 | 52382 | $2084$ | 39,8 | 30935 | $21447$ | 40,9 |
| 1.e Other Rodents (other Rodentia) | 64474 | 58827 | 5647 | 9,6 | 47451 | $1137 \overline{6}^{-}$ | 19,3 |
| 1.f Rabbits (Oryctolagus cuniculus) | $\begin{array}{r} 31268 \\ \hline 1 \\ \hline \end{array}$ | $\begin{array}{r} 26767 \\ \hline \end{array}$ | $\begin{array}{r} 4500 \\ 6 \\ \hline \end{array}$ | 16,8 | $\begin{array}{r} 29315 \\ 6 \\ \hline \end{array}$ | 25481 | 9,5 |
| 1.g Cats (Felis catus) | 3898 | 3808 | 90 | 2,4 | 3624 | -184 | -4,8 |
| 1.h Dogs (Canis familiaris) | 24119 | 21116 | 3003 | 14,2 | 22010 | 894 | 4,2 |
| 1.i Ferrets (Mustela putorius furo) | 2690 | 2078 | 612 | 29,4 | 2512 | 434 | 20,1 |
| 1.j Other Carnivores | 8711 | 3110 | 5601 | $\begin{array}{r} 180, \\ 1 \end{array}$ | 1734 | -1376 | 44,2 |
| 1.k Horses, donkeys and cross breds (Equidae) | 5312 | 4677 | 635 | 13,6 | 4310 | -367 | -7,8 |
| 1.I Pigs (Sus) | 66305 | 61164 | 5141 | 8,4 | 56657 | -4507 | -7,4 |
| 1.m Goats (Capra) | 2146 | 3016 | -870 | 28,8 | 1958 | -1058 | $35,1$ |
| 1.n Sheep (Ovis) | 30021 | 30979 | -958 | -3,1 | 26840 | -4139 | $\begin{array}{r} - \\ 13,4 \end{array}$ |
| 1.0 Cattle (Bos) | 36271 | 26569 | 9702 | 36,5 | 21694 | -4875 | 18,3 |
| 1.p Prosimians (Prosimia) | 677 | 1095 | -418 | 38,2 | 677 | -418 | 38,2 |
| 1.q New World Monkeys (Ceboidea) | 1564 | 1192 | 372 | 31,2 | 1564 | 372 | 31,2 |
| 1.r Old World Monkeys (Cercopithecoidea) | 8208 | 8075 | 133 | 1,6 | 8151 | 76 | 0,9 |
| 1.s Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |


| 1.t Other Mammals <br> (other Mammalia) | 9950 | 3618 | 6332 | 175, | 4701 | 1083 | 29,9 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.u Quail (Coturnix <br> coturnix) | 9246 | 12984 | -3738 | $-\overline{0}$ | 7212 | -5772 | $-\overline{4}$ |
| 1.v Other birds (other <br> Aves) | 64981 | 52198 | 1278 | 24,5 | 44528 | - | 44,4 |
| 1.w Reptiles (Reptilia) | 2477 | 3168 | -691 | - | 853 | -2315 | 14,7 |
| 1.x Amphibians <br> (Amphibia) | 74620 | 59689 | 1493 | 25,0 | 59402 | -287 | $-0,5$ |
| 1.y Fish (Pisces) | 17491 | 15864 | 1627 | 10,3 | 16271 | 40700 | 2,6 |
|  | 78 | 03 | 75 |  | 03 |  |  |
| 1.z TOTAL | 12117 | 10731 | 1386 | 12,9 | 11070 | 33927 | 3,2 |
|  | 583 | 020 | 563 |  | 299 | 9 |  |

The total number of hamsters, goats, prosimians, quail and reptiles have all decreased from $40 \%$ to $22 \%$.

The biggest percentual change has, however, been noted in the increase of the use of other carnivores. This increase is essentially due to the addition of data from the new Member States (see Table 1.0) although these species are not used in great numbers (from 3110 to 8711). This is further contrasted against a decrease in their use in EU 15. The other large increase both in EU 25 and also in EU 15 is for the use of other mammals ( 3618 to 9950 ).

One new Member State reported significant use of 'other carnivores', 'other mammals', cattle, 'other rodents', quails and horses, pigs and other birds, in comparison with other Member States. This was attributed to wildlife and environmental research studies in that specific geographical location, and testing in the areas of agricultural and animal breeding specific to that Member State. For further details see section B.

Among the other significant increases in the species used in greater numbers, one should mention the increase in the use of ferrets ( $29 \%$ ), of cattle ( $36 \%$ ), of other birds ( $25 \%$ ) and of amphibians ( $25 \%$ ). These increases, apart from ferrets, are all to be attributed to some of the new Member States.

The use of non-human primates remained as in previous reports at around $0,1 \%$ of the total number of animals used. However, by looking at the species, the number of prosimians used decreased by $38 \%$ while new world monkeys increased by $31 \%$.

Member States reported that these changes may be attributed to changes in regulatory requirements for pharmaceuticals and in toxicological safety testing.

As in 2002, no great apes were used for experimental or other scientific purposes in 2005.

## III.1.4. Comparison with the data of the previous reports for the EU 15

Since the total number of animals includes the data from the 10 new Member States it is not possible to draw a comparison per se with the results of the previous reports. However, to allow for some comparisons of trends of the animal use, separate Table 1 bis and 1 tris were drawn. Table 1 bis contains the data of EU 15 and Table 1 tris the data of EU 10 respectively.

In EU 15, the total number of animals used increased in 2005 by 339,279 which represents an increase of $3,1 \%$ with regard to 2002.

By examining the data by species, the major increase observed in 2005 is the additional use of about 579,000 mice ( $10,6 \%$ ). However this increase of mice is partly compensated by a decrease of the number of rats, hamsters and other rodents used ( $36 \%$ ). In 2005 there is also an increase of the number of rabbits used for experimental purposes $(9,5 \%)$.

Among the other classes of animals, the use of ferrets for carnivores ( $20,8 \%$ ) and the use of other mammals $(30 \%)$ has increased. The changes in the use of non-human primates as explained in chapter III.1.3 are mostly results of changes in EU 15 as only 57 old world monkeys were used in EU 10 in 2005.

On the other hand, the use of all species, within the class of artio and perissodactyla have decreased in comparison to 2002. The same is observed with birds. Finally, one can observe a substantial decrease of $73 \%$ in the use of reptiles.

Further breaking down the category 'other', Member States reported use of the following species:

Other rodents: gerbils, old world jerboas (Jaculus jaculus); chinchilla, beaver, ground squirrel, hamsters, aremenio (Cricetulus migratorius) and different species of mice;

Other carnivores: wild-life species used for zoological and ecological studies (e.g. foxes, badgers, seals), otters, fitchew;

Other mammals: boars, bats and shrews, llama, mole, European bison and red deer;
Other birds: mainly coturnix japonica and bob-white quail, poultry species, and zebra finches, canary, parakeet, parrot and farmed avian species for example, (Gallus gallus domesticus)

Table 1.1: Total number of animals used for experimental purposes in the EU Member States
Data of 2005 (*)

| Species | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | LT | LU | MT | NL |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice | 128634 | 488125 | 967 | 82252 | 1084358 | 208375 | 15340 | 393217 | 4350 | 1510334 | 138312 | 17776 | 534614 | 10480 | 5116 | 3280 | 0 | 240048 |
| 1.b. Rats | 11920 | 106483 | 0 | 31703 | 435417 | 85664 | 6024 | 125754 | 484 | 424387 | 109479 | 7722 | 279774 | 2376 | 493 | 720 | 0 | 116608 |
| 1.c. GuineaPigs | 3149 | 39530 | 0 | 4075 | 37761 | 5046 | 574 | 16780 | 0 | 79350 | 8360 | 4 | 11533 | 297 | 0 | 100 | 0 | 7479 |
| 1.d.Hamsters | 117 | 1874 | 0 | 220 | 7916 | 402 | 0 | 908 | 0 | 8691 | 137 | 0 | 1537 | 0 | 0 | 0 | 0 | 5322 |
| 1.e. Other Rodents | 107 | 2260 | 0 | 5798 | 7622 | 6381 | 40 | 294 | 0 | 12683 | 381 | 0 | 2303 | 0 | 0 | 0 | 0 | 3089 |
| 1.f. Rabbits | 18439 | 21159 | 0 | 5567 | 103329 | 5805 | 1255 | 11878 | 66 | 93282 | 9152 | 379 | 9916 | 166 | 158 | 20 | 0 | 8251 |
| 1.g. Cats | 12 | 81 | 0 | 29 | 1023 | 16 | 0 | 168 | 0 | 1313 | 124 | 119 | 30 | 0 | 0 | 0 | 0 | 334 |
| 1.h. Dogs | 85 | 1295 | 0 | 264 | 4868 | 566 | 14 | 685 | 0 | 5539 | 1206 | 167 | 1064 | 0 | 0 | 0 | 0 | 1049 |
| 1.i. Ferrets | 0 | 154 | 0 | 159 | 560 | 19 | 0 | 237 | 0 | 155 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 256 |
| 1.j. Other Carnivores | 0 | 0 | 0 | 7 | 235 | 242 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 151 |
| 1.k. Horses, donkeys and cross breds | 71 | 108 | 0 | 314 | 755 | 62 | 1 | 42 | 0 | 223 | 6 | 189 | 63 | 0 | 0 | 0 | 0 | 1705 |
| 1.I. Pigs | 818 | 1876 | 0 | 1392 | 13166 | 7697 | 448 | 4818 | 0 | 6587 | 882 | 382 | 2579 | 0 | 0 | 0 | 0 | 9853 |
| 1.m. <br> Goats | 44 | 157 | 0 | 56 | 275 | 199 | 0 | 119 | 0 | 442 | 2 | 0 | 20 | 0 | 0 | 0 | 0 | 328 |
| 1.n. Sheep | 195 | 445 | 0 | 720 | 3517 | 156 | 99 | 821 | 0 | 4992 | 381 | 601 | 584 | 0 | 0 | 0 | 0 | 2667 |
| 1.o. Cattle | 536 | 944 | 0 | 711 | 2909 | 489 | 0 | 294 | 0 | 1296 | 32 | 2109 | 1174 | 0 | 0 | 0 | 0 | 4410 |
| 1.p. <br> Prosimia ns | 0 | 0 | 0 | 0 | 99 | 0 | 0 | 0 | 0 | 578 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. N W Monkeys | 0 | 0 | 0 | 0 | 408 | 0 | 0 | 1 | 0 | 433 | 0 | 0 | 17 | 0 | 0 | 0 | 0 | 50 |


| 1.r. O W <br> Monkeys | 56 | 449 | 0 | 51 | 1579 | 0 | $\mathbf{1}$ | 81 | 0 | 2778 | 6 | 0 | 395 | 0 | 0 | 0 | 0 | 277 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.s Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other <br> Mammals | 0 | 59 | 0 | 188 | 115 | 185 | 0 | 60 | 0 | 0 | 0 | 48 | 68 | 0 | 0 | 0 | 0 | 13 |
| 1.u. Quail | 14 | 425 | 0 | 30 | 2457 | 0 | 0 | 1 | 0 | 4023 | 283 | 0 | 0 | 0 | 0 | 0 | 0 | 152 |
| 1.v. Other <br> birds | 1011 | 13266 | 0 | 126211 | 39150 | 7784 | 21 | 8424 | 0 | 102240 | 17151 | 2024 | 31697 | 0 | 0 | 0 | 0 | 111081 |
| 1.w.Reptiles | 40 | 144 | 0 | 1475 | 136 | 54 | 0 | 10 | 0 | 0 | 25 | 0 | 378 | 0 | 0 | 0 | 0 | 7 |
| 1.x. <br> Amphibia | 865 | 6177 | 0 | 293 | 10432 | 840 | 975 | 419 | 0 | 15675 | 1709 | 0 | 4636 | 0 | 0 | 0 | 0 | 3231 |
| ns |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

(*) France reporting for 2004

Table 1.1 Bis: Total number of animals used for experimental purposes in the 15 EU Member States reporting before 2005
Data of 2005 (*)

| Species | AT | BE | DE | DK | EL | ES | FR | IE | IT | LU | NL | PT | FI | SE | UK |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice | 128634 | 488125 | 1084358 | 208375 | 15340 | 393217 | 1510334 | 17776 | 534614 | 3280 | 240048 | 28318 | 120636 | 213727 | 1052064 | 6 |
| 1.b. Rats | 11920 | 106483 | 435417 | 85664 | 6024 | 125754 | 424387 | 7722 | 279774 | 720 | 116608 | 6793 | 28358 | 83321 | 411501 | 2 |
| 1.c. GuineaPigs | 3149 | 39530 | 37761 | 5046 | 574 | 16780 | 79350 | 4 | 11533 | 100 | 7479 | 379 | 563 | 2014 | 28918 |  |
| 1.d. <br> Hamster | 117 | 1874 | 7916 | 402 | 0 | 908 | 8691 | 0 | 1537 | 0 | 5322 | 129 | 126 | 167 | 3746 |  |
| 1.e. Other Rodents | 107 | 2260 | 7622 | 6381 | 40 | 294 | 12683 | 0 | 2303 | 0 | 3089 | 0 | 3187 | 1269 | 8216 |  |
| 1.f. Rabbits | 18439 | 21159 | 103329 | 5805 | 1255 | 11878 | 93282 | 379 | 9916 | 20 | 8251 | 594 | 1214 | 2112 | 15523 |  |
| 1.g. Cats | 12 | 81 | 1023 | 16 | 0 | 168 | 1313 | 119 | 30 | 0 | 334 | 0 | 0 | 220 | 308 |  |
| 1.h. Dogs | 85 | 1295 | 4868 | 566 | 14 | 685 | 5539 | 167 | 1064 | 0 | 1049 | 36 | 103 | 1166 | 5373 |  |
| 1.i. Ferrets | 0 | 154 | 560 | 19 | 0 | 237 | 155 | 0 | 0 | 0 | 256 | 0 | 80 | 47 | 1004 |  |
| 1.j. Other Carnivores | 0 | 0 | 235 | 242 | 0 | 0 | 0 | 0 | 0 | 0 | 151 | 0 | 5 | 163 | 938 |  |
| 1.k. Horses, donkeys and crossbreeds | 71 | 108 | 755 | 62 | 1 | 42 | 223 | 189 | 63 | 0 | 1705 | 8 | 125 | 650 | 308 |  |
| 1.I. Pigs | 818 | 1876 | 13166 | 7697 | 448 | 4818 | 6587 | 382 | 2579 | 0 | 9853 | 113 | 1471 | 2722 | 4127 |  |
| 1.m. Goats | 44 | 157 | 275 | 199 | 0 | 119 | 442 | 0 | 20 | 0 | 328 | 4 | 73 | 23 | 274 |  |
| 1.n. Sheep | 195 | 445 | 3517 | 156 | 99 | 821 | 4992 | 601 | 584 | 0 | 2667 | 290 | 445 | 256 | 11772 |  |
| 1.0. Cattle | 536 | 944 | 2909 | 489 | 0 | 294 | 1296 | 2109 | 1174 | 0 | 4410 | 45 | 455 | 727 | 6306 |  |
| 1.p. <br> Prosimia ns | 0 | 0 | 99 | 0 | 0 | 0 | 578 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 1.q. N W | 0 | 0 | 408 | 0 | 0 | 1 | 433 | 0 | 17 | 0 | 50 | 0 | 0 | 12 | 643 |  |


| Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.r. O W Monkeys | 56 | 449 | 1579 | 0 | 1 | 83 | 2778 | 0 | 395 | 0 | 277 | 0 | 0 | 63 | 2472 |  |
| 1.s. Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 1.t. Other Mammals | 0 | 59 | 115 | 185 | 0 | 60 | 0 | 48 | 68 | 0 | 13 | 1 | 972 | 639 | 2541 |  |
| 1.u. Quail | 14 | 425 | 2457 | 0 | 0 | 1 | 4023 | 0 | 0 | 0 | 152 | 0 | 0 | 0 | 140 |  |
| 1.v. Other birds | 1011 | 13266 | 39150 | 7784 | 21 | 8424 | 102240 | 2024 | 31697 | 0 | 111081 | 112 | 5773 | 7838 | 114860 |  |
| 1.w.Reptiles | 40 | 144 | 136 | 54 | 0 | 10 | 0 | 0 | 378 | 0 | 7 | 0 | 0 | 0 | 84 |  |
| $\text { 1.x. }{ }^{\text {Amphibia }}$ | 865 | 6177 | 10432 | 840 | 975 | 419 | 15675 | 0 | 4636 | 0 | 3231 | 51 | 20 | 5496 | 10585 |  |
| 1.y. Fish | 1199 | 33965 | 64337 | 35958 | 901300 | 30584 | 50397 | 6420 | 14584 | 0 | 14838 | 4748 | 93220 | 183049 | 192504 |  |
| 1.z. TOTAL | 167312 | 718976 | 822424 | 365940 | 926092 | 595597 | 2325398 | 37940 | 896966 | 4120 | 531199 | 41621 | 256826 | 505681 | 1874207 | 11 |

(*) France reporting for 2004

EN

Table 1.1 Tris: Total number of animals used for experimental purposes in the 10 New EU Member States
Reporting for 2005

| Species | CY | CZ | EE | HU | LV | LT | MT | PO | SI | SK | Totals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 967 | 82252 | 4350 | 138312 | 10480 | 5116 | 0 | 126492 | 8556 | 14975 | 391500 |
| 1.b. Rats (Rattus norvegicus) | 0 | 31703 | 484 | 109479 | 2376 | 493 | 0 | 51558 | 2732 | 6761 | 205586 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 0 | 4075 | 0 | 8360 | 297 | 0 | 0 | 10763 | 38 | 594 | 24127 |
| 1.d. Hamsters (Mesocricetus ) | 0 | 220 | 0 | 137 | 0 | 0 | 0 | 243 | 0 | 0 | 600 |
| 1.e. Other Rodents (other Rode |  | 5798 | 0 | 381 | 0 | 0 | 0 | 10826 | 18 | 0 | 17023 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 0 | 5567 | 66 | 9152 | 166 | 158 | 0 | 3101 | 533 | 782 | 19525 |
| 1.g. Cats (Felis catus) | 0 | 29 | 0 | 124 | 0 | 0 | 0 | 121 | 0 | 0 | 274 |
| 1.h. Dogs (Canis familiaris) | 0 | 264 | 0 | 1206 | 0 | 0 | 0 | 618 | 15 | 6 | 2109 |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 159 | 0 | 0 | 0 | 0 | 0 | 19 | 0 | 0 | 178 |
| 1.j. Other Carnivores (other Carnivores) | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 6970 | 0 | 0 | 6977 |
| 1.k. Horses, donkeys and crossbred | 0 | 314 | 0 | 6 | 0 | 0 | 0 | 681 | 1 | 0 | 1002 |
| 1.I. Pigs (Sus) | 0 | 1392 | 0 | 882 | 0 | 0 | 0 | 7358 | 16 | 0 | 9648 |
| 1.m. Goats (Capra) | 0 | 56 | 0 | 2 | 0 | 0 | 0 | 130 | 0 | 0 | 188 |
| 1.n. Sheep (Ovis) | 0 | 720 | 0 | 381 | 0 | 0 | 0 | 2023 | 57 | 0 | 3181 |
| 1.0. Cattle (Bos) | 0 | 711 | 0 | 32 | 0 | 0 | 0 | 13834 | 0 | 0 | 14577 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. Old World Monkeys | 0 | 51 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 57 |


| (Cercopithecoidea) |  |  |  |  |  |  |  |  |  |  |  |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other <br> Mammalia) | 0 | 188 | 0 | 0 | 0 | 0 | 0 | 5061 | 0 | 0 | 5249 |
| 1.u. Quail (Coturnix <br> coturnix) | 0 | 30 | 0 | 283 | 0 | 0 | 0 | 1470 | 0 | 251 | 2034 |
| 1.v. Other birds (other Aves) | 0 | 126211 | 0 | 17151 | 0 | 0 | 0 | 61148 | 22 | 0 | 204532 |
| 1.w.Reptiles (Reptilia) | 0 | 1475 | 0 | 25 | 0 | 0 | 0 | 121 | 3 | 0 | 1624 |
| 1.x. Amphibians (Amphibia) | 0 | 293 | 0 | 1709 | 0 | 0 | 0 | 13216 | 0 | 0 | 15218 |
| 1.y. Fish (Pisces) | 0 | 69418 | 0 | 9581 | 0 | 0 | 0 | 43076 | 0 | 0 | 122075 |
| 1.z. TOTAL | 967 | 330933 | 4900 | 297209 | 13319 | 5767 | 0 | 358829 | 11991 | 23369 | 1047284 |

Table 1.2: Classes of animals used for experimental purposes in the EU Member States
Data of 2005 (*)

| Species | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | L |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 128634 | 488125 | 967 | 82252 | 1084358 | 208375 | 15340 | 393217 | 4350 | 1510334 | 138312 | 17776 | 534614 | 10480 | 5 |
| Rats | 11920 | 106483 | 0 | 31703 | 435417 | 85664 | 6024 | 125754 | 484 | 424387 | 109479 | 7722 | 279774 | 2376 |  |
| Guinea-Pigs | 3149 | 39530 | 0 | 4075 | 37761 | 5046 | 574 | 16780 | 0 | 79350 | 8360 | 4 | 11533 | 297 |  |
| Golden hamsters + other rodents | 224 | 4134 | 0 | 6018 | 15538 | 6783 | 40 | 1202 | 0 | 21374 | 518 | 0 | 3840 | 0 |  |
| Rabbits | 18439 | 21159 | 0 | 5567 | 103329 | 5805 | 1255 | 11878 | 66 | 93282 | 9152 | 379 | 9916 | 166 |  |
| Cold-blooded animals(1) | 2104 | 40286 | 0 | 71186 | 74905 | 36852 | 902275 | 31013 | 0 | 66072 | 11315 | 6420 | 19598 | 0 |  |
| birds (2) | 1025 | 13691 | 0 | 126241 | 41607 | 7784 | 21 | 8425 | 0 | 106263 | 17434 | 2024 | 31697 | 0 |  |
| Artio+Perissodactyla (3) | 1664 | 3530 | 0 | 3193 | 20622 | 8603 | 548 | 0 | 0 | 13540 | 1303 | 3281 | 4420 | 0 |  |
| Carnivores (4) | 97 | 1530 | 0 | 459 | 6686 | 843 | 14 | 1090 | 0 | 7007 | 1330 | 286 | 1094 | 0 |  |
| Prosimians+monk3115+eys+ apes | 56 | 449 | 0 | 51 | 2086 | 0 | 1 | 84 | 0 | 3789 | 6 | 0 | 412 | 0 |  |
| Other Mammals | 0 | 59 | 0 | 188 | 115 | 185 | 0 | 60 | 0 | 0 | 0 | 48 | 68 | 0 |  |
| Total | 167312 | 718976 | 967 | 330933 | 1822424 | 365940 | 926094 | 595597 | 4900 | 2325398 | 297209 | 37940 | 896966 | 13319 | 5 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Species\% total | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | L |
| Mice | 76,88 | 67,89 | 100 | 24,85 | 59,50 | 56,94 | 1,66 | 66,02 | 88,78 | 64,95 | 46,54 | 46,85 | 59,60 | 78,68 | 88 |
| Rats | 7,12 | 14,81 | 0,00 | 9,58 | 23,89 | 23,41 | 0,65 | 21,11 | 9,88 | 18,25 | 36,84 | 20,35 | 31,19 | 17,84 | 8 |
| Guinea-Pigs | 1,88 | 5,50 | 0,00 | 1,23 | 2,07 | 1,38 | 0,06 | 2,82 | 0,00 | 3,41 | 2,81 | 0,01 | 1,29 | 2,23 | 0 |
| Golden hamsters + other rodents | 0,13 | 0,57 | 0,00 | 1,82 | 0,85 | 1,85 | 0,00 | 0,20 | 0,00 | 0,92 | 0,17 | 0,00 | 0,43 | 0,00 | 0 |
| Rabbits | 11,02 | 2,94 | 0,00 | 1,68 | 5,67 | 1,59 | 0,14 | 1,99 | 1,35 | 4,01 | 3,08 | 1,00 | 1,11 | 1,25 | 2 |
| Cold-blooded animals(1) | 1,26 | 5,60 | 0,00 | 21,51 | 4,11 | 10,07 | 97,43 | 5,21 | 0,00 | 2,84 | 3,81 | 16,92 | 2,18 | 0,00 | 0 |
| birds (2) | 0,61 | 1,90 | 0,00 | 38,15 | 2,28 | 2,13 | 0,00 | 1,41 | 0,00 | 4,57 | 5,87 | 5,33 | 3,53 | 0,00 | 0 |
| Artio+Perissodactyla (3) | 0,99 | 0,49 | 0,00 | 0,96 | 1,13 | 2,35 | 0,06 | 1,02 | 0,00 | 0,58 | 0,44 | 8,65 | 0,49 | 0,00 | 0 |
| Carnivores (4) | 0,06 | 0,21 | 0,00 | 0,14 | 0,37 | 0,23 | 0,00 | 0,18 | 0,00 | 0,30 | 0,45 | 0,75 | 0,12 | 0,00 | 0 |
| Prosimians+monkeys+ apes | 0,03 | 0,06 | 0,00 | 0,02 | 0,11 | 0,00 | 0,00 | 0,01 | 0,00 | 0,16 | 0,00 | 0,00 | 0,05 | 0,00 | 0 |


| Other Mammals | 0,00 | 0,01 | 0,00 | 0,06 | 0,01 | 0,05 | 0,00 | 0,01 | 0,00 | 0,00 | 0,00 | 0,13 | 0,01 | 0,00 | 0 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |  |

Malta has reported 0 animals used in 2005
(*) France reporting for 2004
(1) $=$ Reptiles + amphibians + fish
(2) = Quails and other birds
(3) $=$ Horses, donkeys and cross bred + pigs + goats and sheep + cattle
(4) $=$ cats + dogs + ferrets + other carnivores

## III.2. Results of EU Table 1: $\underline{\text { Origin of animals used }}$

## III.2.1. The data on the origin of the species

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 25 Member States are reported in Table 1.3 at the end of this chapter. The consolidated table only indicates species for which the origin must be reported.

In addition, EU Table 1 requires that Member States report the number of animals re-used in experiments.

## III.2.2. Treatment and interpretation of the data

The data of column 1.3 and 1.4 of Table 1.3 of this report have been grouped to represent animals coming from the Community.

Figure 1.2 represents the percentage of origin of animals versus the species.

Figure 1.2: Origin of species


The chart shows that the majority of the species originated from the EU countries. However, certain species such as cats, dogs and ferrets and old world monkeys are of nonEuropean origin.

## III.2.3. Comparison with data of the previous report

The general pattern on the origin of the species is quite similar to that observed in the previous reports. It should be noted however, that for the first time in 2005 the prosimians
were all of EU origin. A similar trend can also be observed with the new world monkeys where an increasing amount was either of EU or ETS 123 origin at the expense of other countries. Also, old world monkeys coming from EU origins increased. On the other hand the number of cats not of European origin has increased in comparison to the report of 2002.

Table 1.3: Number of animals used in relation to their place of origin
Data of 2005

| 1.1.Species | 1.2. Total | 1.3.Animals coming from registered breeding or supplying establishments within the reporting country | 1.4. <br> Animals coming from elsewhere in the EC | 1.5.Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6.Animals coming from other origins | 1.7.Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 6430346 | 5408519 | 842034 | 38621 | 141172 | 254 |
| 1.b. Rats (Rattus norvegicus) | 2336032 | 2002798 | 294875 | 17328 | 21031 | 118 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 257307 | 178363 | 69291 | 3245 | 6408 | 2 |
| 1.d. Hamsters (Mesocricetus ) | 31535 | 25276 | 4448 | 641 | 1170 | 0 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 312681 | 294616 | 15595 | 839 | 1631 | 13488 |
| 1.g. Cats (Felis catus) | 3898 | 2251 | 492 | 34 | 1121 | 1007 |
| 1.h. Dogs (Canis familiaris) | 24119 | 15542 | 2732 | 220 | 5625 | 3763 |
| 1.i. Ferrets (Mustela putorius furo) | 2690 | 1662 | 240 | 50 | 738 | 22 |
| 1.p. Prosimians (Prosimia) | 677 | 578 | 99 | 0 | 0 | 111 |
| 1.q. New World Monkeys (Ceboidea) | 1564 | 1244 | 195 | 65 | 60 | 410 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 8210 | 1459 | 719 | 38 | 5994 | 1740 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |


| 1.u. Quail (Coturnix coturnix) | 9246 | 8860 | 0 | 152 | 234 | 0 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.z. TOTAL | 9418305 | 7941168 | 1230720 | 61233 | 185184 |  |

Note 1 Column 1.5 concerns only those Member countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column
(Note 2: Only species for which origin has to be reported are included in this table)
Note 3: $\quad$ The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2.

## III.3. Results of EU Table 2: Purposes of the experiments

## III.3.1. The data on purpose of the experiments

The consolidated data on purposes of the experiments of the 25 Member States are presented in Table 2.1 at the end of this chapter.

## III.3.2. Treatment and interpretation of the data

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in the 25 Member States in 2005. In order to facilitate the presentation of results some species and some purposes were grouped.

The percentage of the number of animals used for selected purposes is presented in Figure 2.1.

Figure 2.1
Purposes of experiments


As in previous years, more than $60 \%$ of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biology studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of $15,3 \%$ of the total number of animals reported in 2005.

Toxicological and other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes.

## III.3.3. Comparison with the data of the previous report

It must be remembered that the comparison is aiming to detect changes in trends rather than drawing formal conclusions. The most significant change that can be identified is the number of animals used for toxicological and other safety evaluation, which has dropped from about 9,9\%
(data of 2002) to $8 \%$ for the data submitted by 25 Member States for this report. The decrease is also important in total numbers, i.e. from $1,066,047$ to $1,026,286$ animals while at the same time covering the 10 new Member States.

The percentage of animals used for education and training is also showing a decreasing trend while other purposes seem to indicate an increase. In terms of numbers of animals the decrease ranges from 341,967 to 198,994 and the increase from 597,960 to 984,238 respectively.

The decrease of animals used for education and training can be attributed to both an uptake of alternative techniques and the re-use of animals.
'Other' purposes covers amongst other things virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgensis, oncological treatment, pharmaceutical R\&D, combined drug testing and genetics.

Table 2.2: Number of animals used for selected purposes versus species

| Species |  | Resear lopment and quality control of product s and devices for <br> human medicin e and dentistr $y$ and for veterina ry medicin e) | Toxicolo gical and other safety evaluatio ns (includin g safety evaluatio n of products ) | Diagn osis of diseas e | Educati on and training | Other | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | $\begin{array}{r} 246547 \\ 4 \end{array}$ | $\begin{array}{r} 272725 \\ \hline \end{array}$ | 384741 | $\begin{array}{r} 22552 \\ 4 \\ \hline \end{array}$ | 86597 | $\begin{array}{r} 5513 \\ 56 \\ \hline \end{array}$ | 6440946 |
| Rats | 677533 | $\begin{array}{r} 116151 \\ 7 \\ \hline \end{array}$ | 350275 | 13564 | 50048 | $\begin{array}{r} 7287 \\ 6 \\ \hline \end{array}$ | 2325813 |
| Other rodents | 53241 | 230403 | 56006 | 4512 | 2606 | 6548 | 353316 |
| Rabbits | 15463 | 237411 | 38761 | 8322 | 3856 | 8829 | 312642 |
| Carnivores | 11605 | 9309 | 14884 | 348 | 674 | 2339 | 39159 |
| Artio+perissodactyla | 64419 | 41079 | 4542 | 4100 | 9491 | $\begin{array}{r} 1634 \\ 1 \end{array}$ | 139972 |
| Prosimians+monkeys+ apes | 1456 | 1397 | 7004 | 16 | 42 | 536 | 10451 |
| Other mammals | 8978 | 214 | 15 | 0 | 4 | 739 | 9950 |


| Birds | 251443 | 249024 | 53935 | 9723 | 5440 | 8949 | 659059 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
|  |  |  |  |  |  | 4 |  |
| Cold-blooded animals | 485858 | 942973 | 116123 | 5905 | 40236 | 2351 | 1826275 |
|  |  |  |  |  |  | 80 |  |
| TOTAL | 403547 | 560058 | 1026286 | 27201 | 198994 | 9842 | 1211758 |
|  | 0 | 1 |  | 4 |  | 38 | 3 |

Figure 2.2 presents the number of animals used for selected purposes by classes of species.
From Figure 2.2 one can see that the highest amount of use of mice and rats is attributed to fundamental biology and also of research, development and control of products and devices for medicine, dentistry and veterinary medicine. The use of cold-blooded animals is following a similar pattern for different purposes.

Figure 2.2
Species and experimental purposes


Table 2.1: Number of animals used in experiments for selected purposes Purposes versus species
data of 2005*

| 2.1Species | 2.2. <br> Biologic <br> al <br> studies <br> of a <br> fundam <br> ental <br> nature | 2.3. Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4.Produc <br> tion and quality control of products and devices for human medicine and dentistry | 2.5.Producti <br> on and quality control of products and devices for veterinary medicine | 2.6.Toxicolo gical and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine | 2.7.Dia <br> gnosis of diseas e | 2.8.Educ <br> ation and training | $\begin{gathered} \text { 2.9.Oth } \\ \text { er } \end{gathered}$ | $\begin{gathered} \text { 2.10.To } \\ \text { tal } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | $\begin{array}{r} 246547 \\ \hline 4 \end{array}$ | 1639698 | 902318 | 185238 | 384741 | $\begin{array}{r} 22552 \\ 4 \end{array}$ | 86597 | 551356 | $\begin{array}{r} 644094 \\ \hline 6 \end{array}$ |
| 1.b. Rats (Rattus norvegicus) | 677533 | 920875 | 209791 | 30851 | 350275 | 13564 | 50048 | 72876 | $\begin{array}{r} 232581 \\ \hline \end{array}$ |
| 1.c. Guinea-Pigs (Cavia porcellus) | 12911 | 47490 | 111505 | 24323 | 53498 | 2150 | 1691 | 3739 | 257307 |
| 1.d. Hamsters (Mesocricetus) | 10716 | 6167 | 274 | 10098 | 1670 | 1395 | 390 | 825 | 31535 |
| 1.e. Other Rodents (other Rodentia) | 29614 | 30359 | 0 | 187 | 838 | 967 | 525 | 1984 | 64474 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 15463 | 32814 | 185572 | 19025 | 38761 | 8322 | 3856 | 8829 | 312642 |
| 1.g. Cats (Felis catus) | 1123 | 1044 | 138 | 687 | 222 | 64 | 129 | 491 | 3898 |
| 1.h. Dogs (Canis familiaris) | 1997 | 4457 | 244 | 1182 | 14621 | 243 | 500 | 616 | 23860 |
| 1.i. Ferrets (Mustela putorius furo) | 510 | 1299 | 42 | 14 | 41 | 41 | 45 | 698 | 2690 |
| 1.j. Other Carnivores (other | 7975 | 0 | 0 | 202 | 0 | 0 | 0 | 534 | 8711 |


| Carnivore) |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.k. Horses, donkeys and cross breds (Equidae) | 1293 | 472 | 203 | 1957 | 40 | 182 | 973 | 192 | 5312 |
| 1.I. Pigs (Sus) | 27052 | 15159 | 489 | 6610 | 3349 | 1888 | 5854 | 5821 | 66222 |
| 1.m. Goats (Capra) | 828 | 280 | 84 | 41 | 39 | 214 | 317 | 343 | 2146 |
| 1.n. Sheep (Ovis) | 10442 | 2721 | 5731 | 1217 | 457 | 871 | 956 | 7626 | 30021 |
| 1.o. Cattle (Bos) | 24804 | 3691 | 55 | 2369 | 657 | 945 | 1391 | 2359 | 36271 |
| 1.p. Prosimians (Prosimia) | 384 | 0 | 0 | 0 | 97 | 0 | 0 | 196 | 677 |
| 1.q. New World Monkeys (Ceboidea) | 357 | 327 | 43 | 0 | 650 | 16 | 5 | 166 | 1564 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 715 | 654 | 373 | 0 | 6257 | 0 | 37 | 174 | 8210 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 8978 | 144 | 0 | 70 | 15 | 0 | 4 | 739 | 9950 |
| 1.u. Quail (Coturnix coturnix) | 1722 | 0 | 0 | 0 | 3191 | 0 | 169 | 3913 | 8995 |
| 1.v. Other birds (other Aves) | 249721 | 104833 | 12727 | 131464 | 50744 | 9723 | 5271 | 85581 | 650064 |
| 1.w.Reptiles (Reptilia) | 1646 | 13 | 0 | 0 | 12 | 0 | 774 | 32 | 2477 |
| 1.x. Amphibians (Amphibia) | 55349 | 253 | 0 | 0 | 542 | 99 | 15666 | 2711 | 74620 |
| 1.y. Fish (Pisces) | 428863 | 933278 | 280 | 9149 | 115569 | 5806 | 23796 | 232437 | $\begin{array}{r} 174917 \\ 8 \end{array}$ |
| 1.z. TOTAL | $\begin{array}{r} 403547 \\ 0 \end{array}$ | 3746028 | 1429869 | 424684 | 1026286 | $\begin{array}{r} 27201 \\ \hline \end{array}$ | 198994 | 984238 | $\begin{array}{r} 121175 \\ 83 \end{array}$ |

(*)France reporting for 2004

## III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoints

## III.4.1. The data on toxicological and safety evaluation by type of products/endpoints

The consolidated table giving the number of animals used in toxicological and other safety evaluation of products (EU Table 3) in 25 Member States is presented in Table 3.1 at the end of this chapter.

The percentage of the number of animals used for different types of product is presented in Figure 3.1.

## III.4.2. Treatment and interpretation of the data

Figure 3.1
Animals used in toxicological and other safety experiments


In table 3.1 the number of animals used for toxicological or other safety evaluation is broken down into type of products for which testing was required.

Only $8 \%$ of the total number of animals used for experimental purposes is used for toxicological and other safety evaluation. This accounts for 1,026,286 animals (see III.3.3)

The percentage of animals used for toxicological evaluation of 4 groups of products/substances, i.e., animal feed, additives for human food consumption, cosmetics and household, is very small $(4,3 \%)$ when compared to the other products groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents $50,9 \%$ of the animal used for toxicological or other safety evaluations.

The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used $19 \%$ of the animals for toxicological and other safety evaluations.

There is a strong decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture, products for potential contaminants of the environment (decrease ranging from above 123,000 to below 98,000 ) and also tests for products for household and for additives in food for human consumption, categories using lower numbers, in comparison to the data submitted in the last statistical report.

There is a noticeable increase ( $50 \%$ ) in the number of animals used for testing cosmetics or toiletries, however, the actual numbers of animals in this category remain low (5,571 in total). This increase, attributed mainly to one old Member State, is worth noting in light of the legal requirement to phase out animal testing for cosmetics in the EU. There is also a significant increase in the number of animals used for tests for additives in food for animal consumption ( 3,447 to $34,225-10$ fold).

It should also be noted that in comparison to the 2002 report there is a significant increase in the number of animals used for other toxicological or safety evaluation (ranging from around 110,000 to 180,000 ). This category could benefit from further analysis. Member States reported that it concerned new methods and tests, such as: tests on transmission of microcystins on embryonic membrane; bioassays; toxicity evaluation for humans via the environment; and control of safety for toys.

Table 3.1: Number of animals used in toxicological and other safety evaluation Products versus species

Data of 2005*

| 3.1.Species | 3.2. <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3. <br> Produc <br> ts/ <br> substa <br> nces <br> used or intende d to be used mainly in agricult ure | 3.4.Prod <br> ucts/ <br> substan ces used or intended to be used mainly in industry | 3.5.Prod <br> ucts/ <br> substan ces used or intended to be used mainly in the househo Id | 3.6.Prod ucts/ substan ces used or intended to be used mainly as cosmeti cs or toiletries | 3.7.Prod ucts/ substan ces used or intended to be used mainly as additive s in food for human consum ption | 3.8.Prod ucts/ substan ces used or intended to be used mainly as additive s in food for animal consum ption | 3.9.Poten tialor actual contamin ants in the general environm ent which do not appear in other columns | 3.10.Other toxicological or safety evaluations | $\begin{gathered} \begin{array}{c} \text { 3.11.To } \\ \text { tal } \end{array} \\ \hline \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 210840 | 18546 | 26677 | 72 | 1797 | 1268 | 1630 | 9264 | 116850 | $\begin{aligned} & \hline 386 \\ & 944 \end{aligned}$ |
| 1.b. Rats (Rattus norvegicus) | 210719 | 41903 | 44768 | 294 | 2226 | 2644 | 704 | 8883 | 36707 | $\begin{aligned} & 348 \\ & 648 \end{aligned}$ |
| 1.c. Guinea-Pigs (Cavia porcellus) | 35123 | 3051 | 7128 | 177 | 940 | 46 | 0 | 156 | 6877 | 53498 |
| 1.d. Hamsters (Mesocricetus ) | 1065 | 571 | 18 | 0 | 0 | 0 | 0 | 0 | 16 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 300 | 68 | 28 | 0 | 0 | 0 | 0 | 442 | 0 | 838 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 26030 | 3593 | 4433 | 116 | 608 | 141 | 113 | 25 | 4094 | 39153 |
| 1.g. Cats (Felis catus) | 222 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 222 |
| 1.h. Dogs (Canis familiaris) | 12671 | 509 | 278 | 0 | 0 | 0 | 0 | 29 | 1118 | 14605 |
| 1.i. Ferrets (Mustela putorius furo) | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |


| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.k. Horses, donkeys and cross breds (Equidae) | 35 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 40 |
| 1.I. Pigs (Sus) | 2246 | 90 | 47 | 0 | 0 | 76 | 444 | 103 | 241 | 3247 |
| 1.m. Goats (Capra) | 24 | 5 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 39 |
| 1.n. Sheep (Ovis) | 351 | 10 | 0 | 0 | 0 | 0 | 10 | 72 | 14 | 457 |
| 1.o. Cattle (Bos) | 489 | 48 | 0 | 0 | 0 | 0 | 105 | 0 | 15 | 657 |
| 1.p. Prosimians (Prosimia) | 97 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 613 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 37 | 650 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 5057 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 1194 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 |
| 1.u. Quail (Coturnix coturnix) | 0 | 3161 | 0 | 0 | 0 | 0 | 0 | 25 | 0 | 3186 |
| 1.v. Other birds (other Aves) | 9246 | 3728 | 98 | 0 | 0 | 0 | 31119 | 1437 | 5116 | 50744 |
| 1.w.Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 1.x. Amphibians (Amphibia) | 0 | 400 | 0 | 0 | 0 | 0 | 100 | 0 | 42 | 542 |
| 1.y. Fish (Pisces) | 6937 | 21944 | 12998 | 560 | 0 | 0 | 0 | 64286 | 7799 | $\begin{array}{r} 114 \\ 524 \\ \hline \end{array}$ |
| 1.z. TOTAL | 522121 | 97632 | 96479 | 1219 | 5571 | 4175 | 34225 | 84732 | 180132 | $\begin{array}{r} 1026 \\ 286 \\ \hline \end{array}$ |

(*) France reporting for 2004

## III.5. Results of EU Table 4: $\underline{\text { Animals used for studies of diseases }}$

## III.5.1. The data on animals used for studies of diseases

The consolidated table of results on animals used for studies of diseases (EU Table 4) in the 25 Member States is presented in Table 4.1 at the end of this chapter.

## III.5.2. Treatment and interpretation of the data

Table 4.1 gives the number of animals used per type of studies on diseases. In 2005, the number of animals used for the study of both animal and human diseases represented more than half $(57,5 \%)$ the total number of animals used for experimental purposes in the EU.

Figure 4.1 presents the percentage of animals used in studies per type of diseases.
The percentage of the number of animals used for studies of human diseases represents $81 \%$ of the total number of animals used for all studies of diseases.

Figure 4.1
Proportion of animals used for the study of diseases


In 2005, the proportion and the number of animals used (ranging from 900,000 to $1,329,000$ ) for the studies of animal diseases have increased significantly when compared with the report of 2002 .

It should be remembered that the studies on specific animal diseases are important in the light of epidemics of farm animals such as in the case of cows, foot and mouth disease, swine fever and more recently avian flew. Animals used also covers studies on genetic diseases.

An important part, around $60 \%$, of the increase of the total use of mice $(579,000)$ in comparison with 2002, can be attributed to different studies of diseases.

Table 4.1: Number of animals used in experiments for studies on human and animal diseases Main category of diseases versus species

Data of 2005 *

| 4.1 Species | $\qquad$ | 4.3 Human nervous and mental disorders | 4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | 4.7 Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 233054 | 843362 | 801787 | 1862317 | 158718 | 3899238 |
| 1.b. Rats (Rattus norvegicus) | 154838 | 610191 | 80825 | 642300 | 5251 | 1493405 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 4721 | 7581 | 781 | 57019 | 5200 | 75302 |
| 1.d. Hamsters (Mesocricetus) | 2121 | 4471 | 579 | 7302 | 2931 | 17404 |
| 1.e. Other Rodents (other Rodentia) | 84 | 24311 | 487 | 12750 | 3038 | 40670 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 11601 | 3769 | 631 | 23941 | 7864 | 47806 |
| 1.g. Cats (Felis catus) | 13 | 203 | 52 | 339 | 992 | 1599 |
| 1.h. Dogs (Canis familiaris) | 1538 | 367 | 347 | 6001 | 2395 | 10648 |
| 1.i. Ferrets (Mustela putorius furo) | 228 | 159 | 33 | 1693 | 71 | 2184 |
| 1.j. Other Carnivores (other Carnivore) | 2 | 0 | 0 | 500 | 540 | 1042 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 8 | 29 | 8 | 110 | 919 | 1074 |
| 1.I. Pigs (Sus) | 4902 | 943 | 198 | 8548 | 11226 | 25817 |
| 1.m. Goats (Capra) | 184 | 25 | 3 | 481 | 205 | 898 |
| 1.n. Sheep (Ovis) | 759 | 523 | 52 | 7138 | 7953 | 16425 |


| 1.o. Cattle (Bos) | 140 | 1841 | 0 | 2608 | 7727 | 12316 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.p. Prosimians (Prosimia) | 0 | 383 | 0 | 0 | 383 |  |
| 1.q. New World Monkeys <br> (Ceboidea) | 58 | 204 | 2 | 810 | 0 | 1074 |
| 1.r. Old World Monkeys <br> (Cercopithecoidea) | 53 | 167 | 179 | 2882 | 9 | 3290 |
| 1.s. Apes (Hominoidea) <br> 1.t. Other Mammals (other <br> Mammalia) <br> 1.u. Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.v. Other birds (other Aves) | 250 | 189 | 3 | 1777 | 65 | 2284 |
| 1.w.Reptiles (Reptilia) | 0 | 197 | 0 | 25 | 0 | 222 |
| 1.x. Amphibians (Amphibia) | 1443 | 6282 | 13 | 0 | 27269 | 159253 |
| 1.y. Fish (Pisces) | 1067 | 1338 | 29 | 24 | 79 | 231 |
| 1.z. TOTAL | 300 | 3898 | 2923 | 10297 | 277 | 15902 |

[^2]Table 4.2: Number of animals used in studies of diseases by classes of animals

| Classes of animals | Human <br> Cardiovascular <br> diseases | Human <br> nervous <br> and mental <br> disorder | Human <br> cancer (excl. <br> evaluation of <br> carcino <br> hazards) | Other human <br> diseases | Specific <br> animal <br> diseases | Total |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: |
| Mice | 233054 | 843362 | 801787 | 1862317 | 158718 | 3899238 |
| Rats | 154838 | 610191 | 80825 | 642300 | 5251 | 1493405 |
| Guinea-Pigs | 4721 | 7581 | 781 | 57019 | 5200 | 75302 |
| Other rodents | 2205 | 28782 | 1066 | 20052 | 5969 | 58074 |
| Rabbits | 11601 | 3769 | 631 | 23941 | 7864 | 47806 |
| Carnivores | 1781 | 729 | 432 | 8533 | 3998 | 15473 |
| Artio + Perrisodactyla | 5993 | 3361 | 261 | 18885 | 28030 | 56530 |
| Prosimians+Monkeys+Apes | 111 | 754 | 181 | 3692 | 9 | 4747 |
| Other Mammals | 250 | 189 | 3 | 1777 | 65 | 2284 |
| Birds | 1443 | 6479 | 0 | 27294 | 159253 | 194469 |
| Cold-blooded animals | 1380 | 5351 | 3344 | 157257 | 954890 | 1122222 |
| TOTAL | 417377 | 1510548 | 889311 | 2823067 | 1329247 | 6969550 |


| Classes of animals\% | Human <br> Cardiovascular <br> diseases | Human <br> nervous <br> and mental <br> disorder | Human <br> cancer (excl. <br> evaluation of <br> carcino <br> hazards) | Other human <br> diseases | Specific <br> animal <br> diseases | Total |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: |
| Mice | 5,98 | 21,63 | 20,56 | 47,76 | 4,07 | 100,00 |
| Rats | 10,37 | 40,86 | 5,41 | 43,01 | 0,35 | 100,00 |
| Guinea-Pigs | 6,27 | 10,07 | 1,04 | 75,72 | 6,91 | 100,00 |
| Other rodents | 3,80 | 49,56 | 1,84 | 34,53 | 10,28 | 100,00 |
| Rabbits | 24,27 | 7,88 | 1,32 | 50,08 | 16,45 | 100,00 |


| Carnivores | 11,51 | 4,71 | 2,79 | 55,15 | 25,84 | 100,00 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: |
| Artio + Perrisodactyla | 10,60 | 5,95 | 0,46 | 33,41 | 49,58 | 100,00 |
| Prosimians+Monkeys+Apes | 2,34 | 15,88 | 3,81 | 77,78 | 0,19 | 100,00 |
| Other Mammals | 10,95 | 8,27 | 0,13 | 77,80 | 2,85 | 100,00 |
| Birds | 0,74 | 3,33 | 0,00 | 14,04 | 81,89 | 100,00 |
| Cold-blooded animals | 0,12 | 0,48 | 0,30 | 14,01 | 85,09 | 100,00 |
| TOTAL | 5,99 | 21,67 | 12,76 | 40,51 | 19,07 | 100,00 |

Species of Table 4.1 were grouped into classes of animals to present Table 4.2. The relative percentage of animals per classes of species used in studies by type of diseases has been calculated and is also presented in the lower part of Table 4.2.

Figure 4.2 presents the proportion of animals used by classes per type of studies of diseases.

Figure 4.2
Proportion of animals used by classes per type of studies of diseases


The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Two groups of animals i.e. birds and cold-blooded animals account for more than $80 \%$ of such studies. Member States reported that it is still current practice to test vaccines on these types of species. However, in some Member States only birds are used if the infection concerns bird species.

In 2005, the proportion of other mammals used for specific animal diseases has decreased but increased proportionally in studies of other human diseases.

Overall the general pattern of the proportion of animals used for the studies of diseases presented very little change when compared to the previous statistical report.

## III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

## III.6.1. The data on animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The consolidated table for the 25 Member States reporting the origin of the regulatory requirements in relation to animals used for the production and quality control of products for human medicine and dentistry and for veterinary medicine (EU Table 5) is presented in Table 5.1 of this report.

## III.6.2. Treatment and interpretation of the data

The number of animals used in tests for the production and quality control of products for human medicine and dentistry and for veterinary medicine represents $15,3 \%$ of the total number of animals used for experimental purposes. Figure 5.1 gives the percentages of the animals used for different regulatory purposes in this area.

Figure 5.1
Percentages of animals used for regulatory requirements for the production and quality control of products and devices for human medicine, dentistry and for veterinary medicine


The largest proportion of animals in this area (57\%) was used to simultaneously satisfy requirements from several legislations such as national, Community, Council of Europe or others. The testing carried out to satisfy the EU legislation including the European Pharmacopoeia covered $33,3 \%$ of the animals used in this area.

The increase of the percentage, from $43,1 \%$ to $56,8 \%$, of the number of animals used to satisfy simultaneously several pieces of legislation in comparison to 2002, is clearly showing an encouraging trend. This is likely to reflect a positive increase in harmonisation of different legislative requirements.

Another positive trend is the reduction of the number of animals, from 352,000 to 95,739, used for "no regulatory requirements".

Table 5.1: Number of animals used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine
Regulatory requirements versus species
Data of 2005 *

| 5.1. Species | 5.2 . <br> National legislation specific to a single EC Member State1 | 5.3. EC <br> legislation including European Pharmacopoeia (requirements) | 5.4. <br> Member Country of Council of Europe (but not EC) legislation2) | 5.5. Other legislation | 5.6. Any combination of 5.2/ $5.3 /$ 5.4/ 5.5 | $\begin{gathered} \text { 5.7. No } \\ \text { regulatory } \\ \text { requirements } \end{gathered}$ | 5.8. Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 24912 | 326864 | 20 | 13463 | 685435 | 36912 | 1087606 |
| 1.b. Rats (Rattus norvegicus) | 5551 | 82479 | 0 | 18436 | 127504 | 6822 | 240792 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 8558 | 44713 | 7 | 6041 | 73163 | 3346 | 135828 |
| 1.d. Hamsters (Mesocricetus) | 0 | 4528 | 0 | 0 | 5449 | 395 | 10372 |
| 1.e. Other Rodents (other Rodentia) | 0 | 0 | 0 | 0 | 187 | 0 | 187 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 2566 | 85556 | 0 | 308 | 87867 | 28300 | 204597 |
| 1.g. Cats (Felis catus) | 76 | 607 | 0 | 13 | 111 | 18 | 825 |
| 1.h. Dogs (Canis familiaris) | 21 | 1016 | 0 | 0 | 241 | 148 | 1426 |
| 1.i. Ferrets (Mustela putorius furo) | 14 | 30 | 0 | 0 | 6 | 6 | 56 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 202 | 0 | 0 | 0 | 0 | 202 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 229 | 219 | 0 | 2 | 281 | 1429 | 2160 |
| 1.I. Pigs (Sus) | 136 | 4363 | 0 | 9 | 1572 | 1019 | 7099 |
| 1.m. Goats (Capra) | 0 | 4 | 0 | 0 | 118 | 3 | 125 |
| 1.n. Sheep (Ovis) | 176 | 838 | 0 | 0 | 3650 | 2284 | 6948 |
| 1.o. Cattle (Bos) | 125 | 1462 | 26 | 10 | 533 | 268 | 2424 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 35 | 0 | 0 | 0 | 8 | 43 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 6 | 0 | 0 | 357 | 10 | 373 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 10 | 60 | 0 | 0 | 0 | 0 | 70 |


| 1.u. Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| :--- | ---: | ---: | ---: | ---: | ---: | ---: | ---: |
| 1.v. Other birds (other Aves) | 3913 | 61303 | 152 | 683 | 63959 | 14181 | 144191 |
| 1.w.Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.y. Fish (Pisces) | 1222 | 3446 | 0 | 0 | 3971 | 590 | 9229 |
| 1.z. TOTAL | 47509 | 617731 | 205 | 38965 | 1054404 | 95739 | 1854553 |

(*) France reporting for 2004
Exampl 5.2 - France is testing due to a UK (or FR) es: specific requirement
5.3 - UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian

Example: requirement
5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

## III.7. Results of EU harmonized Table 6: Origin of regulatory requirements for animals used in toxicological and other safety evaluations

III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting data on animals used in toxicological and other safety evaluations in relation to the origin of regulatory requirements (EU Table 6) is presented in Table 6.1 at the end of this chapter.

## III.7.2. Treatment and interpretation of the data

It can be observed that the use of animals for regulatory requirements in the area of toxicological or other safety evaluation presented in Figure 6.1 follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine presented in the Figure 5.1 in the previous chapter.

As pointed out earlier, the number of animals used in toxicological or other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes in the EU.

Figure 6.1
Percentages of animals used for regulatory requirements for toxicological and other safety evaluation


Animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered more than half of the animals used in this area ( $54,2 \%$ ). The testing required under the EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area namely $23 \%$.

It should be underlined that the proportional decrease of the numbers of animals used for toxicological and other safety evaluation since the last report, from $10 \%$ to $8 \%$, represents at the same time a decrease of about 40,000 animals. The number of animals used "no regulatory requirements" decreased since the last report from 114,000 to 90,000 animals, a drop of 24,000 animals.

Member States who were asked to provide some further explanation as to the reasons for this clear decrease of animals used for no regulatory requirements compared to previous reports, indicated that the decrease was partially attributed to use of alternative in vitro methods and invertebrate animals. For example, safety pharmacological tests such as those used for supplementary batch control by the European Pharmacopoeia. In order to understand what is meant by the term 'no regulatory requirements', for example some Member States indicated that legal obligations to ensure quality and safety of imported drugs would be reported under this category.

The testing to satisfy national legislation specific to a single Member State showed a decrease in this report with respect to the previous one but it represents about 15,500 animals i.e. $1,5 \%$ of the total number used for toxicological and other safety evaluation.

Table 6.1: $\quad$ Number of animals used in toxicological and other safety evaluations
Regulatory requirements versus species
Data of 2005*

| 6.1. Species | 6.2. National legislation specific to a single EC Member State1) | 6.3. EC <br> legislation including European Pharmacopoeia (requirements) | 6.4. Member Country of Council of Europe (but not EC) legislation2) | 6.5. Other legislation | 6.6. Any combination of 5.2/5.3/ 5.4/5.5 | 6.7. No regulatory requirements | 6.8.Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 39972 | 104143 | 170 | 15039 | 189776 | 37144 | 386244 |
| 1.b. Rats (Rattus norvegicus) | 19368 | 61953 | 670 | 15875 | 224860 | 25772 | 348498 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 1009 | 21189 | 70 | 2052 | 27849 | 1329 | 53498 |
| 1.d. Hamsters (Mesocricetus ) | 0 | 182 | 0 | 0 | 1204 | 284 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 0 | 300 | 0 | 0 | 0 | 583 | 883 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 1398 | 9462 | 13 | 2653 | 23162 | 2420 | 39108 |
| 1.g. Cats (Felis catus) | 166 | 46 | 0 | 6 | 4 | 23 | 245 |
| 1.h. Dogs (Canis familiaris) | 977 | 1919 | 0 | 520 | 10842 | 324 | 14582 |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 0 | 0 | 0 | 41 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 0 | 5 | 0 | 0 | 25 | 10 | 40 |
| 1.I. Pigs (Sus) | 57 | 1150 | 0 | 132 | 1642 | 266 | 3247 |
| 1.m. Goats (Capra) | 0 | 26 | 0 | 0 | 3 | 44 | 73 |
| 1.n. Sheep (Ovis) | 4 | 120 | 0 | 0 | 191 | 108 | 423 |
| 1.o. Cattle (Bos) | 12 | 320 | 0 | 15 | 203 | 107 | 657 |
| 1.p. Prosimians (Prosimia) | 0 | 97 | 0 | 0 | 0 | 0 | 97 |
| 1.q. New World Monkeys | 0 | 0 | 0 | 0 | 599 | 51 | 638 |


| (Ceboidea) |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 304 | 0 | 488 | 5312 | 153 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 15 | 0 | 0 | 0 | 0 | 15 |
| 1.u. Quail (Coturnix coturnix) | 0 | 2124 | 0 | 0 | 1037 | 25 | 3186 |
| 1.v. Other birds (other Aves) | 5519 | 4787 | 0 | 522 | 38262 | 1654 | 50744 |
| 1.w.Reptiles (Reptilia) | 12 | 0 | 0 | 0 | 0 | 0 | 12 |
| 1.x. Amphibians (Amphibia) | 542 | 0 | 0 | 0 | 0 | 0 | 542 |
| 1.y. Fish (Pisces) | 27338 | 34565 | 312 | 3029 | 31210 | 19120 | 115574 |
| 1.z. TOTAL | 96374 | 242707 | 1235 | 40331 | 556222 | 89417 | 1026286 |

(*)France reporting for 2004

Example
s :
6.2 - France is testing due to a UK (or FR) specific Note: requirement
6.3-UK is testing according to EC legislation
6.4 - Spain is testing due to a Hungarian requirement
6.5 - Sweden is testing due to a US specific requirement
6.6-Germany is testing due to a Czech requirement (also an EC requirement)
columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol
Exam a test required by French legislation and carried out in ple: Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

## III.8. Results of EU Table 7: $\underline{\text { Animals used in toxicity test for toxicological and other safety }}$ evaluations

## III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting on animals used in toxicity tests for the purpose of toxicological and other safety evaluations of products (EU Table 7) is presented in Table 7.1 at the end of this chapter.

## III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of Table 7.1 have been grouped according to systemic and local toxicity and CMR effects in Table 7.2 of this report. A graph showing the percentage of animals used per toxicity test groups in 2005 is presented in Figure 7.1.

Figure 7.1
Percentages of animals used in toxicity tests for toxicological and other safety evaluation


As pointed out in the previous chapter, the number of animals used in toxicological and other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes.

It can be seen in Figure 7.1 that the largest percentage of use of animals is due to acute and subacute toxicity tests $42 \%$ in 2005. Taking also into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for $53 \%$ of the experimental animals used in this area.

About $17,5 \%$ of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction in 2005. Another important category of use of animals in 2005 is for "other tests" with $22,3 \%$. Breaking down further the category 'other', Member States reported testing in areas such as biological screening for pharmaceutical, healthcare and veterinary products. This includes neurotoxicity, toxicokinetics, testing of acute dermal toxicity, testing of biological evaluation of medical devices: Intracutan testing of reactivity on rabbits, study into penetration of nanoparticle through tissue and their biocompatibility, study into evaluation of sensitization potential of dyestuffs used in textile industry and pharmacological studies included in safety tests.

By looking both in numbers and relative percentages of use of animals in comparison to the previous reports there are three noticeable changes:

One can observe a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests ranging from: $32 \%, 36 \%$ to $42 \%$ respectively. This represents in animal numbers an increase of 39,000 animals since the last report of 2002. Member States attributed the increase in part to several phases in new product development and new legislation for example requiring that all generic substances should be tested.

On the other hand one can observe a steady decrease over the last three reports of the proportion of animals used for toxicity tests to reproduction going down from: $15 \%, 12 \%$ to $10 \%$ respectively.

Another important decrease in the proportion of animals used is the decrease from 4,5\% to $1,2 \%$ of animals used in toxicity test to aquatic vertebrates.

Some Member States presume that the decrease in regulatory testing can indeed be attributed to alternative methods but others think that replacement methods have a much greater impact on R\&D than on regulatory requirements. They point out that the statistics drawn up annually include re-use of animals which plays an important role.

Table 7.1: Number of animals used in toxicological and other safety evaluations
Type of tests versus species
Data of 2005*

| 7.1. Species | 7.2. Acute and sub-acute toxicity testing methods (including limit test) |  |  | 7.3. <br> Skin <br> irritati <br> on | 7.4 . <br> Skin <br> sensi <br> tisati <br> on | 7.5. <br> Eye irritati on | 7.6. <br> Subchroni c and chroni <br> c <br> toxicity | 7.7. <br> Carci <br> nogenic ity | 7.8. <br> Devel opmental toxicity | 7.9. <br> Mutagenic ity | 7.10. <br> Repr <br> o- <br> ducti <br> ve <br> toxicit <br> y | 7.11. <br> Toxicity to aquatic vertebr a-tes not include d in other column s | $7.12 .$ Other | $\begin{aligned} & \hline 7.13 . \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 33024 | 86669 | 68682 | 2805 | $\begin{array}{r} 2135 \\ 0 \end{array}$ | 0 | 25550 | $\begin{array}{r} 1962 \\ 4 \end{array}$ | 2612 | $\begin{array}{r} 1947 \\ 9 \end{array}$ | 908 | 0 | $\begin{array}{r} 1055 \\ 41 \end{array}$ | $\begin{array}{r} 38624 \\ 4 \end{array}$ |
| 1.b. Rats (Rattus norvegicus) | 19756 | 18614 | 78707 | 1156 | 303 | 142 | 65466 | $\begin{array}{r} 2240 \\ 0 \end{array}$ | 23886 | $\begin{array}{r} 1572 \\ 7 \\ \hline \end{array}$ | $\begin{array}{r} 5151 \\ 8 \end{array}$ | 0 | $\begin{array}{r} 5082 \\ 9 \end{array}$ | $\begin{array}{r} 34850 \\ 4 \end{array}$ |
| 1.c. Guinea-Pigs (Cavia porcellus) | 1415 | 993 | 17572 | 2144 | $\begin{array}{r} 2218 \\ 4 \\ \hline \end{array}$ | 0 | 628 | 0 | 0 | 0 | 0 | 0 | 8556 | 53492 |
| 1.d. Hamsters (Mesocricetus ) | 0 | 64 | 603 | 0 | 0 | 0 | 38 | 0 | 0 | 20 | 0 | 0 | 945 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 56 | 142 | 300 | 0 | 0 | 0 | 300 | 0 | 0 | 0 | 0 | 0 | 40 | 838 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 36 | 49 | 2944 | 5130 | 52 | 4033 | 1693 | 0 | 8078 | 31 | 4640 | 0 | $\begin{array}{r} 1246 \\ 7 \\ \hline \end{array}$ | 39153 |
| 1.g. Cats (Felis catus) | 0 | 0 | 108 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 114 | 222 |


| 1.h. Dogs (Canis familiaris) | 182 | 659 | 5170 | 0 | 0 | 0 | 6998 | 0 | 0 | 0 | 29 | 0 | 1567 | 14605 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 0 | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 30 | 40 |
| 1.I. Pigs (Sus) | 8 | 49 | 304 | 8 | 0 | 0 | 971 | 0 | 89 | 0 | 100 | 0 | 1718 | 3247 |
| 1.m. Goats (Capra) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 39 | 39 |
| 1.n. Sheep (Ovis) | 0 | 0 | 32 | 0 | 0 | 0 | 0 | 0 | 35 | 0 | 37 | 0 | 353 | 457 |
| 1.o. Cattle (Bos) | 0 | 0 | 73 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 584 | 657 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 60 | 0 | 0 | 0 | 32 | 0 | 0 | 0 | 0 | 0 | 5 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 85 | 222 | 0 | 0 | 0 | 185 | 0 | 90 | 0 | 0 | 0 | 68 | 638 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 1 | 2014 | 0 | 0 | 33 | 3406 | 0 | 131 | 0 | 187 | 0 | 485 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 1.u. Quail (Coturnix coturnix) | 2253 | 348 | 105 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 480 | 0 | 0 | 3186 |
| 1.v. Other birds (other Aves) | 1671 | 260 | 11403 | 1000 | 0 | 0 | 158 | 0 | 0 | 0 | 128 | 0 | $\begin{array}{r} 3612 \\ 4 \end{array}$ | 50744 |
| 1.w.Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 42 | 0 | 0 | 0 | 500 | 542 |
| 1.y. Fish (Pisces) | 54830 | 10449 | 11146 | 0 | 0 | 0 | 6443 | 0 | 5484 | 226 | 5284 | 12675 | 9037 | $\begin{array}{r} 11557 \\ 4 \end{array}$ |
| 1.z. TOTAL | $\begin{array}{r} 11323 \\ 1 \end{array}$ | $\begin{array}{r} 11838 \\ 2 \end{array}$ | 199496 | $\begin{array}{r} 1224 \\ 3 \end{array}$ | $\begin{array}{r} 4388 \\ 9 \end{array}$ | 4208 | $\begin{array}{r} 11186 \\ 8 \end{array}$ | $\begin{array}{r} 4202 \\ \hline \end{array}$ | 40447 | $\begin{array}{r} 3548 \\ 3 \\ \hline \end{array}$ | $\begin{array}{r} 6331 \\ \hline \end{array}$ | 12675 | $\begin{array}{r} 2290 \\ 29 \end{array}$ | $\begin{array}{r} 10262 \\ 86 \\ \hline \end{array}$ |

(*) France reporting for 2004

Table 7.2: Grouping of certain type of tests on animals of table 7.1

| 7.1. Species | Acute and sub-acute toxicity testing methods (including limit test) | Irritation /sensitization tests | Subchronic and chronic toxicity | Mutagenicity and carcinogenicity | Reproductive and developmental toxicity | Toxicity to aquatic vertebrates not included in other columns | other | To |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 188375 | 24155 | 25550 | 39103 | 3520 | 0 | 105541 | 38 |
| 1.b. Rats (Rattus norvegicus) | 117077 | 1601 | 65466 | 38127 | 75404 | 0 | 50829 | 34 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 19980 | 24328 | 628 | 0 | 0 | 0 | 8556 | 5 |
| 1.d. Hamsters (Mesocricetus) | 667 | 0 | 38 | 20 | 0 | 0 | 945 |  |
| 1.e. Other Rodents (other Rodentia) | 498 | 0 | 300 | 0 | 0 | 0 | 40 |  |
| 1.f. Rabbits (Oryctolagus cuniculus) | 3029 | 9215 | 1693 | 31 | 12718 | 0 | 12467 | 3 |
| 1.g. Cats (Felis catus) | 108 | 0 | 0 | 0 | 0 | 0 | 114 |  |
| 1.h. Dogs (Canis familiaris) | 6011 | 0 | 6998 | 0 | 29 | 0 | 1567 | 1 |
| 1.i. Ferrets (Mustela putorius furo) | 41 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 1.k. Horses, donkeys and cross breds (Equidae) | 10 | 0 | 0 | 0 | 0 | 0 | 30 |  |
| 1.I. Pigs (Sus) | 361 | 8 | 971 | 0 | 189 | 0 | 1718 |  |
| 1.m. Goats (Capra) | 0 | 0 | 0 | 0 | 0 | 0 | 39 |  |
| 1.n. Sheep (Ovis) | 32 | 0 | 0 | 0 | 72 | 0 | 353 |  |
| 1.o. Cattle (Bos) | 73 | 0 | 0 | 0 | 0 | 0 | 584 |  |
| 1.p. Prosimians (Prosimia) | 60 | 0 | 32 | 0 | 0 | 0 | 5 |  |


| 1.q. New World Monkeys (Ceboidea) | 307 | 0 | 185 | 0 | 90 | 0 | 68 |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.r. Old World Monkeys (Cercopithecoidea) | 2015 | 33 | 3406 | 0 | 318 | 0 | 485 |  |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 1.t. Other Mammals (other Mammalia) | 0 | 0 | 0 | 0 | 0 | 0 | 15 |  |
| 1.u. Quail (Coturnix coturnix) | 2706 | 0 | 0 | 0 | 480 | 0 | 0 |  |
| 1.v. Other birds (other Aves) | 13334 | 1000 | 158 | 0 | 128 | 0 | 36124 | 5 |
| 1.w.Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 12 |  |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 42 | 0 | 500 |  |
| 1.y. Fish (Pisces) | 76425 | 0 | 6443 | 226 | 10768 | 12675 | 9037 | 11 |
| 1.z. TOTAL | 431109 | 60340 | 111868 | 77507 | 103758 | 12675 | 229029 | 102 |

## III.9. Results of EU Table 8: $\underline{\text { Type of toxicity tests carried out for toxicological }}$ and other safety evaluations of products

## III.9.1. The data on type of toxicity tests carried out for toxicological and other safety evaluations of products

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products, for the 25 Member States reporting (EU Table 8) is presented in Table 8.1 of this report. There are discrepancies between the total numbers of animals per types of tests in Table 7 in comparison with the total numbers of animals per types of tests of Table 8. Logically these should be the same. These discrepancies originate from 10 Member States; however, when the data was submitted no explanation was given as to the reasons. The overall total number of animals for toxicological and other safety evaluations remains coherent.

## III.9.2. Treatment and interpretation of the data

As pointed out earlier it is important to keep in mind that animals used in toxicological and other safety evaluation represent $8 \%$ of the total number of animals used for experimental purposes. The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products has not been done in the previous reports due to inconsistencies in the data in the past. The results in this area are therefore analysed and compared in this report for the first time.

Figure 8.1 represents the percentages of the number of animals used in toxicological testing or other safety evaluations in relation to the type of products or purposes. In order to give a better graphical presentation of the results, some type tests have been grouped according to systemic and local toxicity and carcinogenic, mutagenic and toxicity to reproduction effects in Table 8.2 of this report.

Figure 8
Percentages of animals used for toxicity tests for toxicological and other safety evaluation by types of products


Figure 8.1 shows a decrease in the proportion of animals used in acute and sub-acute toxicity tests in comparison with other tests when moving down in the graph for products used A) for human medicine, dentistry and veterinary medicine, B) for agriculture, C) for industry, D) for household, E) for cosmetics, F) for additives in food consumption and G) for additives in food for animal consumption. However, the animals used in acute and sub-acute toxicity tests for other toxicological and safety evaluations would benefit from further analysis.

Contrary to acute and sub-acute toxicity one can observe an increase in the proportion of animals used for irritation and sensitization tests. While further down the graph amongst the four first types of products, a maximum amount of testing takes place for products used in cosmetics and toiletries.

The proportion of animals used in sub-chronic and chronic testing seems to follow the same pattern as for irritation sensitization tests with the highest proportion used for D ) household products and F ) additives in food for human consumption.

The pattern of use of carcinogenicity, mutagenicity and toxicity to reproduction tests is rather scattered between the different types of products and more difficult to interpret.

The proportion of animals used for G) additives in food for animal consumption is governed by about $90 \%$ by other tests. This group would benefit from further analysis.

Table 8.1: $\quad$ Number of animals used in toxicological and other safety evaluations Type of tests versus products

Data of 2005*

| 8.1. Products | 8.2. Acute and sub-acute toxicity testing methods (including limit test) |  |  | 8.3. <br> Skin <br> irritati <br> on | 8.4. <br> Skin sensiti sation | 8.5 . <br> Eye <br> irrita <br> tion | 8.6. Sub- <br> chronic and chronic toxicity | 8.7. <br> Carci nogenici ty | 8.8. <br> Devel op- <br> ment al toxicit y | 8.9. <br> Mutagenic ity | 8.10. <br> Repr <br> o- <br> ducti <br> ve <br> toxicit <br> y | 8.11. <br> Toxicity <br> to <br> aquatic <br> vertebr <br> a-tes <br> not <br> include <br> d in <br> other column <br> S | $\begin{aligned} & 8.12 . \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 8.13 . \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 18820 | 38091 | 155459 | 4097 | 15296 | $\begin{array}{r} 145 \\ 2 \end{array}$ | 67651 | $\begin{array}{r} 2658 \\ 9 \end{array}$ | $\begin{array}{r} 1823 \\ 8 \end{array}$ | $\begin{array}{r} 2100 \\ 5 \end{array}$ | $\begin{array}{r} 3078 \\ 8 \end{array}$ | 3419 | $\begin{array}{r} 1272 \\ 84 \end{array}$ | $\begin{array}{r} 52818 \\ 9 \end{array}$ |
| 8.b. Products/ substances used or intended to be used mainly in agriculture | 21368 | 5956 | 11467 | 872 | 6486 | 654 | 12535 | 3100 | $\begin{array}{r} 1015 \\ 8 \end{array}$ | 1831 | $\begin{array}{r} 1259 \\ 9 \end{array}$ | 1847 | 8687 | 97560 |
| 8.c. Products/ substances used or intended to be used mainly in industry | 18963 | 4047 | 13416 | 4743 | 9264 | $\begin{array}{r} 111 \\ 1 \end{array}$ | 13177 | 2644 | 3230 | 8371 | $\begin{array}{r} 1004 \\ 3 \end{array}$ | 2136 | 5684 | 96829 |


| 8.d. Products/ substances used or intended to be used mainly in the household | 20 | 18 | 11 | 48 | 154 | 70 | 568 | 3 | 0 | 51 | 0 | 0 | 276 | 1219 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries | 0 | 349 | 684 | 469 | 2222 | 300 | 966 | 0 | 368 | 213 | 0 | 0 | 0 | 5571 |
| 8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption | 6 | 40 | 1283 | 3 | 98 | 3 | 1767 | 0 | 0 | 239 | 1210 | 0 | 572 | 5221 |
| 8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption | 0 | 907 | 239 | 30 | 0 | 0 | 160 | 24 | 0 | 0 | 423 | 0 | $\begin{array}{r} 3169 \\ 2 \end{array}$ | 33475 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns | 32120 | 9894 | 5959 | 0 | 0 | 0 | 3793 | 7045 | 4541 | 594 | 5393 | 6524 | 7885 | 83748 |
| 8.i. Other toxicological or safety evaluations | 20974 | 58282 | 8840 | 668 | 4921 | 478 | 23062 | 1459 | 2756 | 4836 | 2088 | 4593 | $\begin{array}{r} 4151 \\ 7 \\ \hline \end{array}$ | $\begin{array}{r} 17447 \\ 4 \\ \hline \end{array}$ |
| 8.j. TOTAL | 112271 | $\begin{array}{r} 11758 \\ 4 \end{array}$ | 197358 | 10930 | 38441 | $\begin{array}{r} \hline 406 \\ 8 \end{array}$ | 123679 | $\begin{array}{r} 4086 \\ 4 \end{array}$ | $\begin{array}{r} 3929 \\ 1 \end{array}$ | $\begin{array}{r} 3714 \\ 0 \\ \hline \end{array}$ | $\begin{array}{r} 6254 \\ 4 \end{array}$ | 18519 | $\begin{array}{r} 2235 \\ 97 \end{array}$ | $\begin{array}{r} 10262 \\ 86 \end{array}$ |

(*) France reporting for 2004

Table 8.2: Number of animals used in toxicological and other safety evaluation per types of products

| 8.1. Products | Acute and subacute toxicity testing methods (including limit test) | Irritation/sensitization tests | Subchronic and chronic toxicity | Mutagenicity and carcinogenicity | Reproductive and developmental toxicity | Toxicity to aquatic vertebrates not included in other columns | Other | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 212370 | 20845 | 67651 | 47594 | 49026 | 3419 | 127284 | 528189 |
| 8.b. Products/ substances used or intended to be used mainly in agriculture | 38791 | 8012 | 12535 | 4931 | 22757 | 1847 | 8687 | 97560 |
| 8.c. Products/ substances used or intended to be used mainly in industry | 36426 | 15118 | 13177 | 11015 | 13273 | 2136 | 5684 | 96829 |
| 8.d. Products/ substances used or intended to be used mainly in the household | 49 | 272 | 568 | 54 | 0 | 0 | 276 | 1219 |
| 8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries | 1033 | 2991 | 966 | 213 | 368 | 0 | 0 | 5571 |
| 8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption | 1329 | 104 | 1767 | 239 | 1210 | 0 | 572 | 5221 |


| 8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption | 1146 | 30 | 160 | 24 | 423 | 0 | 31692 | 33475 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns | 47973 | 0 | 3793 | 7639 | 9934 | 6524 | 7885 | 83748 |
| 8.i. Other toxicological or safety evaluations | 88096 | 6067 | 23062 | 6295 | 4844 | 4593 | 41517 | 174474 |
| 8.j. TOTAL | 427213 | 53439 | 123679 | 78004 | 101835 | 18519 | 223597 | 1026286 |


[^0]:    OJ L 358, 18.12.1986, p.1
    COM (94) 195 final COM (1999) 191 final
    COM (2003) 19 final
    COM (2005) 7 final

[^1]:    $6 \quad$ OJ C 331, 23.12.86, p. 2.

[^2]:    France reporting for 2004

