

EN

EN

EN



EUROPEAN COMMISSION

Brussels, 30.9.2010
COM(2010) 511 final

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

**Sixth Report on the Statistics on the Number of Animals used for Experimental and
other Scientific Purposes in the Member States of the European Union**

SEC(2010) 1107

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

**Sixth Report on the Statistics on the Number of Animals used for Experimental and
other Scientific Purposes in the Member States of the European Union**

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
III.	RESULTS	5
III.1.	Results of EU Table 1: <i>Species and number of animals</i>	5
III.1.1.	Results concerning species used	5
III.1.2.	Comparison with the data of the previous reports	6
III.2.	Results of EU Table 1: <i>Origin of animals used</i>	7
III.3.	Results of EU Table 2: <i>Purposes of the experiments</i>	8
III.4.	Results of EU Table 3: <i>Toxicological and safety evaluation by type of product/endpoint</i>	9
III.5.	Results of EU Table 4: <i>Animals used for studies of diseases</i>	10
III.6.	Results of EU Table 5: <i>Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine</i>	11
III.7.	Results of EU harmonized Table 6: <i>Origin of regulatory requirements for animals used in toxicological and other safety evaluations</i>	12
III.8.	Results of EU Table 7: <i>Animals used in toxicity tests for toxicological and other safety evaluations</i>	13
III.9.	Results of EU Table 8: <i>Type of toxicity tests carried out for toxicological and other safety evaluations of products</i>	14

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 purposes¹, 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 drafted in accordance with the provisions of the above mentioned directive which were published in 1994² and 1999³, covering data on experimental animals collected in 1991 and 1996 respectively in the Member States, allowed only a limited

¹ OJ L 358, 18.12.1986, p.1.

² COM (94) 195 final

³ COM (1999) 191 final

amount of statistical analysis due to the absence of a consistent system of reporting the data. In 1997 an agreement was reached between the Commission and the competent authorities of the Member States to submit data for future reports using a format of eight harmonized tables. The third and fourth statistical reports published in 2003⁴ and 2005⁵ covering data collected in 1999 and 2002 were based on these tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. The Fifth Statistical Report, published in 2007⁶, contained for the first time data collected in the 10 Member States which joined the EU in 2004. In the Sixth Statistical Report the complete set of standardized tables provided by all 27 Member States were successfully evaluated, although comparison of the results with previous reports was essentially qualitative owing to the addition of data from the new Member States.

This Sixth Statistical Report includes data submitted by Romania and Bulgaria, which joined the EU in 2007. It gives an overview of the number of animals used in the Member States for experimental purposes for the year 2008, with the exception of one Member State which provided data from 2007, and summarizes the data and conclusions found in the Commission Staff Working Document – *Sixth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union*.

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

All 27 Member States submitted the data in the agreed EU format. The data quality control showed acceptable quality for the data submitted for 2008. This applies also to the new Member States Bulgaria and Romania who reported for the first time.

The individual data from the Member States together with their respective comments and interpretations can be found in the Staff Working Document.

II.2. General assessment

As the two newest Member States Bulgaria and Romania have submitted data for the first time (representing below 1,0% of the total number of animals used in the EU 27), it is in principle not possible to draw accurate quantitative conclusions on the evolution of the use of animals for experimental purposes in the EU by comparing data with those of the previous reports. However, some comparisons in trends have been attempted, and significant changes in use have been highlighted in the report.

The total number of animals used for experimental and other purposes in 2008 in the 27 Member States EU (27) is just above 12,0 million.

As in previous reports rodents together with rabbits represent more than 80% of the total number of animals used in the EU. Mice are by far the most commonly used species accounting for 59% of the total use, followed by rats with 17%.

⁴ COM (2003) 19 final
⁵ COM (2005) 7 final
⁶ COM (2007) 675 final

The second most used group of animals was, as in previous years, cold-blooded animals which represent almost 10%. The third largest group of animals used was birds with a little over 6% of the total use.

As stated in the previous two statistical reports no Great Apes were used in experiments in the EU in 2008.

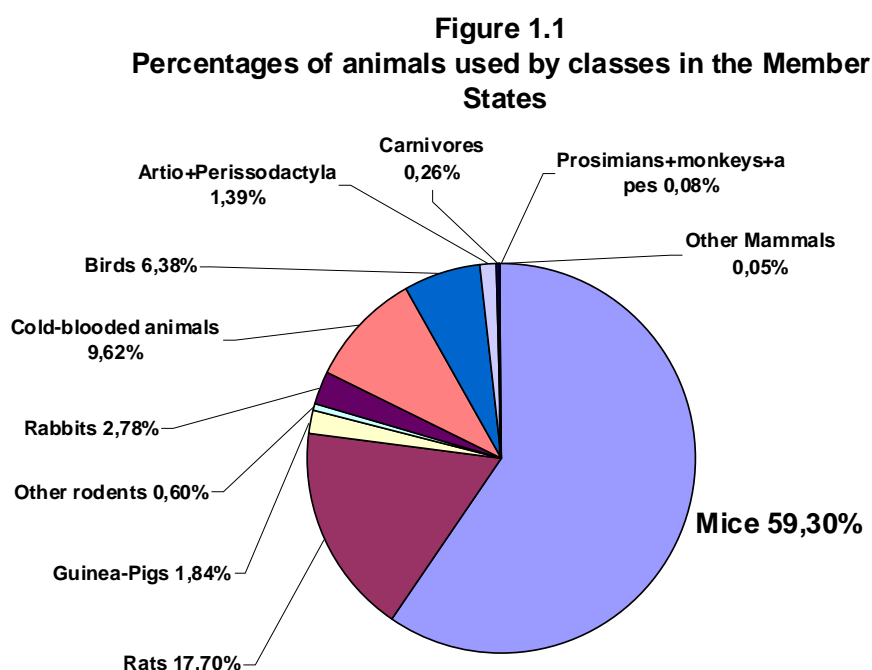
III. RESULTS

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

III.1.1. Results concerning species used

Malta has hitherto reported no animal use for scientific purposes, but reported the use of 690 animals in 2008.

Mice (59%) and Rats (17%) were by far the most used species (Figure 1.1.).



Rodents together with rabbits represent more than 80% of the total number of animals used. The second most used group of animals was, as in the previous years cold-blooded animals namely reptiles, amphibians and fish representing 9,6% followed by birds with 6,3%.

The Artiodactyla and Perissodactyla group including horses, donkeys and crossbreeds (Perissodactyla), pigs, goats, sheep and cattle (Artiodactyla) represents 1,4% 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 0,08% of the animals used in 2008.

III.1.2. Comparison with the data of the previous reports

The aim of this report is to indicate whether important changes have occurred related to use of different species, although rigorous comparisons cannot be made with previous reports.

Comparison between proportions of classes of animals used in 1996, 1999, 2002, 2005 and 2008

Class of species	1996(*)	1999	2002(**)	2005(***)	2008(****)
% Rodents-rabbits	81,3	86,9	78,0	77,5	82,2,
% Cold-blooded animals	12,9	6,6	15,4	15,	9,6
% Birds		4,7	5	5,4	6,4
% Artio and Perissodactyla		1,2	1,2	1,1	1,4

(*) 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

(****) 27 Member States reporting for 2008, one for 2007

Overall, the percentage of rodents and rabbits shows some fluctuation, but remains close to 80%. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 10 to 15%. In 2008 the use of cold-blooded animals has dropped considerably to below 10%. However, in 1999 a much lower percentage of 6,6% was observed. Birds representing the third largest percentage of animals used, seems to be in constant increase over the years from 4 to 6,4%. The group of horses, donkeys and cross-bred animals (perissodactyla) and pigs, goats, sheep and cattle (artiodactyla) fluctuates at around 1%.

The inclusion of the data from Bulgaria and Romania did not lead to an increase in the total number of animals, on the contrary, there is a decrease of more than 116,500 animals. However, noticeable changes have occurred for the use of some individual species compared to data from the 2005 report.

Significant increases occurred in 2008 for mice, rabbits, pigs and 'other birds' where percentage changes ranged from 5% to 28%. The increase in the number of mice used since 2005 is 691,842 animals which represents 9,71% of the total number of mice used in 2008. The total number of pigs, goats, prosimians, and reptiles has increased by between 28 - 46%. On the other hand the total number of rats, guinea-pigs, other rodents, dogs, cattle and other mammals as well as amphibians and fish used has decreased substantially since the last report. When expressed in percentages these decreases range from more than 70% to around 10%.

The largest percentile change has been noted in the decrease of the use of other carnivores. However, these species are not used in great numbers (from 8,711 to 2,853). There is also a large decrease of 75% in the total number of 'other mammals'.

The following animals which are normally used in fewer numbers, show an increase in use: ferrets (16%), horses, donkeys and cross-breeds (11%), goats (44%) and reptiles (39%).

It is also worth noting the large decrease in the use of new world monkeys of 73% as well as a decrease of 11% of old world monkeys. As in 2002 and 2005, no great apes were used for experimental or other scientific purposes in 2008.

Member States provided examples of the type of species covered by category 'other' as follows:

Other rodents: gerbils, old world jerboas (*Jaculus jaculus*); chinchillas, beavers, ground squirrels, hamsters, grey dwarf hamsters (*Cricetulus migratorius*) and different species of mice.

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

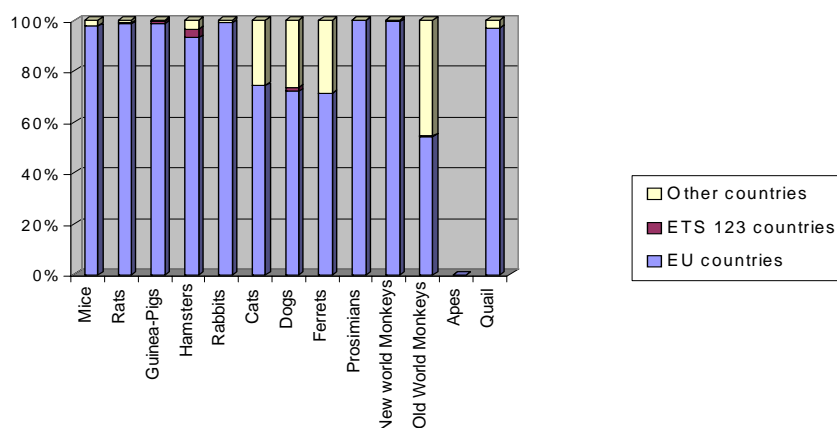
Other mammals: boars, bats and shrews, llamas, moles, European bison and red deer.

Other birds: mainly Japanese Quail (*coturnix japonica*) and bob-white quail, poultry species, and zebra finches, canary, parakeet, parrot and farmed avian species for example, chickens.

III.2. Results of EU Table 1: Origin of animals used

According to the standardised EU tables the origin must only be reported for certain selected animal species.

Figure 1.2: Origin of species

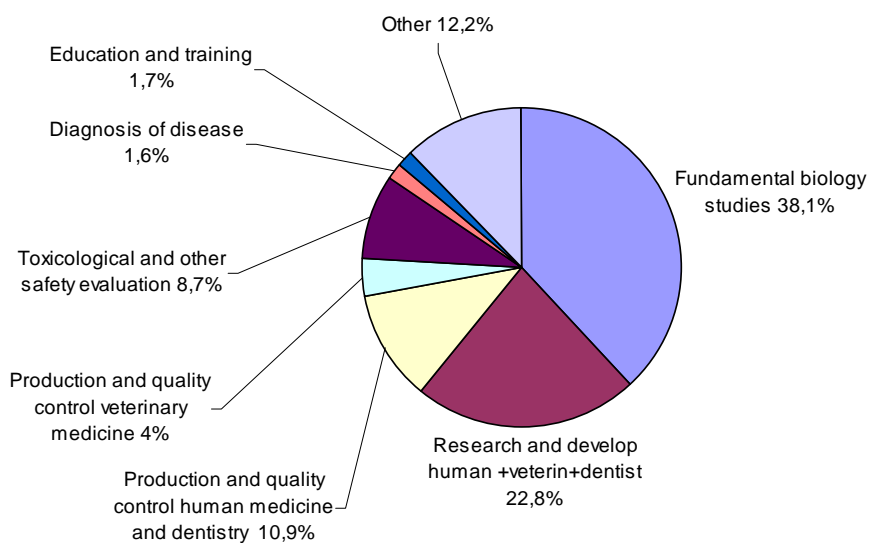


The chart shows clearly that the majority of the species originated from EU countries. However, certain species such as cats, dogs, ferrets and old world monkeys are of non-European origin. The origin of the species were quite similar to that observed in previous reports. However, for the first time in 2005 the prosimians used were all of EU origin and have remained so. A similar trend can also be observed with new world monkeys where almost all originate from either EU Member States or countries which are a party to the Council of Europe Convention ETS 123. Finally, also old world monkeys coming from the EU increased from about 26% in 2005 to more than 50% in 2008. The number of cats of EU origin also increased whereas dogs and ferrets of non-European origin have remained unchanged since 2005.

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

More than 60% of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biology studies (Fig 2). Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 14,9% of the total number of animals. Toxicological and other safety evaluation represented 8,7% of the total number of animals used for experimental purposes.

Figure 2
Purposes of experiments



Bearing in mind that the comparison aims to detect changes in trends rather than draw formal conclusions, the most significant change that has taken place since 2005 is that the number of animals used for research and development for human medicine, dentistry and veterinary medicine has dropped sharply from 31% to 22,8% (in terms of animal numbers the decrease is from 3,746,028 to 2,733,706). To be noted in particular was the significant reduction of more than 800,000 cold-blooded animals since the last report of 2005. On the other hand the percentage of animals used for fundamental biological research has increased from 33% to 38% (that is, from 4,035,470 to 4,575,054) as well as for 'other purposes', from 8% to 12%. It should be underlined that both fundamental biology and research and development in human and veterinary medicine are the areas using by far the highest number of animals for experimental purposes in the EU. For additional details see the Staff Working Document.

The number of animals used for toxicological and other safety evaluation has remained virtually unchanged since the last report and amounts to 8,7% of the total number of animals used for experimental purposes in the EU. This represents 1,042,153 animals.

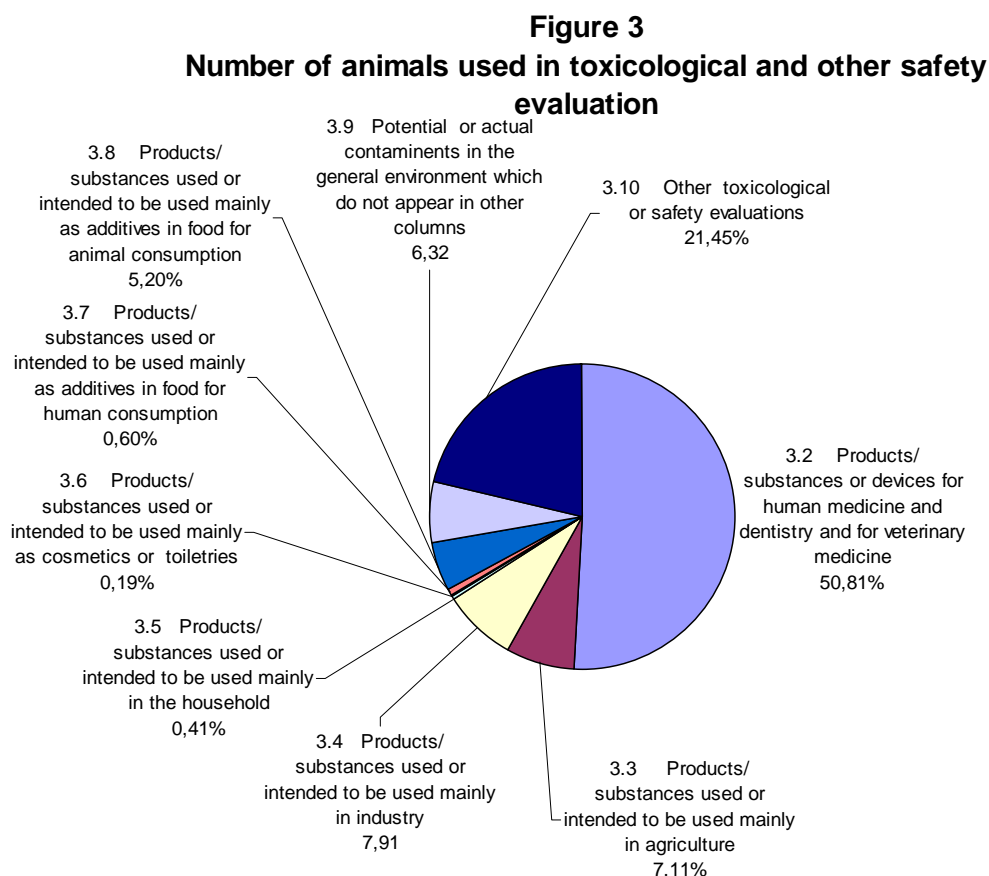
There is a substantial increase in the use of mice and rabbits for the production and quality control of products and devices for human medicine and dentistry', but also an increase in use of mice, pigs and birds for 'fundamental biological research' and in 'other experiments'. Several Member States confirmed that this increase in the use of mice is attributed to new research possibilities offered by the transgenic species. These animal models are being used for both human and animal health studies. An increase was also reported for the purpose of

experiments in anatomy and developmental biology, physiology, genetics and cancer research, and for immunology and microbiology.

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

The number of animals used for toxicological and other safety evaluation for different products or environmental test schemes amounts to 1,042,153, which represents 8,7% of the total number of animals used for experimental purposes in the EU.

Of this total, animals used for toxicological or other safety evaluations of products or devices used for human medicine, veterinary medicine and dentistry represented 50,8% and was therefore the purpose using the largest number of the animals. The percentage of animals used for toxicological evaluation of three groups of products/substances, i.e. additives in food for human consumption, cosmetics and household products, is very small (1,18%) when compared to the other product groups. The percentages of animals used for toxicological or other safety evaluation of industrial and agricultural products are respectively representing 7,1% and 7,9% of the number of animal used for that purpose (see Fig. 3). Other toxicological and safety evaluation represented more than 21%.



There is a clear decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture and for potential contaminants of the environment. The decrease ranges respectively from above 96,000 to about 82,000; from below 98,000 to about 74,000 and from above 84,000 to about 65,000 in comparison to the data submitted in the 2005 statistical report. There is also a significant decrease in the number of animals used for

testing of products for cosmetics and toiletries ranging from 5,500 to just below 2,000 (a 65% drop). This radical change should be seen in light of the legal requirement to phase out animal testing for cosmetics in the EU.

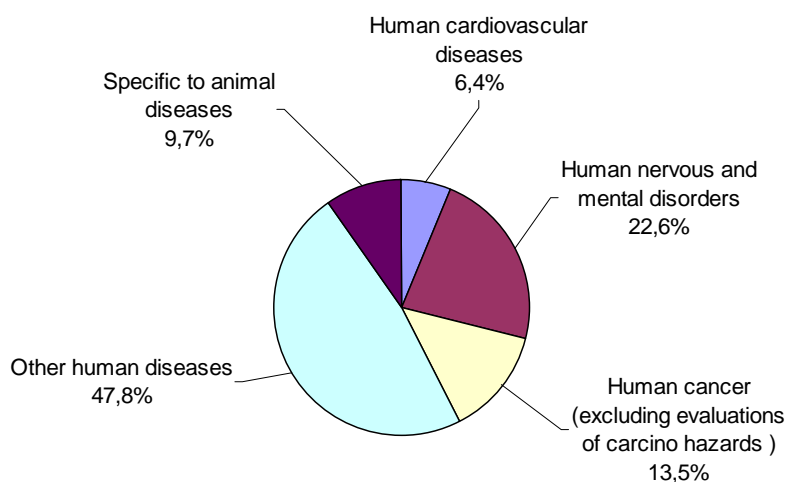
There is, however, a significant increase since 2005 in the number of animals used for tests for additives in food for animal consumption (from 34,225 to 54,164). There is also a significant increase in the number of animals used for 'other' toxicological or safety evaluation (ranging from around 180,000 to about 220,000). Member States reported that this particular use of animals 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 of toys.

III.5. Results of EU Table 4: Animals used for studies of diseases

The number of animals used in 2008 for studies of both animal and human diseases represented approximately 52% of the total number of animal used for experimental purposes.

The proportion of animals used for studies of human diseases represents more than 90% of the total number of animals used for all disease studies. (Fig 4.1)

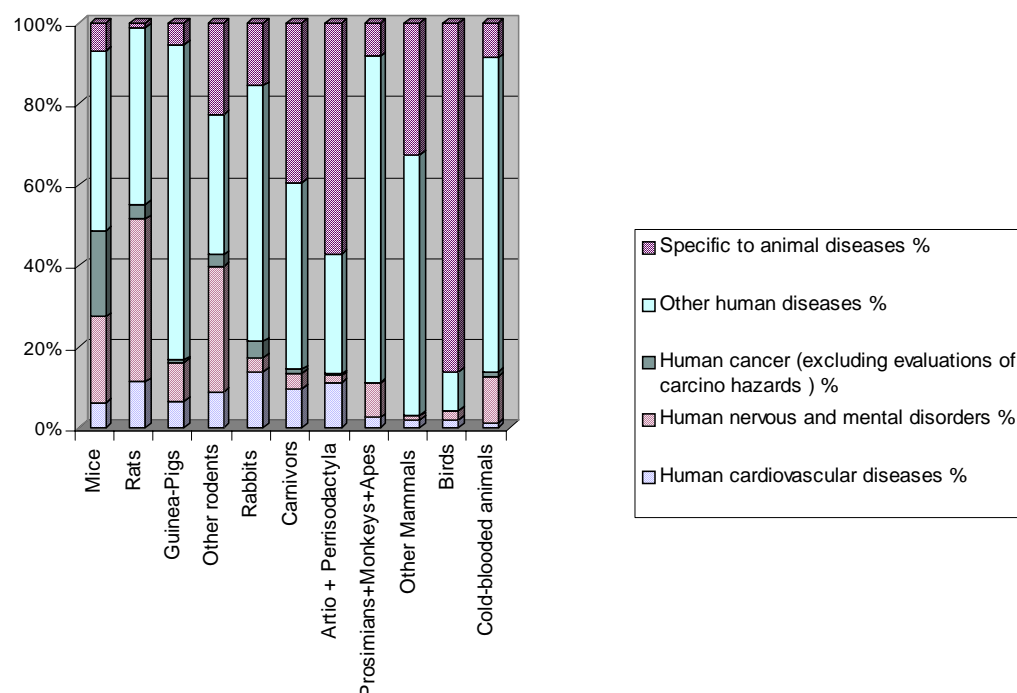
Figure 4.1
Proportion of animals used for the studies of diseases



There has been a 50% decrease in animals used for studies on animal diseases - from 1,329,000 to 614,000. The use of cold-blooded species has decreased from around 954,000 animals in 2005 to 43,914 in 2008. However, the use of mice has increased substantially. Around 35% of the increase (about 681,000) can be attributed to disease studies.

There has also been an increase in the number of birds used for studies on animal diseases. Member States reported studies on bird flu, Gumboro disease and bronchitis including studies on quality and safety of vaccines.

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



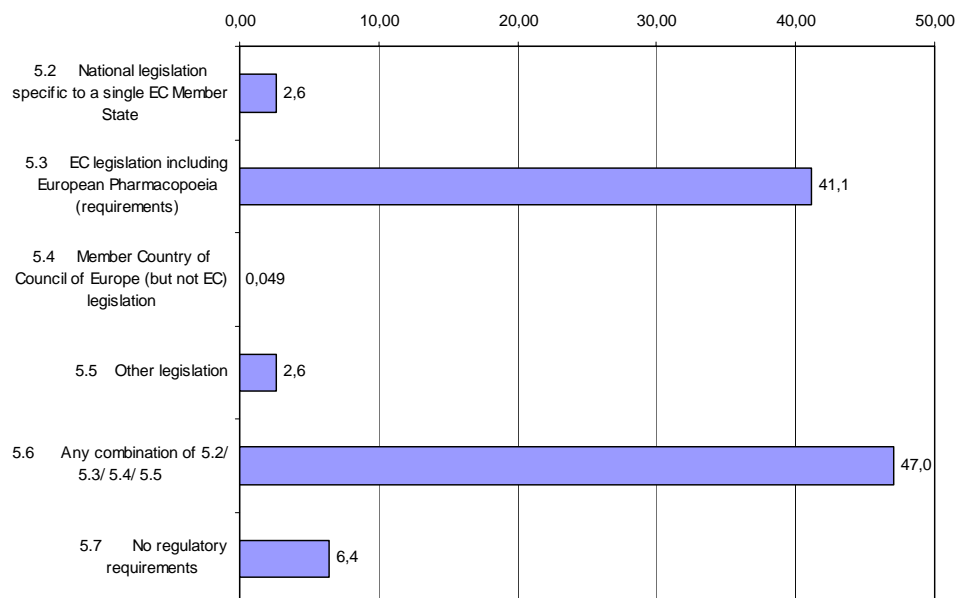
In Figure 4.2 the top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Significant numbers of both artiodactyla and perissodactyla and birds are used for this purpose. Member States reported that it is still current practice to test vaccines on these species. However, in some Member States birds are only used if the infection concerns bird species.

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

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 14,9% of the total number of animals used for experimental purposes.

The largest proportion of animals in this area (47%) was used to satisfy requirements from several pieces of legislation (national, from the EU, the Council of Europe member country legislation, and from legislation outside of the EU (Fig 5)). 41,1% of the animals were used to satisfy EU legislative requirements including the European Pharmacopoeia.

Figure 5
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



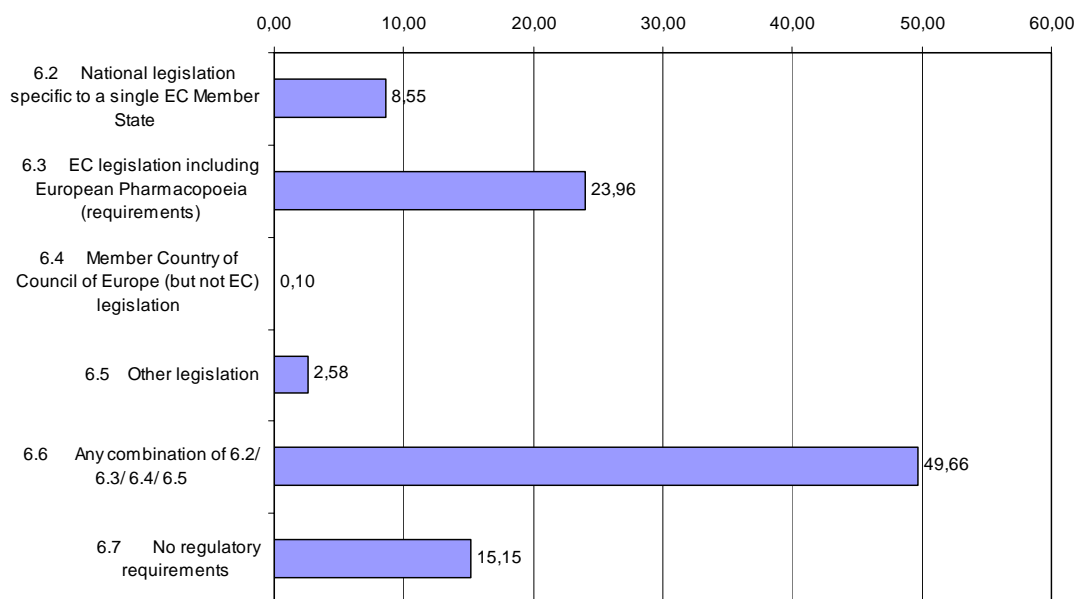
In comparison to the last report there is a net increase in the number of animals used to satisfy simultaneously several pieces of legislation. On the other hand there is a net increase of tests carried out to satisfy EU legislation including the European Pharmacopoeia. Consequently, there is a net decrease in the number of animals used to satisfy national legislation, which is an encouraging trend showing an attempt to move towards EU harmonisation of regulatory requirements.

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

As pointed out earlier, the number of animals used in toxicological or other safety evaluation represents 8,7% of the total number of animals used for experimental purposes in the EU.

Of this total, animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered almost half of the animals used in this area (50%). The testing required under EU legislation including the European Pharmacopoeia accounted for the second highest percentage in this area, namely 24%.

Figure 6
Percentages of animals used for regulatory requirements for toxicological and other safety evaluation



In comparison to the last report there is a slight decrease in the proportion of animals used to simultaneously satisfy several pieces of regional legislation from 54% to 50%.

On the other hand there is a substantial increase in the proportion of animals used for no regulatory requirements from 5 to over 15,0%. In order to explain what is meant by the term 'no regulatory requirements', some Member States gave as an example projects using in-house methods to verify the safety and efficacy of veterinary biologicals and medicinal products using animals, and carried out according to a company's standards. The results may be accepted by that Member State national authority, although not required by legislation.

The testing carried out in 2008 to satisfy national legislation specific to a single Member State showed a decrease of about 7,500 animals which represents roughly a 1,2% decrease compared to the last report.

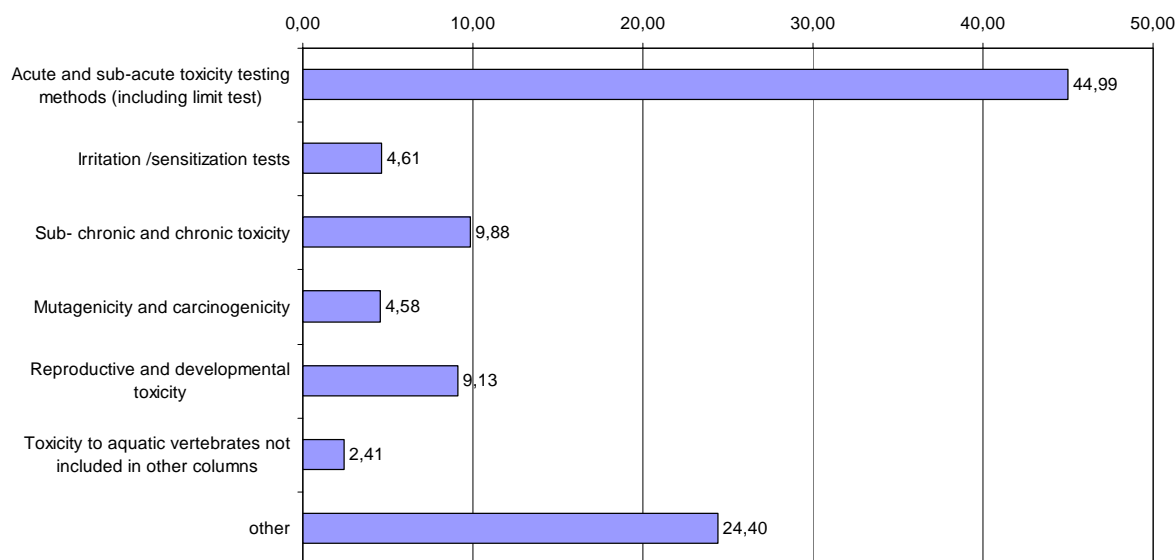
III.8. Results of EU Table 7: Animals used in toxicity tests for toxicological and other safety evaluations

The largest percentage (almost 45%) of use of animals in toxicological and other safety evaluations is due to acute and sub-acute toxicity tests. Also taking into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for 55% in this area (Fig 7).

13,7% of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction. Another important category of use of animals in 2008 was for 'other tests' with 24%. 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 biological evaluation of medical devices: Intracutaneous testing of reactivity in rabbits, studies into the penetration of nanoparticles

through tissue and their biocompatibility, studies into the evaluation of sensitization potential of dyestuffs used in the textile industry and pharmacological studies included in safety tests.

Figure 7
Percentages of animals used in toxicity tests for toxicological and other safety evaluation



There is a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests, ranging from 36% - 42% to almost 45% respectively. Since the last report, this represents in animal numbers an increase of more than 37,000 animals. 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.

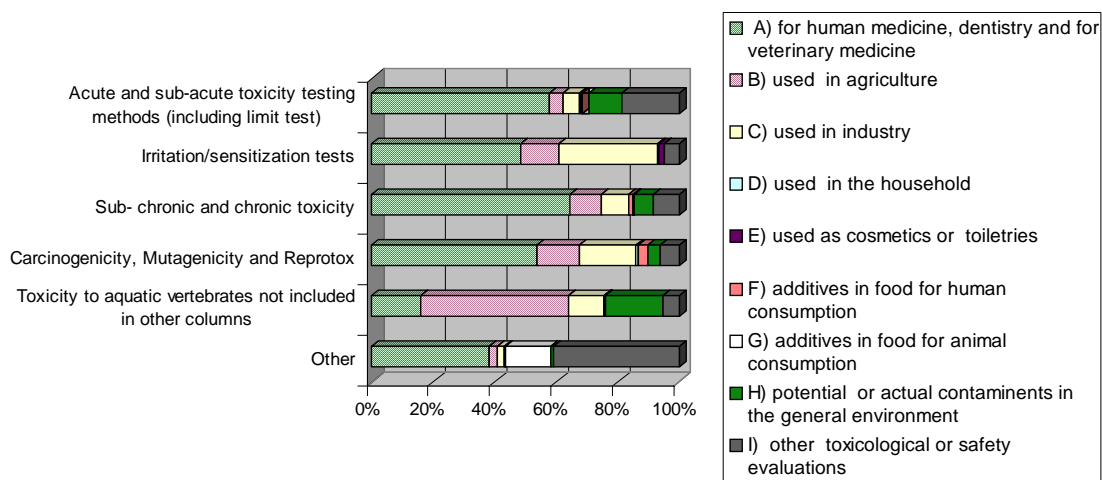
On the other hand there is a steady decrease over the last three reports of the animals used for reproductive toxicity testing from: 12% to 10% and to 9% respectively. In terms of animals it means a saving since the 2005 report of 8,650 animals.

III.9. Results of EU Table 8: Type of toxicity tests carried out for toxicological and other safety evaluations of products

Figure 8 shows that the majority of animals tested in acute/sub-acute toxicity are intended for the purpose of human medicine, dentistry and veterinary medicine. This is followed by tests carried out for other toxicological or safety evaluations, and then for agriculture and industrial products.

The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products was done for the first time in the Fifth Statistical Report. However, because the graph in that report represented more the relative importance of tests within a type of product rather than the proportion of animals used per type of test for the different products, the graph was modified accordingly for this report.

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



Products intended for medicine, dentistry and veterinary medicine require the highest proportion of animals for the different types of tests i.e. approximately 50%. The next highest proportion is for 'other' toxicological evaluations, above 20%, followed by animals used in tests for products for agriculture and for industry each above 7%.