COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

FOURTH 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(2005) 45}

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I. INTRODUCTION

The objective of this Report is to present to the Council and to the European Parliament statistics on the number of laboratory animals used in the EU, 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].

Three Reports have been published so far:

– The first Report[2], published in 1994, covered data on animals used in the year 1991;

– The second Report[3] was published 1999 and covered the data from 1996[4];

– The third Report[5] was published in 2003 and covered the data from 1999.

The data in the first Report were quite mixed, since the Directive provides only little detail on the reporting requirements. However, a set of eight statistical standard reporting tables (EU Tables) was agreed between the Commission services and the competent authorities of the Member States during the compilation period of the second Report. A few Member States used these Tables already for their reporting to the second Report.

For the third Report fourteen Member States submitted their data in accordance with the EU Tables, only one Member State used a different format because an amendment regarding data reporting was still needed in the existing federal law.

For the present fourth Report, all fifteen Member States used the agreed EU Tables. Data were collected in 2002 with the exception of one Member State who collected data in 2001.

This Report is accompanied by a "Commission Staff Working Paper - Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union in the year 2002" (SEC (2004) XXX). The Staff Working Paper provides more details and also includes data from the single Member States and their respective comments. However, all conclusions at EU level are fully presented in this Report.

1 OJ L 358, 18.12.1986, p. 1.
2 COM(1994) 195 final.
3 COM(1999) 191 final.
4 including 1997 data from France.
5 COM(2003) 19 final.

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

For the first time all Member States used the agreed EU Tables to submit their data. Data were collected in 2002, except for France who reported data from 2001.

Member States in most cases applied a quality control check. This check greatly improved the coherence of the data amongst the different Tables.

II.2. General assessment

The main difference with the previous Reports is that the data now cover the complete range of procedures and their purposes. This allows, for the first time, for a more precise and comprehensive picture at EU level.

Data are far more coherent amongst the different Tables than in previous Reports. Nevertheless, for the next Report coherence still needs to be improved. In this regard, the accession of the ten new Member States will require additional efforts.

Data analysis in this Report could be extended to all eight EU Tables, thanks to the exclusive use of the EU Tables for data submission.

Results in this Report were compared with previous Reports. However, comparisons were limited, because previous Reports were compiled on the basis of non-standard data.

In addition, where comparisons are made in this Report, readers should note that one Member State (France) reported data from 1997 and 2001 (for the third and fourth Reports) whereas the other Member States reported from 1996 and 2002, respectively. Nevertheless, assuming that fluctuations in the annual numbers of animals used in a country are limited, it is safe to make semi-quantitative estimates of the observed trends.

The total number of animals used for experimental and other scientific purposes in 2002 was 10.7 million (with data from France from 2001). This indicates an increase beyond the 9.8 million counted in 1999, but it is still a decrease compared to the 11.6 million of 1996.

By far the biggest group of animals used was rodents and rabbits, as in the previous Reports. A significant increase in the use of fish has made the group of cold-blooded animals account for over 15 % of all animals used.

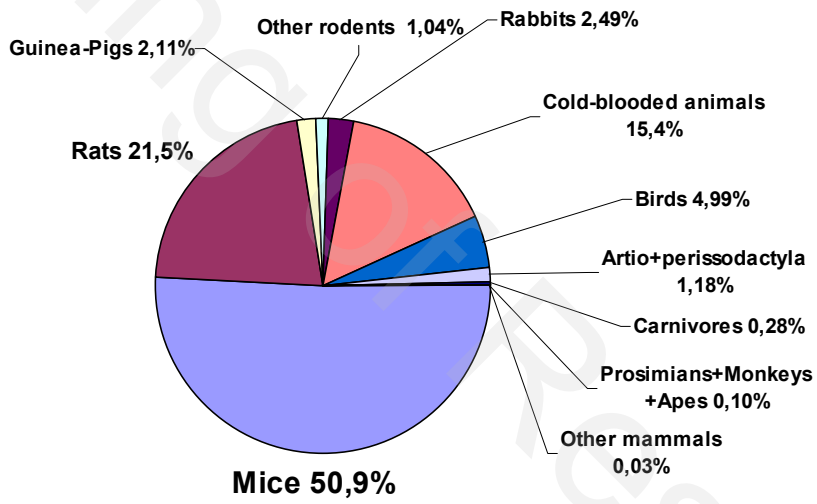
Readers should note that the numbering of tables and figures in this Report is linked to the numbers of the EU Tables and not to the numbering of the chapters of the Report. Furthermore, the numbering of tables and figures in the Report is coherent with the numbering in the above-mentioned Commission Staff Working Paper.

III. RESULTS

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

The total number of animals used in the EU Member States in 2002 (France reporting for 2001) was 10.7 million. Mice (51 %) and rats (22 %) were by far the most used species (fig. 1.1). Rodents and rabbits together represented more that ¾ of all animals used (78 %). Cold-blooded animals (15 %) were used much more than compared to the previous report (6.6 %). The Artio and Perissodactyla group including horses, donkeys and cross-breds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represented only 1.2 %. Carnivores represented 0.3 % of the total number of animals used and primates represented 0.1 %.

Figure 1.1
Classes of animals



Comparison with previous years

In 2002 the total number of animals used increased by about 917,000 (9.3 %) with regard to 1999 (table 1.3). The increase was mainly due to the additional use of about 970,000 fish (while other animal species decreased), raising the total of fish to almost 1.6 million.

The proportion of rodents and rabbits used throughout 1996, 1999 and 2002 shows some fluctuation around 80 % (table 1.3). For cold-blooded animals the proportion used in 1996 and 2002 is about 14 %, with a significant low in 1999 of 7 %.

Furthermore, the number of rats and guinea-pigs decreased from 1999 to 2002 (data not shown here). There was only a relatively low increase in the use of mice but a more pronounced increase in the number of rabbits. The use of old world monkeys increased, too. However, in 2002 no great apes were used. - Although one Member State reported new and

old world monkeys together in 1999, one can nevertheless make the qualitative observation that in 2002 there was a decrease in the use of new world monkeys.

An increase was similarly observed in the number of sheep, cattle and the number of other birds than quails used in 2002 in comparison to 1999. Goats on the other hand indicate a decrease.

Table 1.3: Comparison between the numbers and proportions of classes of animals used in 1996, 1999 and 2002

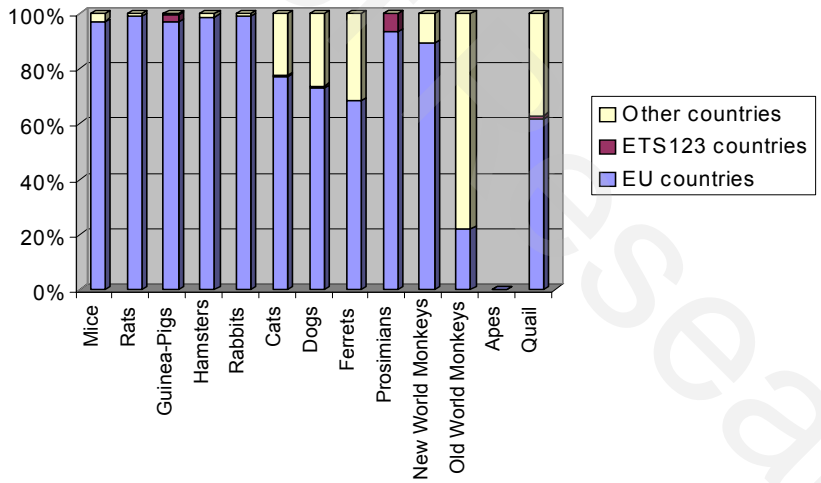
	1996	1999	2002
Total number of animals used	11,646,130 *	9,814,171	10,731,020 **
% Rodents-rabbits	81.3	86.9	78.04
% Cold-blooded animals	12.9	6.6	15.4

* 14 Member States reporting for 1996, one for 1997
** 14 Member States reporting for 2002, one for 2001

III.2. Further results from 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 in 2002 originated from the EU (fig. 1.2). However, for certain species (shown on the right side of the graph) there was a clear shift towards non-European origin. Note that in 2002 no apes were used.

Figure 1.2: Origin of species



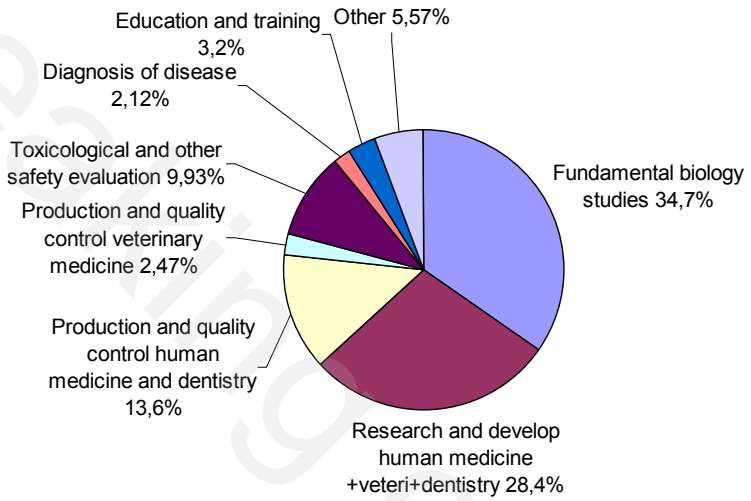
Comparison with 1999

In comparison with 1999 there was an increase in the proportion of new world monkeys and quails of European origin. In contrast to this, there was a decrease of the proportion of hamsters and old world monkeys of European origin.

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

In 2002 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). About 16 % were used in production and quality control of products and devices in human medicine, veterinary medicine and dentistry, and about 10 % for toxicological and other safety evaluation.

Figure 2.1
Purposes of experiments



Comparison with previous years

The percentage of animals used for research, development and quality control in the areas of human medicine, dentistry and veterinary medicine reached a high of 52 % in 1999, but was about 45 % in the other years (table 2.3). For fundamental biology studies the percentage increased from 25 % to 35 % since 1996. By comparison, the percentages of animals used for toxicological and safety evaluation remained very stable at about 10 %.

Table 2.3: Comparison between the relative percentages of animal used for selected purposes in 1996, 1999 and 2002

Purpose	1996 *	1999 **	2002
Research, development and quality control in human medicine, veterinary medicine and dentistry	44%	52%	44.5%
Fundamental biology studies	25%	30%	35%
Toxicological and safety evaluation	9%	10%	9.9%

* 13 Member States reported purposes of experiments
** 14 Member Sates reported purposes of experiments

With regard to selected species used for selected purposes, the global pattern (not illustrated here) has not changed much since 1999 (N.B.: Such data was not reported by Germany in 1999), except for an increase of 27 % of the number of mice used in biological studies and for an average increase of about 14 % of the number of cold-blooded animals used for

fundamental biological studies, for research of products in human medicine, dentistry and veterinary science, for toxicological evaluation and also for education and training.

Diagnosis of disease

The diagnosis of diseases is important in the light of epidemics of farm animals such as mad cow disease, foot and mouth disease and swine fever.

Since 1999 the percentage of rodents and rabbits used has increased from 79 % to 91 %, the use of cold-blooded animals decreased from 15 % to 1 %. The use of other animals did not change notably.

III.4. Results from EU table 3: Toxicological or safety evaluation for type of products/endpoints

Only 10 % of the total number of animals used for experimental purposes were used for toxicological and other safety evaluation. From these 10 %, 51 % were used for products or devices used for human medicine, veterinary medicine and dentistry (fig. 3.1), and only 2.1 % were used for the toxicological evaluation of animal feed, additives for human food consumption, cosmetics and household.

The group of products/substances falling under the scrutiny of authorities concerned with the safety of health and the environment from chemical products, such as industrial chemicals and pesticides, used 24 % of the animals for toxicological and other safety evaluations.

Comparison with 1999

The proportion of animals used for toxicological and other safety evaluation of products to be used mainly in industry and agriculture has increased from 19 % to 24 %. Similarly, the proportion of animals used for the evaluation of potential or actual contaminants in the general environment has increased form 7 % to 12 %.

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

In 2002 the number of animals used for studies of diseases of both humans and animals represented 58 % of the total number of animals used for experimental purposes (fig. 4.1).

Comparison with the data of 1999

In 2002 the pattern of study diseases was similar to that observed in 1999, except for an increase (from 10 to 15 %) of the proportion of animals used to study specific animal diseases and a marked decrease from (50 to 42 %) of the proportion of animals used for studying other human diseases.

Figure 3.1 Animals used in toxicological or other safety evaluations of products

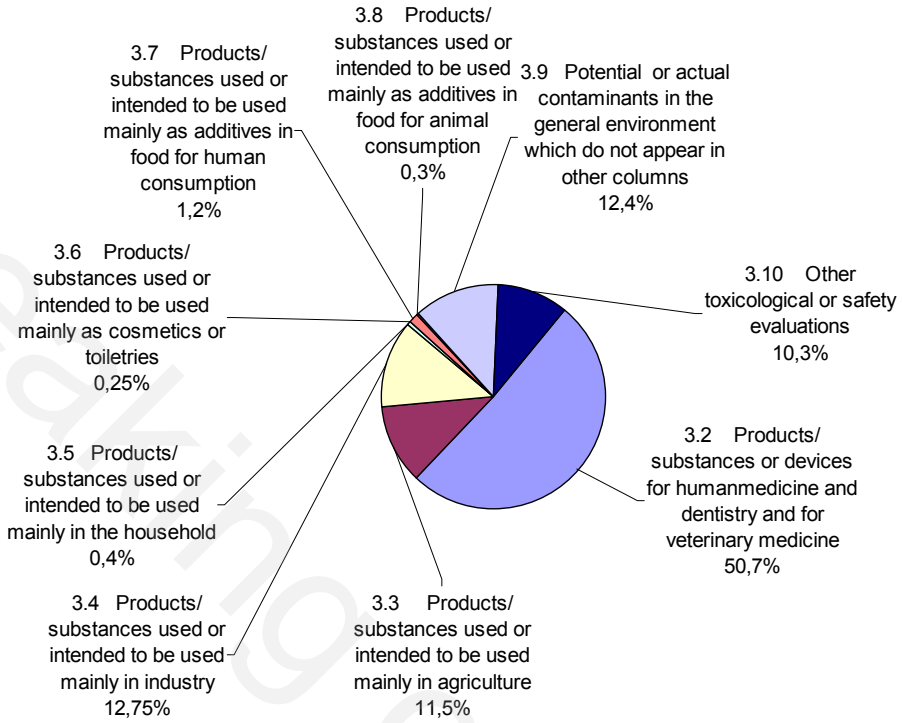
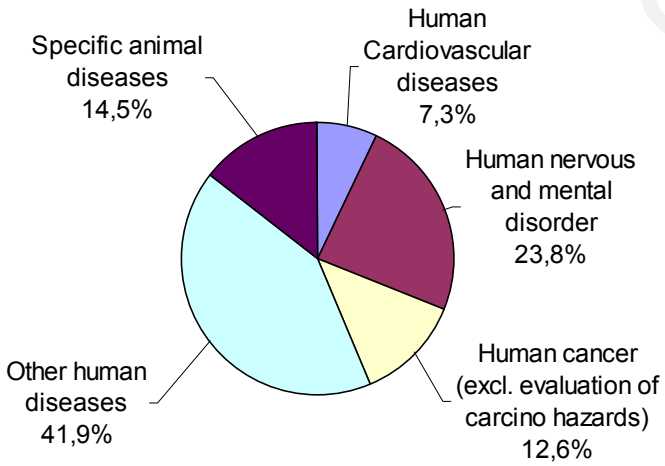


Figure 4.1

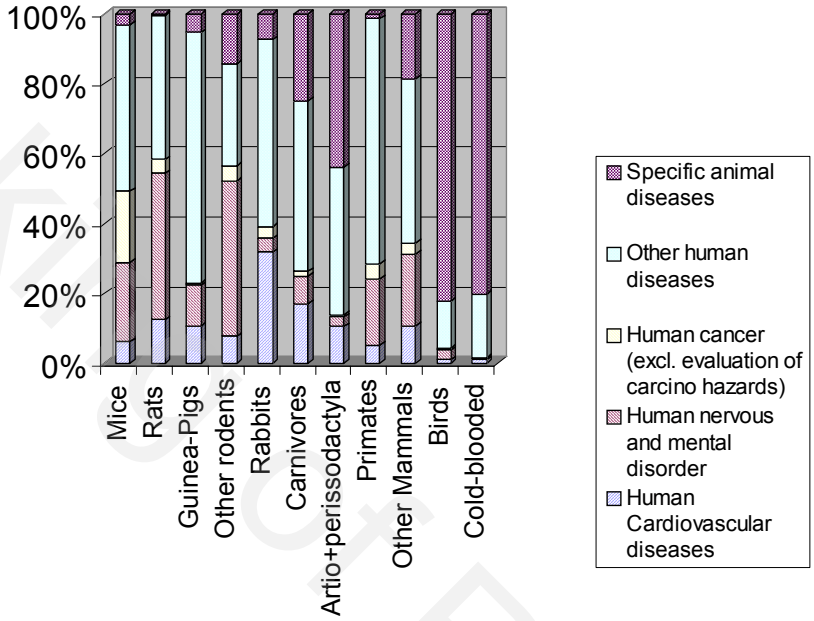
Proportion of animals used in studies of diseases



The relative percentage of animals used for studies on diseases is shown in figure 4.2. Birds and cold-blooded animals were used to more than 80 % for studies on specific animal diseases. Some Member States indicated that both birds and fish were used for the purpose of vaccine testing, others could not confirm this.

The pattern has not significantly changed since 1999 except for an increase in the percentage of use of cold-blooded animals for studies of animal diseases (from 56 to 80 %).

Figure 4.2
Species of animals used in studies of diseases



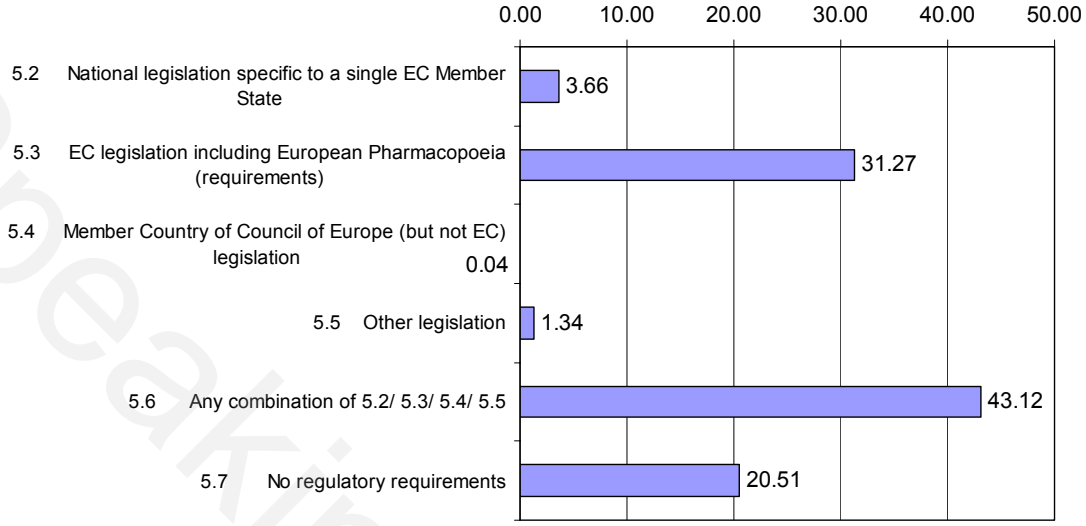
III.6. Results from EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The number of animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine represented 16 % 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.

The largest proportion (43 %) of animals in this area was used to simultaneously satisfy requirements from several legislations (national, Community, Council of Europe, and others). Some 21 % of the animals were not required for any regulatory purposes. To explain this relatively high proportion Member States reported a range of reasons, such as early stages in developmental processes or pilot studies, or additional tests to confirm earlier ambiguous test results. Member States also considered that some unclear data reporting may have been a reason.

Remark: In 1999 the data provided by the Member States for EU Table 5 showed too much variability. Therefore, no interpretation of the data was possible, and consequently no comparison is possible now.

Figure 5.1: Percentage of animals used for regulatory requirements in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine



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

The use of animals for regulatory requirements in the area of toxicology and other safety evaluations (fig. 6.1) follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine (fig. 5.1).

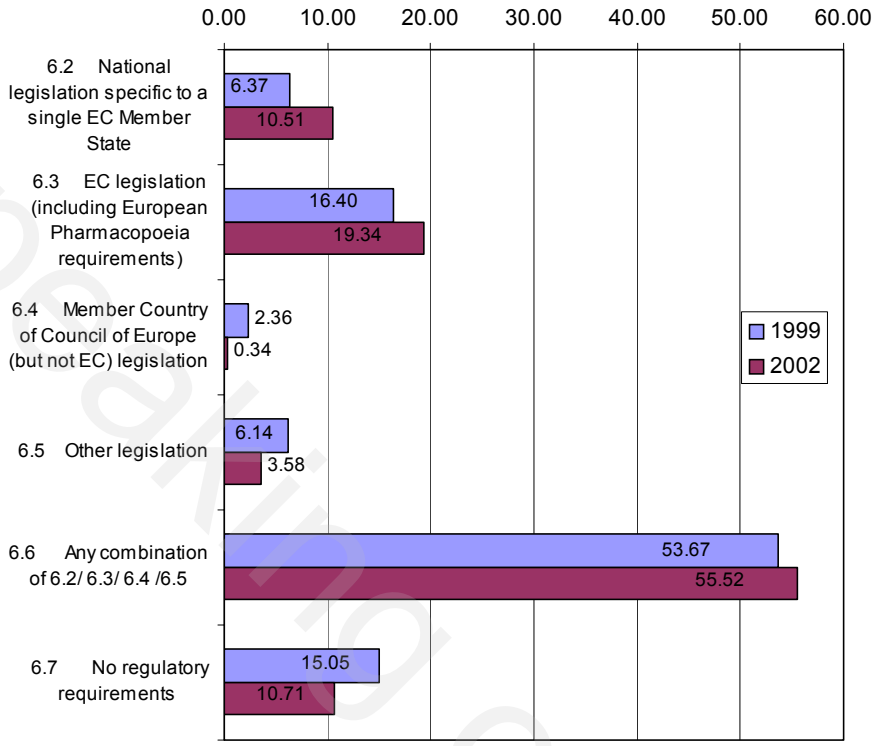
Comparison with 1999

Animals used to simultaneously satisfy regulatory requirements from several legislations covered over half of the animal used in this area and have basically remained at the same level (about 55 %).

The testing to satisfy national legislation specific to a single Member State related, for example, to national health and safety requirements at the work place. Testing for such purposes appears to have increased from 6 % to 11 %, but Member States considered that this effect might partly be due to the complexity of data collected from the reporting institutions.

Contrary to the animals used in the areas of human medicine, dentistry and in veterinary medicine (fig. 5.1), the proportion of animals attributed to "no regulatory requirement" in the area of toxicology and other safety evaluations appears to have decreased from 15 % to 11 %. Member States reported a number of possible reasons for this effect, similar to the explanations for the area of human medicine and dentistry and for veterinary medicine (fig. 5.1).

Figure 6.1: Comparison of percentages of animals used for regulatory requirements for toxicological or other safety evaluation in 1999 and 2002



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

Figure 7.1 shows the percentage of animals used per toxicity test (group) in 1999 and 2002.

Comparison with 1999

As pointed out earlier, the number of animals used in toxicological and other safety evaluation represented 10 % of the total number of animals used for experimental purposes in the EU.

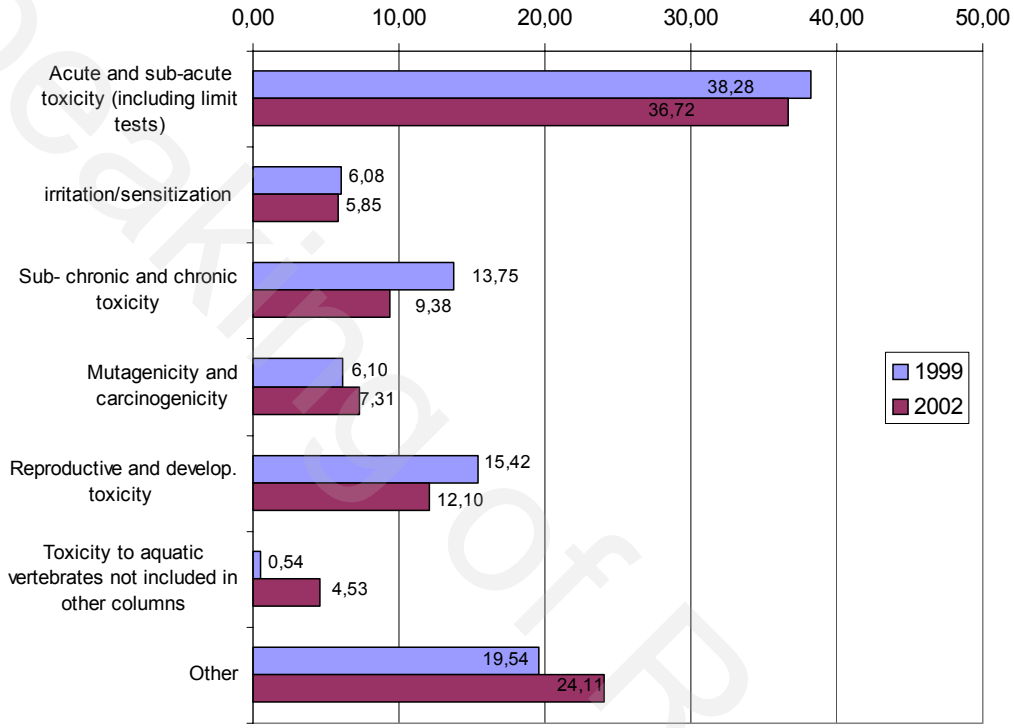
The largest percentage of animals was due to acute and sub-acute toxicity tests, about 37 % in 2002 and in 1999. With the addition of sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounted for 46 % and 52 %, respectively, in 2002 and 1999. About 20 % of the animals were used for tests on carcinogenicity, mutagenicity and toxicity to reproduction in both years.

In comparison with the data of 1999, there is a certain decrease in the percentage of animals used for sub-chronic and chronic toxicity tests from about 14 % to 9 % and for reproductive and developmental toxicity from about 15 % to 12 %, and an increase in the percentage of animals used in detecting toxicity to aquatic vertebrates from 0.5 % to 4.5 %.

An increase is also observed, from about 20 % to 24 %, in the percentage of animals used for "other" toxicity tests than those listed in the statistical Table. 24 % is about ¼ of all such

animals and thus a considerable proportion. Member States considered that this may be due to a variety of tests conducted by universities or institutions, which may not follow specific guidelines and were therefore summed up by researchers under "other". Member States also indicated that "other" might include tests linked to haemotoxicology, toxicokinetics, pyrogenicity, biocompatibility, immunotoxicology, enzyme induction and allergic reactions of animals.

Figure 7.1
Comparison of the percentages of animals used in toxicity tests for toxicological or other safety evaluation in 1999 and 2002



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

As pointed out earlier, animals used in toxicological and other safety evaluation represent 10 % of the total number of animals used for experimental purposes in the EU.

A substantial number of toxicity tests were performed for products or devices for human medicine, dentistry and veterinary medicine. Other notable groups of products requiring toxicological testing were products used mainly in agriculture and products intended mainly for industry.

Remark: In 1999 the data provided by the Member States for EU Table 8 showed too much variability. Therefore, no interpretation of the data was possible, and consequently no comparison is possible now.