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**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**

{SEC(2007)1455}

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1. 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 published in 1994² and 1999³ 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

¹ OJ L 358, 18.12.1986, p.1.

² COM (94) 195 final

³ COM (1999) 191 final

published in 2003⁴ and 2005⁵ 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.

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 2004. It gives an overview of the year 2005 with the exception of one Member State who reported data of 2004.

This Report summarizes the data and conclusions found in the Commission Staff Working Document - "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".

I. DATA SUBMITTED AND GENERAL ASSESSMENT

I.1. Data submitted by the Member States

All Member States submitted the data for 2005 in the agreed EU format. Regarding the quality of data, Member States have applied a quality control check on their respective set of data. 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.

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 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.

I.2. General assessment

The EU 10 are reporting data for the first time, therefore it is not possible to draw 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 will be attempted and significant changes in use will be highlighted in the report. Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States (EU 25) amounts to 12,1 million (with data from France of 2004). The number of animals used in the EU 10 represents 8,6% of the total number of animals used in the EU 25.

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.

⁴ COM (2003) 19 final

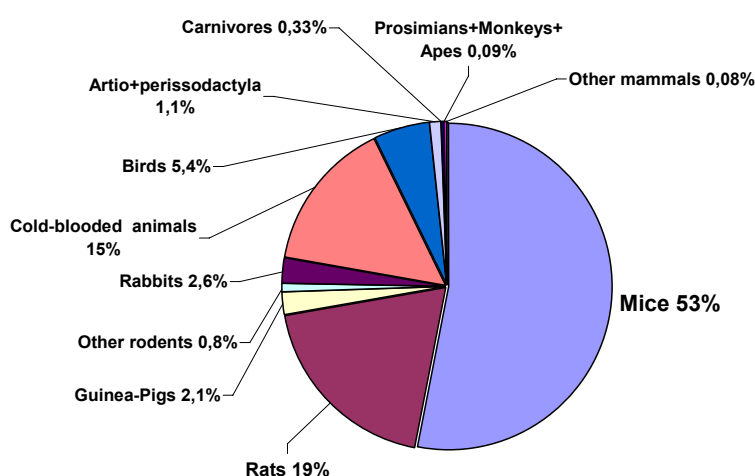
⁵ COM (2005) 7 final

II. RESULTS

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

The total number of animals used in 2005 in the EU 25 amounts to 12,1 million animals. Mice (53%) and rats (19%) were by far the most used species (fig.1.1). Rodents together with rabbits represent 77,5% of the total number of animals used. Cold-blooded animals with 15% represented the second most used group of animals followed by birds with 5,4%. The Artio and Perissodactyla group including horses, donkeys and crossbreeds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represented only 1,1%. Carnivores represented 0,3% of the total number of animals used in 2005 and non-human primates represent 0,1%.

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



III.1.1. Comparison with the data of the previous reports

The number of animals used in the EU 10, which reported for the first time, 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.

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

| Class of species | 1996(*) | 1999 | 2002(**) | 2005(***) |
|------------------------|---------|------|----------|-----------|
| % Rodents-rabbits | 81,3 | 86,9 | 78,0 | 77,5 |
| % Cold-blooded 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

(***) 25 Member States reporting for 2005, one for 2004

From the above table, 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 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. The total number of hamsters, goats, prosimians, quails 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', although these species are not used in great numbers (from 3110 to 8711). This is further contrasted against a decrease in their use in the EU 15. The other large increase both in the EU 25 and also in the EU 15 is for the use of 'other mammals' (from 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 the Staff Working Document, 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.

III.1.2. Comparison with the data of the previous reports for the EU 15

Since the total number of animals include the data from the 10 new Member States it is not possible to draw comparison *per se* with the results of the previous reports. However, to allow for some comparisons of trends of the animal use, a comparison of the number of animals used by the EU 15 in 2002 and by the EU 15 in 2005 was made.

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 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 perisodactyla 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; 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;

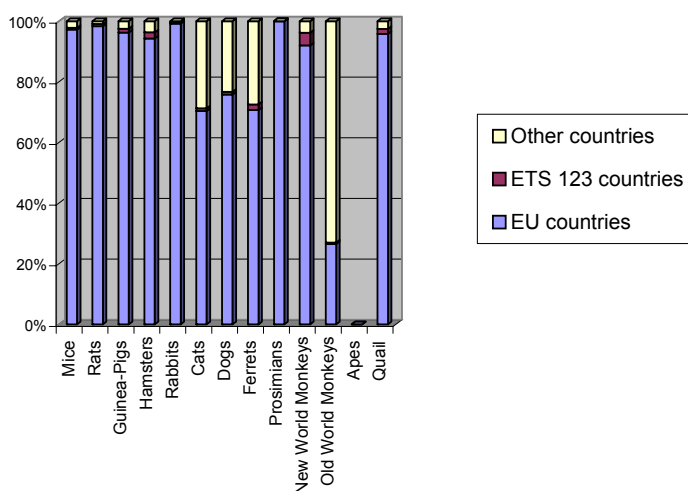
Other mammals: boars, bats and shrews, llama, mole, European bison and red deer;

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.

III.2. Further results of EU Table 1: Origin of animals used

Although the origin only has to be reported for selected animal species, it is evident that the majority of the species originated mainly from EU countries (fig 1.2), with the exception of old world monkeys.

Figure 1.2: Origin of species

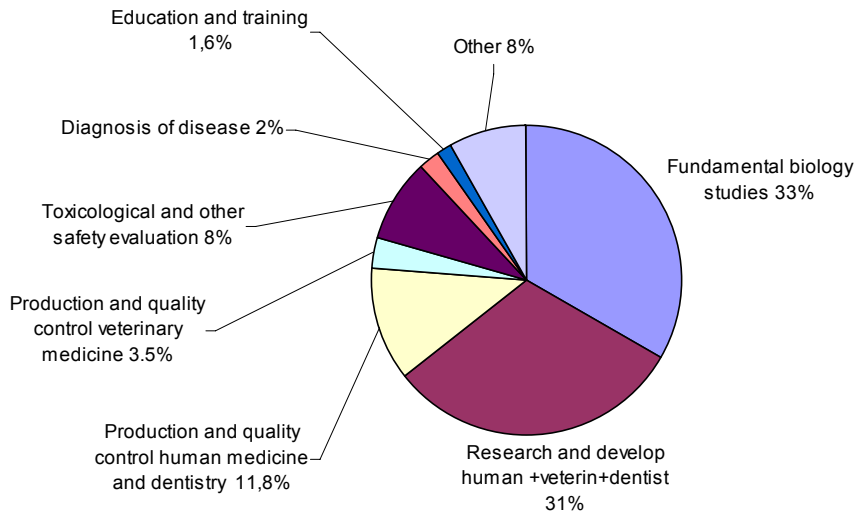


The general pattern on the origin of the species is quite similar to that observed in the previous reports. It should be noted however, that for the first time in 2005 the prosimians were all of EU origin. A similar trend can also be observed with the new world monkeys where an increasing amount was 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.

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 2.1). 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 represented 8% of the total number of animals used for experimental purposes.

Figure 2.1
Purposes of experiments



Comparison with the data of the previous report

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%. 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.

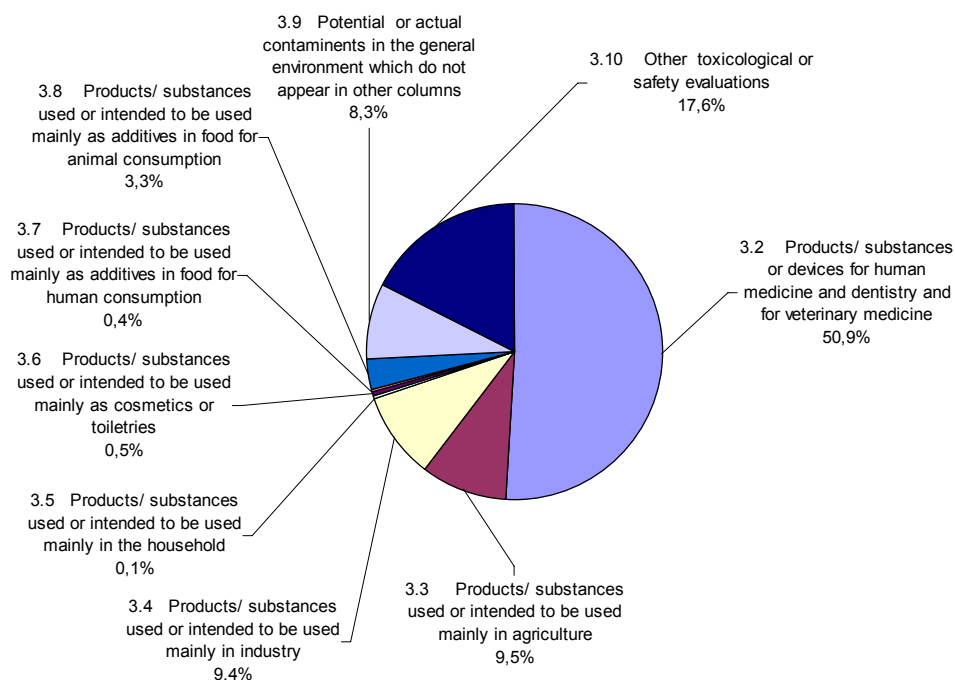
'Other' purposes covers amongst other things virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgenesis, oncological treatment, pharmaceutical R&D, combined drug testing and genetics.

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

Only 8% of the total number of animals used for experimental purposes is used for toxicological and other safety evaluation. Products or devices used for human medicine, veterinary medicine and dentistry represents 50,9% (fig 3.1) of the animals used for toxicological or other safety evaluations. The percentage of animals used for toxicological evaluation of 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.

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.

Figure 3.1
Animals used in toxicological and other safety experiments



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.

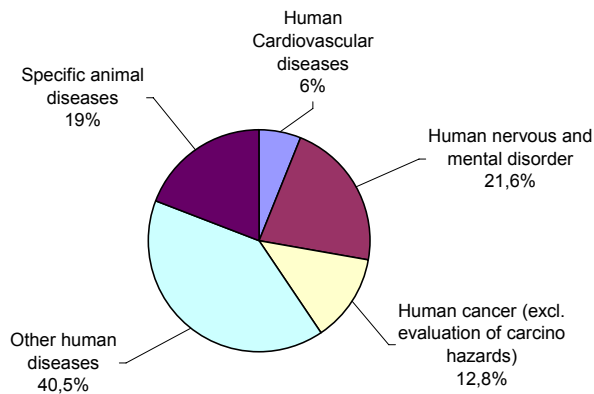
There is however a noticeable increase in the number of animals used for cosmetics or toiletries (50%), however, the actual numbers of animals in this category remain low (5,571 in total). This increase, attributed mainly to one old Member State, is worth noting in light of the legal requirement to phase 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 be noted that in comparison to 2002 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). 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.

III.5. Results of EU Table 4: Animals used for studies of 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. 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 (fig 4.1).

Figure 4.1
Proportion of animals used for the study of diseases



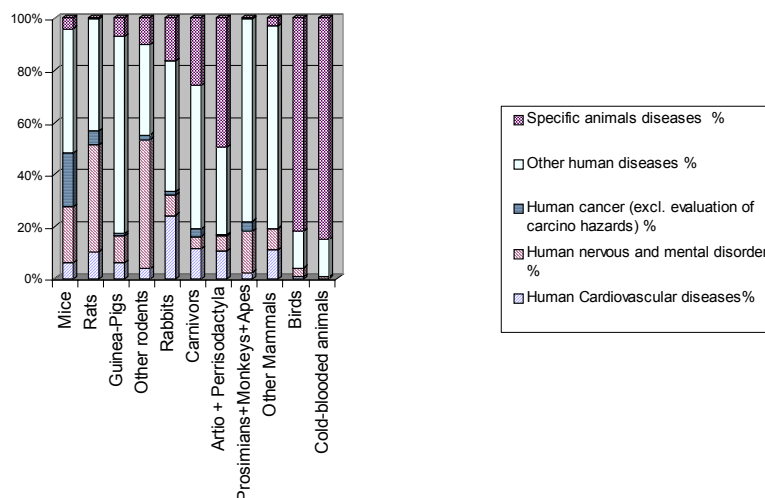
In 2005, the proportion and the number of animals used (ranging from 900,000 to 1,329,000) for the studies of animal diseases have increased significantly when compared with the report of 2002.

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 flu. Animals used cover also study 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.

The relative percentage of animals per classes of species used in studies by type of diseases is presented in fig 4.2. The top of each bar shows the 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. It was reported that a significant number of vaccines are tested on these groups of animals.

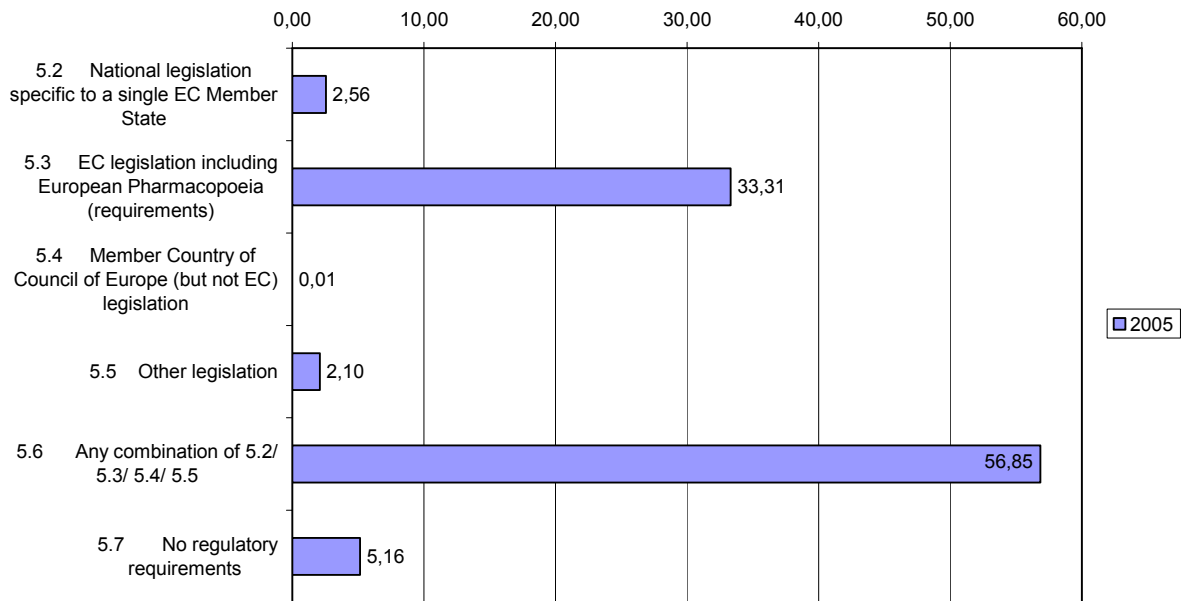
Figure 4.2
Proportion of animals used by classes per type of studies of diseases



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 15,3% of the total number of animals used for experimental purposes. 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 (fig 5.1). The testing carried out to satisfy the EU legislation including the European Pharmacopoeia covered 33,3% of the animals used 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 increase of the percentage, from 43,1% to 56,8%, of the number of animals used due to requirements laid down simultaneously by several pieces of legislation in comparison to 2002, is clearly showing a positive trend. This is likely to reflect an increased harmonisation of different legislative requirements.

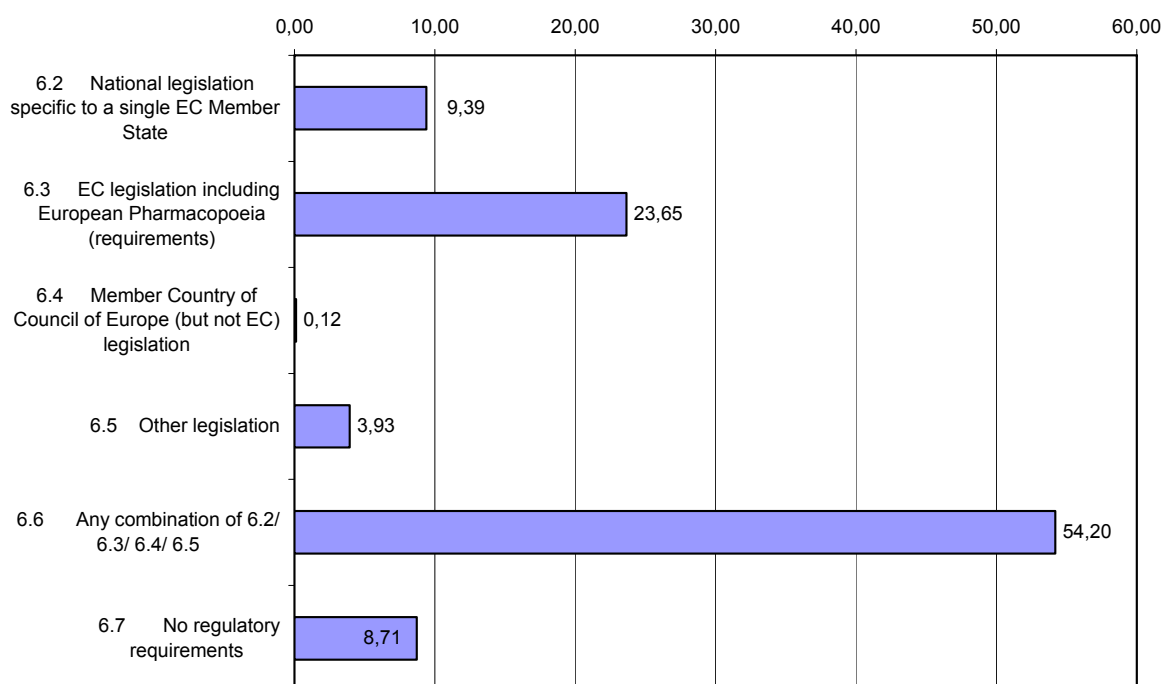
Another positive trend is the reduction of the number of animals, from 352,000 to 95,739, used for 'no regulatory requirements'.

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% of the total number of animals used for experimental purposes in the EU.

Animals used to simultaneously satisfy regulatory requirements from several legislations covered more than half of the animals used in this area (54,2%) (fig 6.1). The testing required under the EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area, namely 23%.

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



It should be underlined that the proportional decrease of the numbers of animals used for toxicological and other safety evaluations 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 for '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.

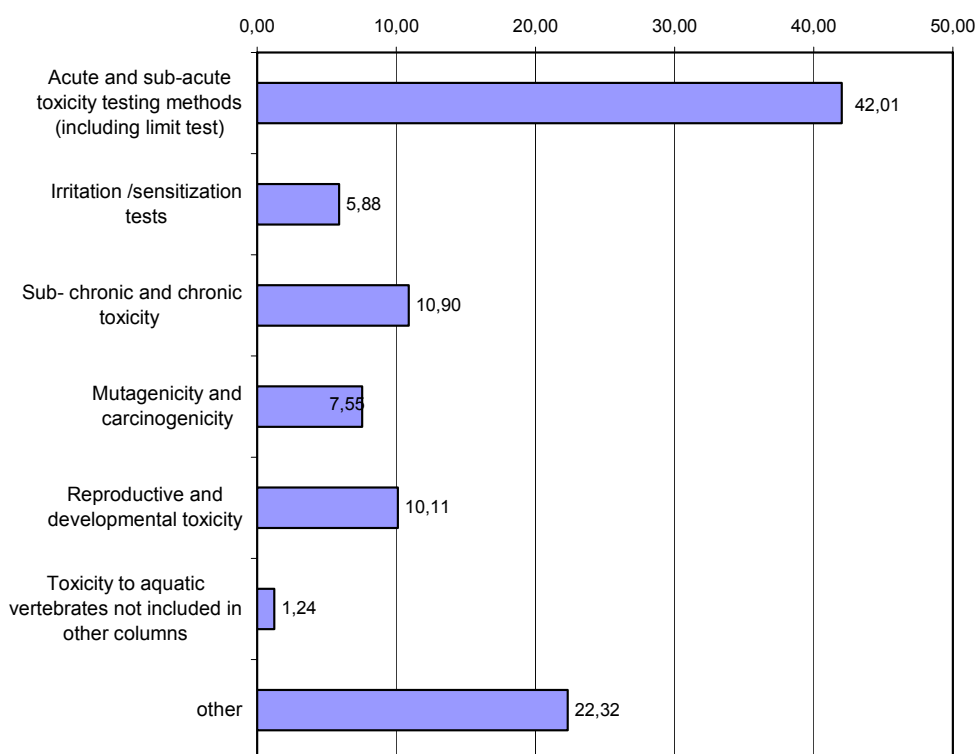
The testing to satisfy national legislation specific to a single Member State showed a decrease in this report with respect to the previous one but it represents about 15,500 animals i.e. 1,5% of the total number used for toxicological and other safety evaluations.

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

It can be seen in Figure 7.1 that the largest percentage of use of animals for toxicological and other safety evaluations is due to acute and sub-acute toxicity tests, 42% in 2005. Also taking 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.

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



There is an increase from 32%, 36% to 42% over the last three reports of the proportion of animals used for acute and sub-acute tests 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, from 4,5% to 1,2%, is seen in animals used in toxicity tests for aquatic vertebrates.

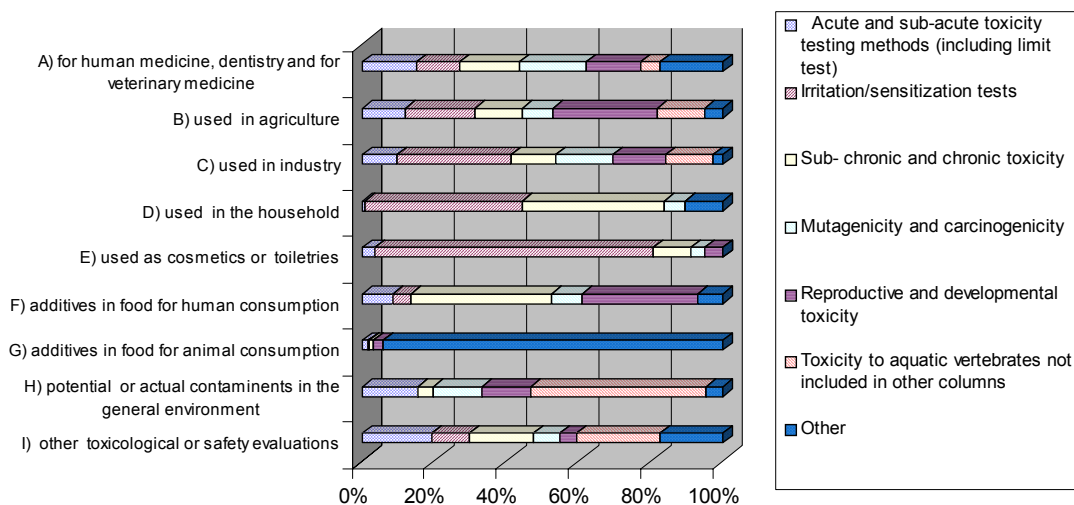
III.9. Results of EU Table 8: Type of toxicity tests carried out for toxicological and other safety evaluations of products

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. It 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 purposes, E) for cosmetics, F) for additives in food for human consumption and G) for additives in food for animal consumption.

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 and sensitization tests with the highest proportion used for D) household products and F) additives in food for human consumption.

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



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. It would be valuable to break down the term 'other' for future reporting.