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PART II

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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**

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Important notice

This Report is a document of the Commission services and cannot be considered binding to this institution in any way.

**PART B I: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE
MEMBER STATES**

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AUSTRIA

Statistical data submitted

The statistical data have been submitted by the “*Bundesministerien für Gesundheit und Frauen- Land und Forstwirtschaft, Umwelt und Wasserwirtschaft – Wirtschaft und Arbeit - Bildung, Wissenschaft und Kultur*” (Federal Ministries for Health and Women -Agriculture Forestry, the Environment and Water Mangement – Economic Affairs and Labour - Education, Science and Culture).

Comments from the Austrian authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Austria are regulated by the **Tierversuchsgesetz** (Animal Experiments Act) (Federal Law of 27 September 1989 on experiments using live animals, Federal Law Gesetz, (BGBL. No 501/1989, as most recently amended by Federal Law No.162/2005. Responsibility for enforcing the Animal Experiments Act in Austria rests with the Federal Minister for Health and Women, the Federal Minister for Economic affairs and Labour, the Federal Minister for Agriculture, Forestry, the Environment and Water Management and the Federal Minister for Education, Science and Culture.

Animal experiments are permitted in Austria only if the **stringent requirements of the Animal Experiments Act** are met and only for one of the **following reasons**:

- a) for research and development
- b) for vocational training
- c) for medical diagnosis and therapy
- d) for testing natural or synthetic materials, preparations or products
- e) for detecting environmental risks
- f) for obtaining materials

Animal experiments may only be carried out providing that

1. There is a justified interest in carrying out the experiment, i.e.
 - a) for preventing, detecting or curing diseases in human beings or animals,
 - b) for detecting or influencing physiological conditions or functions in human beings or animals,
 - c) for securing scientific knowledge
 - d) for providing vocational training or,
 - e) for obviating environmental risks, and providing that

2. The objectives pursued by the experiments cannot be achieved by other methods or procedures (alternative techniques) or, in the case of vocational training, by using other teaching aids, in particular films or other audiovisual media.

Experiments on animals are never permitted,

- a) if the results of a similar experiment are de facto and de jure accessible and no justified doubts exist as to the accuracy and meaningfulness of the said results,
- b) if no further or new knowledge is likely to come from the experiment,
- c) if the experiment is not necessary, even for control purposes, or
- d) if the results of an animal experiment carried out in Austria or abroad are de facto or de jure accessible, no justified doubts exist regarding the accuracy and meaningfulness of those results and they are officially recognised in Austria on the basis of the relevant statutory provisions.

In addition to the above, the competent Federal Ministers can issue regulations determining which methods are no longer permitted for animal experiments since they are outdated in the light of scientific progress achieved. By way of example, the "LD-50" test has been banned in Austria since 1992.

The Animal Experiments Act directly prohibits the following:

- animal experiments for cosmetic purposes (since 1999), and
- animal experiments involving the Great Apes (since 1. 1. 2006).

Guiding principles

The Animal Experiments Act also contains guiding principles for all scientists and other personnel involved in animal experiments and these are binding, also on the competent authorities. Particular features of these are that:

Animal experiments must be consistent with the principles of scientific research and the hypothesis being tested and the procedure selected must be reasonable in the light of acknowledged scientific progress. Animal experiments are to be conducted with a view to obtaining as much new knowledge as possible.

The meaningfulness and practicability of model animal experiments are to be continuously and critically assessed with a view to **reducing the number of animal experiments and increasing the use of alternative techniques, adapting them to reflect acknowledged scientific progress**. Results obtained from behavioural research and animal experiments as well as developments in measurement and laboratory techniques are to be taken into account in order to minimize the stress that experimental animals undergo.

All persons involved in carrying out animal experiments are responsible in **ethical and scientific terms** for the tasks they are required to undertake. It is the duty of every scientist to assess the necessity and appropriateness of the animal experiment that he has planned, headed and completed, weighing them against the stress to which the animals are subjected.

Accordingly, Austria's Animal Experiments Act has express provision, as a legal requirement, for applying the principles of the '3 Rs' (reduction, refinement, replacement).

As regards the keeping of experimental animals (caring for and housing the animals) Austria's legislation on animal experiments has not only fully transposed the **guidelines** set out in **Annex II** to Article 5 of Directive 86/609/EEC by law and regulation, but in the interests of animal welfare and of considerably **improving the standards of animal husbandry, it has also made these provisions legally binding.**

Promoting alternatives to animal experiments as a legal obligation

The Federal Ministers responsible for enforcing the Animal Experiments Act (see above) are required by law (the Animal Experiments Act) to promote the development of alternative methods and procedures that do not involve animal experiments (see above) in line with the relevant Federal financial legislation and progress in science and to promote alternative methods and procedures. The aim is to develop alternative methods that are scientifically meaningful and which make it possible to reduce the number of experimental animals and the stress to which they are exposed or even to make animal experiments wholly redundant.

Promoting the objective of the 3Rs is thus an express component of Austria's Animal Experiments Act, the aim being to improve the protection of animals. Over the last decade more than EUR 2.5 million has been spent on researching and developing alternatives to animal experiments, in particular on the part of the Federal Ministry for Education, Science and Culture. Austria also supports, wherever possible, the development, validation and use of alternatives to animal experiments at international level, in particular in the context of the EU and the OECD.

It should also be remembered in this connection that conferences on animal experiments and alternative methods have in the past been organised under Austrian Presidency. By way of example, in November 1998 a conference was organised in conjunction with the European Commission on the subject of "Implementation of the 3 Rs – Objectives for the EU and for science and industry". The aim of this symposium was to promote the implementation of the 3Rs also at EU level. The symposium was attended by the competent authorities from all EU Member States as well as, for the first time, representatives of the third countries that have meanwhile become EU Member States. One of the resolutions adopted at this symposium was forwarded to the Council of Ministers of the EU and to the European Commission for further action. At the beginning of **July 2006** the 13th **Congress on Alternatives to Animal Testing** (meanwhile a tradition) was held in Linz under the patronage of the Austrian EU Presidency offering a much-acclaimed scientific programme on alternatives to animal experiments.

During its EU Presidency in the first half of 2006 Austria sought, in addition to the above, to secure a decision of the Council on the position of the European Community with regard to the proposal to amend Annex A of the European Convention on protecting animals used for experiments and other scientific purposes (see Council of the European Union 7643/06 Legislative Acts and other legal instruments, adopted by the Council on 10 April 2006). As a result, it was possible to ensure that at the fourth multilateral hearing of the parties to this European Convention the European Commission, on behalf of the European Community, was able to support and adopt this revised Appendix A of the Convention that contained guidelines for the housing and care of such animals.

Statistics on animal experiments

Statistics on animal experiments in Austria are produced in accordance with Article 13 of Directive 86/609/EEC pursuant to § 16 of the Animal Experiments Act and the Regulation on Statistics relating to Animal Experiments (Tierversuchsstatistik-Verordnung), which is based on it (BGBl. II No 199/2000), and sets out the standardised statistics for animal experiments which are to be produced annually and be of a binding nature. No later than 1 March every year persons responsible for carrying out animal experiments must submit to the ministry responsible for enforcing the Animal Experiments Act their statistical data relating to their animal experiments during the previous year. The following information is to be provided:

- a) the number and type of experimental animals used overall plus the origin and number, with breakdown, of the animals used,
- b) the number and types of animals used (types of experimental animals, with breakdown),
- c) the number and types of experimental animals used for toxicological and other safety tests,
- d) the number and types of experimental animals used for tests on human and animal diseases,
- e) the number and types of experimental animals used in the manufacture and quality control of products and equipment for human medicine, dentistry and veterinary medicine including, where appropriate, an indication of the relevant statutory provisions,
- f) the number and types of animals used for toxicological and other safety tests, where appropriate with an indication of the relevant statutory provisions as well as the type of test (technique) and products or materials (types of products or materials).

The Federal Ministers responsible for enforcing the Animal Experiments Act are required to produce, by 30 June of every year, a summary report on animal experiment statistics relating to the previous year and publish it in Austria's Official Journal (Amtsblatt zur Wiener Zeitung).

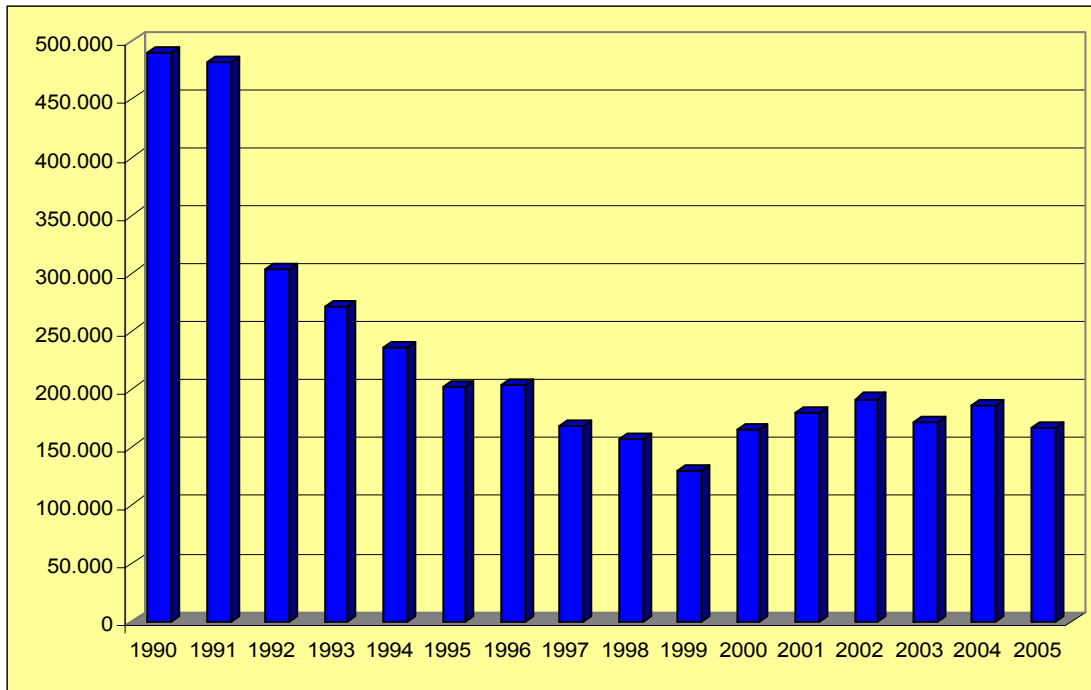
Statistics on animal experiments for 2005

Compared with the previous year there were 10% fewer animal experiments

Compared with other countries there were few animal experiments

As shown in Austria's Official Journal dated 29 June 2006, the 2005 animal experiment statistics show that in 2005 a total of 167,312 animals were used in experiments. This is the lowest figure since 2001.

Compared with earlier years, this indicates a further reduction in the number of animal experiments in Austria as a whole within the "fluctuating" numbers of the past few years (ranging from 160,000 to 200,000). The number of experimental animals is therefore again significantly lower than those for the previous years; for example, in 1996 the number totalled was 203,825, in 1993 it was 272,371 and in 1992 it was 304,308. Compared with 1991 (the first year of statistical coverage) the number of animals used has remained low (at less than 35%). In that year there were 482,166 animals used for experiments, in other words numbers have dropped since then by more than 65%.



The full statistics on animal experiments with all tables produced by the Federal Ministries responsible for enforcing the Animal Experiments Act, namely the Federal Ministry for Health and Women, the Federal Ministry for Economic affairs and Labour, the Federal Ministry for Agriculture, Forestry, the Environment and Water Management and the Federal Ministry for Education, Science and Culture, can be found on the home page of the Federal Ministry for Education, Science and Culture using the following link <http://www.bmbwk.gv.at/tierversuche/statistik2005>

Animal experiments for human beings and animals

The figures for animal experiments in 2005 – primarily on mice and rats – can be explained in general terms by an increase in biomedical research and a rise in the number of biomedical and bioscientific as well as pharmaceutical firms conducting research, in particular research and development of products for human and veterinary medicine, along with the manufacture and quality control of vaccines that are manufactured for the world market to control major diseases, primarily cancer, leukaemia, diseases of the heart and circulation and AIDS. Cancer research concentrates primarily on the development of improved and more effective therapies that are less stressful for patients.

The figures for animal experiments in the field covered by the Federal Ministry for Health and Women have their origin in an increase in the number of samples taken for the (required) quality control as well as the establishment of new standards for pharmaceutical products undergoing development and new research projects, for example the development and production of human vaccines and therapeutic products. The greater emphasis placed on the development of medical and pharmaceutical medicaments means that despite every effort to find alternative methods, animal experiments are, with a view to protecting the health and safety of human beings **and** animals, indispensable as a preliminary stage prior to any decision on clinical trials on humans.

Lastly, animal experiments are necessary for the animal health as such, i.e. for the development of pharmaceutical products for animals by means of clinical tests on and for animals and this has meant that slightly more dogs and cats have been used. Animal experiments are also necessary for the development of diagnostic and therapeutic measures for animals as well, examples being procedures

for the early detection of cardiac insufficiency in cats or clinical studies on vaccines to control infectious diseases in dogs.

Rats and Mice are the primary experimental animals

In 2005 of the 167 312 animals that were used for experiments in Austria, **140 554** (compared with 158 361 in 2004 and 148.382 in 2003) were rats and mice,

3 140 (2004: 4 158 and 2003: 4 958) were guinea pigs; 18 439 (2004: 20 654 and

2003: 13 928) were rabbits, 1 664 were useful domestic farm animals, (sheep, goats, pigs, and cattle etc.), 1 011 were birds, 992 were fish, 865 were amphibians, 85 were dogs (2004: 155 and 2003: 139) and 12 (2004: 18 and 2003: 22) were cats.

No animal experiments for cosmetics

The statutory ban on the use of animals for experiments for cosmetics that has been in place since 1999 has meant that in accordance with §(5) of the Animal Experiments Act it goes without saying that no animal experiments were conducted in Austria for cosmetics. Austria is in this respect particularly committed to protecting Europe's animals.

No primates for experimental purposes

Statutory ban on experiments on or involving primates.

It can happily be reported that in 2005 Austria continued to forgo the use of primates for animal experiments. This is consistent with the pan-European call for restricting such animal experiments as far as possible and replacing them totally in line with "scientific progress". In 2005 the Federal Ministry for Education Science and Culture resubmitted – on the basis of a Resolution of the National Council of December 2004 and following a general examination – a Parliamentary Bill to the National Council for a statutory ban on animal experiments involving primates, which it adopted in December 2005. The provision entered into force on 1 January 2006.

Austria's figures for animal experiments are comparatively low in international terms

With a total of 167.312 experimental animals (primarily mice and rats) used in 2005, Austria had significantly fewer animal experiments in international terms as well as in terms of the animals used for such experiments. By way of example, neighbouring Switzerland used 550 000 animals for experimental purposes in 2005.

These comparatively low figures for the animals used in animal experiments – accounting for a 65% drop since 1991 – can be explained by at least two inter-related lines of development in relation to animal experiments:

1.) The Three "Rs"

Firstly, '**Reduction, Refinement, Replacement**' in relation to animal experiments conducted by scientists, researchers and practical scientists themselves as well as ensuring, as far as possible, the availability of alternative methods to replace animal experiments as this is expressly required by Austria's Animal Experiments Act.

2) Restrictions on the authorization of animal experiments and the promotion of alternative techniques

Secondly, a more restrictive approach on the part of all of the competent authorities to the authorisation of animal experiments in line with the strict requirements of the Animal Experiments Act, which has undergone further improvement since 1999/2000, as have animal experiment regulations in Austria, in accordance with which animal experiments are only permitted subject to very severe restrictions and can be expressly authorised only if the objectives pursued in the experiment cannot be achieved by other methods or procedures (alternative techniques).

Last but not least, it is the public motivation prompted by the award of **national prizes** or **promoting research projects for alternative techniques** as well as propagating at national and international level the use of alternatives to animal experiments that has led to an enhanced awareness of responsibility on the part of the general public with regard to science/research involving animal experiments.

Greater effort to promote the development of alternatives to animal experiments

In September of last year the Federal Ministry for Education, Science and Culture in agreement with all the other Federal Ministries responsible for enforcing the Animal Experiments Act (Federal Ministries for Health and Women, for Economic Affairs and Labour and for Agriculture and Forestry, the Environment and Water) renewed its public call for the submission of research projects targeting alternatives to animal experiments, the aim of which is to provide greater support for alternatives to animal experiments which will be determined ultimately by the number and scale of the projects that are submitted.

It was only last year that the public call for projects by the Federal Ministry for Education Science and Culture was again used to award a **national prize for alternatives to animal experiments**, in other words particular recognition by the State of scientific results already achieved.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	128 634	28 469	99 702	184	279	59
1.b. Rats (<i>Rattus norvegicus</i>)	11 920	5 278	6 642	0	0	47
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	3 149	340	2 809	0	0	0
1.d. Hamsters (<i>Mesocricetus</i>)	117	0	117	0	0	0
1.e. Other Rodents (other <i>Rodentia</i>)	107	60	25	0	22	0
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	18 439	11 165	7 253	0	21	41
1.g. Cats (<i>Felis catus</i>)	12	0	2	0	10	10
1.h. Dogs (<i>Canis familiaris</i>)	85	67	0	0	18	7
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	71	21	0	0	50	12
1.l. Pigs (<i>Sus</i>)	818	594	61	0	163	41
1.m. Goats (<i>Capra</i>)	44	20	0	0	24	3
1.n. Sheep (<i>Ovis</i>)	195	127	20	0	48	34
1.o. Cattle (<i>Bos</i>)	536	352	16	0	168	9
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	56	56	0	0	0	41
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	14	14	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	1 011	352	300	0	359	22
1.w. Reptiles (<i>Reptilia</i>)	40	0	0	0	40	0
1.x. Amphibians (<i>Amphibia</i>)	865	62	40	0	763	0
1.y. Fish (<i>Pisces</i>)	1 199	192	4	0	1 003	0
1.z. TOTAL	167 312	47 169	116 991	184	2 968	326

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamenta l 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	25 313	74 677	20 884	177	2 956	1 296	106	3 225	128 634
2.b. Rats	5 019	2 949	131	232	3 167	0	422	0	11 920
2.c. Guinea-Pigs	24	548	1 411	197	967	0	2	0	3 149
2.d. Hamsters	0	117	0	0	0	0	0	0	117
2.e. Other Rodents	47	0	0	0	0	0	0	60	107
2.f. Rabbits	344	75	17 019	23	928	0	8	42	18 439
2.g. Cats	0	2	0	0	0	10	0	0	12
2.h. Dogs	6	56	0	0	0	0	12	11	85
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	33	10	0	0	0	22	2	4	71
2.l. Pigs	265	255	73	0	0	0	189	36	818
2.m. Goats	0	4	0	0	0	0	40	0	44
2.n. Sheep	20	50	1	42	12	0	70	0	195
2.o. Cattle	333	0	0	12	3	0	140	48	536
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	56	0	0	0	0	0	0	56
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	0	0
2.u. Quail	14	0	0	0	0	0	0	0	14
2.v. Other birds	725	151	4	0	0	60	71	0	1 011
2.w. Reptiles	40	0	0	0	0	0	0	0	40
2.x. Amphibians	860	0	0	0	0	0	5	0	865
2.y. Fish	876	180	0	0	143	0	0	0	1 199
2.z. TOTAL	33 919	79 130	39 523	683	8 176	1 388	1 067	3 426	167 312

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contaminants in the general environment which do not appear in other columns	3.10 Other toxicological or safety evaluations	3.11 Total
3.a. Mice	2 026	0	0	0	0	0	0	0	930	2 956
3.b. Rats	1 415	0	0	0	0	0	0	0	1 752	3 167
3.c. Guinea-Pigs	279	0	0	0	0	0	0	0	688	967
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	715	0	0	0	0	0	0	0	213	928
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	0	0	0	0	0	0	0	0	0	0
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	0	0	0	0	0	0	0	0	0
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	12	12
3.o. Cattle	3	0	0	0	0	0	0	0	0	3
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	0	0	0	0	0	0	143	143
3.z. TOTAL	4 438	0	0	0	0	0	0	0	3 738	8 176

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	1 275	3 407	15 919	45 266	95	65 962
4.b. Rats	506	1 777	609	4 919	0	7 811
4.c. Guinea-Pigs	0	0	0	905	0	905
4.d. Hamsters	0	0	0	117	0	117
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	53	31	89	294	0	467
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	0	0	0	0	0	0
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	0	0
4.l. Pigs	106	0	0	292	0	398
4.m. Goats	0	0	0	4	0	4
4.n. Sheep	2	0	12	26	0	40
4.o. Cattle	0	0	0	0	0	0
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	56	0	56
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	54	0	0	6	0	60
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	25	25	0	12	0	62
4.y. Fish	0	0	0	0	0	0
4.z. TOTAL	2 021	5 240	16 629	51 897	95	75 882

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	177	887	0	0	19 909	88	21 061
5.b. Rats	131	0	0	232	0	0	363
5.c. Guinea-Pigs	0	636	0	197	775	0	1 608
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	12 884	0	32	3 981	145	17 042
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	0	73	73
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	21	22	0	0	0	0	43
5.o. Cattle	12	0	0	0	0	0	12
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	4	0	0	0	0	0	4
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	345	14 429	0	461	24 665	306	40 206

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 – UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	1 595	0	1 060	60	241	2 956
6.b. Rats	0	210	0	2 094	576	287	3 167
6.c. Guinea-Pigs	0	204	0	763	0	0	967
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	595	0	213	77	43	928
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	0	0	0
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	0	0
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	12	12
6.o. Cattle	0	3	0	0	0	0	3
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	0	0	0	143	0	0	143
6.z. TOTAL	0	2 607	0	4 273	713	583	8 176

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
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TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	293	1 580	0	784	0	0	0	0	154	0	0	145	2 956
7.b. Rats	0	726	229	104	0	0	1 596	0	0	12	0	0	500	3 167
7.c. Guinea-Pigs	0	0	119	0	688	0	0	0	0	0	0	0	160	967
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	70	123	0	88	0	0	0	0	0	0	647	928
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	12	12
7.o. Cattle	0	0	3	0	0	0	0	0	0	0	0	0	0	3
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	0	143	0	0	0	0	0	0	0	0	0	0	0	143
7.z. TOTAL	0	1 162	2 001	227	1 472	88	1 596	0	0	166	0	0	1 464	8 176

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	381	2 001	62	8	0	662	0	0	6	0	0	1 318	4 438
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i. Other toxicological or safety evaluations	0	781	0	165	1 464	88	934	0	0	160	0	0	146	3 738
8.j. TOTAL	0	1 162	2 001	227	1 472	88	1 596	0	0	166	0	0	1 464	8 176

BELGIUM

Statistical data submitted

The statistical data have been submitted by the “SPF Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement” (Federal Public Service of Public Health, Food Chain Safety and Environment).

Comments of the Belgian authorities

ANIMALS USED FOR EXPERIMENTAL PURPOSES

STATISTICS ON USE IN BELGIUM IN 2005

1. Laboratories

At the end of 2005, there were 390 approved laboratories in operation which, pursuant to Article 15 of the Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes, provided data on their use of animals for experiments. As in previous years, 25% of laboratories used no animals.

In 2005, four laboratory approvals were withdrawn at the request of the head of the laboratory because it had ceased operations; five new approvals were issued for laboratories and one for a supplier of animals for experimental purposes.

2. Number of animals used in experiments

In all 718 976 animals were used. Of the various species used, rodents and rabbits accounted for 92%, fish, reptiles and amphibians accounted for 6% and birds for 2% of the total.

Dogs, cats and primates accounted respectively for 0.19%, 0.01% and 0.06% of the animals used in 2005 (*Figure 1: Breakdown of species used in experiments*).

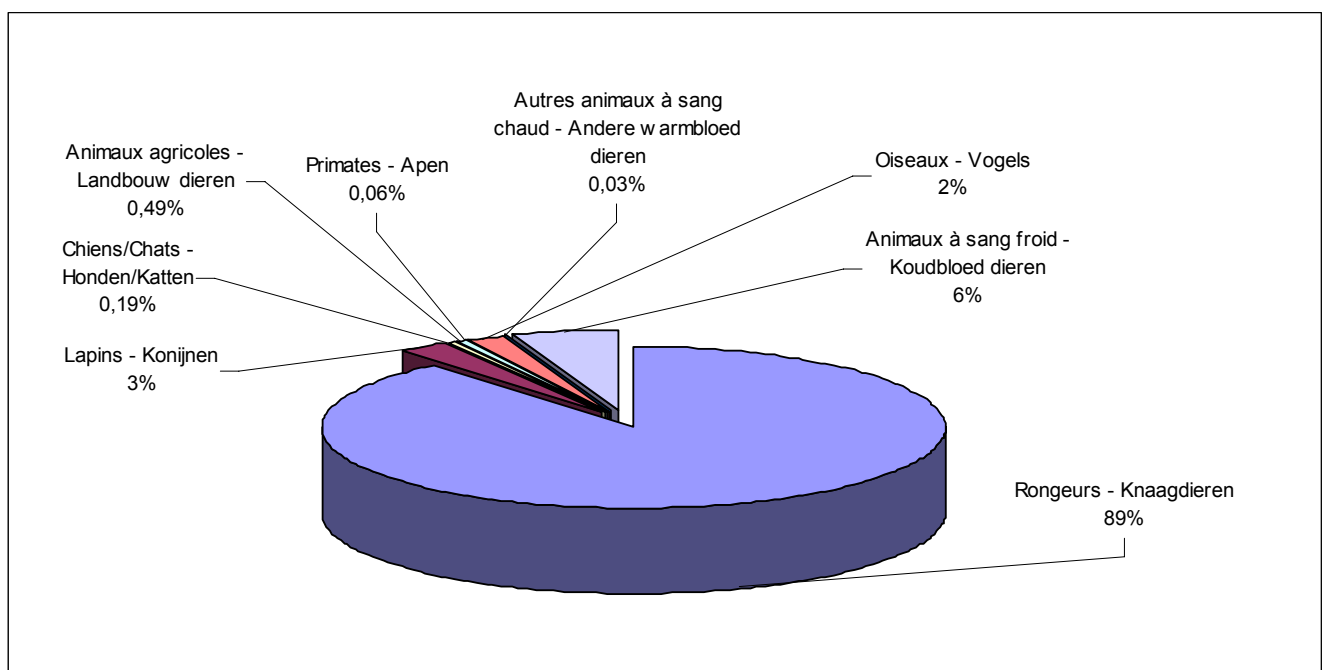


Figure 1: Breakdown of species used in experiments

Animaux agricoles – agricultural animals; Primates – primates; Autres animaux à sang chaud – other warm-blooded animals; Oiseaux – birds; Animaux à sang froid – cold-blooded animals; Rongeurs – rodents; Lapins – rabbits; Chiens/chats – dogs/cats

A comparison of the figures for 2005 with those for previous years (Table 1: Trend in the number of animals used in experiments), shows an increase in the total number of animals of 1.44% over 2004. That increase was due mainly to greater use of fish (+ 13 391, 65%), birds (+ 2 849, 26%), mice (+ 5 315, 1.1%) and, to a lesser extent, dogs (+ 201, 27%) and ferrets (+ 52, 51%). There was a substantial drop in the number of monkeys (- 137, 23%), rats (- 12 710, 11%), other rodents (- 1 661, 42%) and cats (- 103, 56%).

Table 1: Trend in the number of animals used in experiments

	2005	2004	2003	2002	2001
Mice	488125	482810	430251	460487	436266
Rats	106483	119193	128284	116340	112040
Guinea pigs	39530	38781	40510	34305	40204
Hamsters	1874	1688	2590	2645	3163
Other rodents	2260	3921	11332	16670	12693
Rabbits	21159	18577	18714	10805	14631
Total rodents and rabbits	659431	664970	631681	641252	618997
Cats	81	184	90	100	75
Dogs	1295	1014	1000	1071	1036
Ferrets	154	102	36	20	20
Other carnivores	0	0	0	0	0
Total carnivores	1530	1300	1126	1191	1131
Horses, donkeys and cross-breeds	108	65	93	138	102
Pigs	1876	2272	2637	3587	4079
Goats	157	125	114	102	217
Sheep	445	495	339	524	492
Cattle	944	982	1055	1135	714
Total ungulates	3530	3939	4238	5486	5604
Prosimians	0	0	0	0	0
New world monkeys	0	7	7	20	21
Old world monkeys	449	579	281	547	689
Apes	0	0	0	0	0
Total primates	449	586	288	567	710
Other mammals	59	44	22	8	0
Total mammals	664999	670839	637355	648504	626442
Quails	425	350	514	326	134
Other birds	13266	10492	12499	20026	8711
Total birds	13691	10842	13013	20352	8845
Reptiles	144	129	30	15	95
Amphibians	6177	6362	1803	1601	2460
Fish	33965	20574	24363	24619	17375
Total cold-blooded animals	40286	27065	26196	26235	19930
TOTAL ANIMALS	718976	708746	676564	695.091	655.217

The following graph (*Figure 2: Trend in the number of animals used since 1997*) clearly shows that the number of animals used in Belgian laboratories fell between 1997 and 2005 (by 16%), even though there were some unrepresentative annual fluctuations.

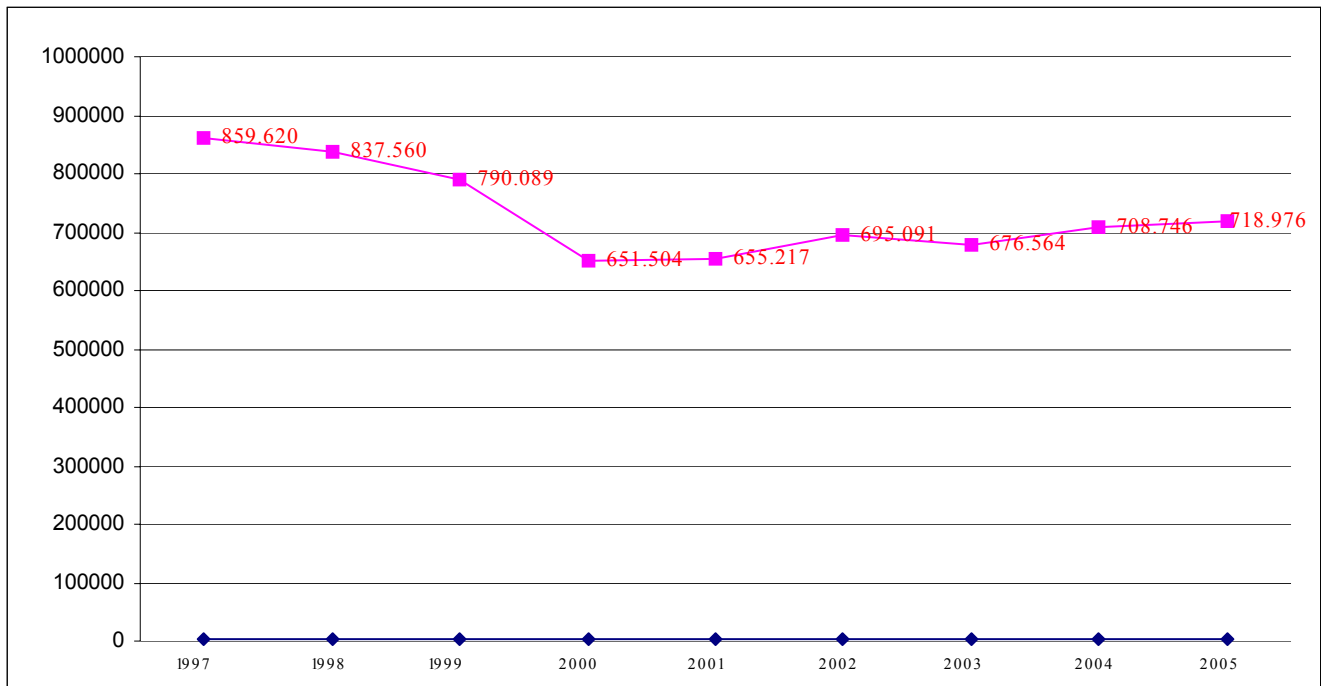


Figure 2: Trend in the number of animals used since 1997

3. Experiments carried out

In descending order, animals were used mainly for research and to develop products and devices used in human and veterinary medicine (33% of the animals used), basic research studies (29%) and tests on the production and quality control of such products and devices (24%) (*Figure 3: Breakdown of the experimental fields*). There has been a steady rise in the number of animals used for basic research and the figure in 2005 was the highest ever for this category. As regards production and quality control tests and toxicology tests, 98% and 90% respectively of the animals were used to meet legal requirements.

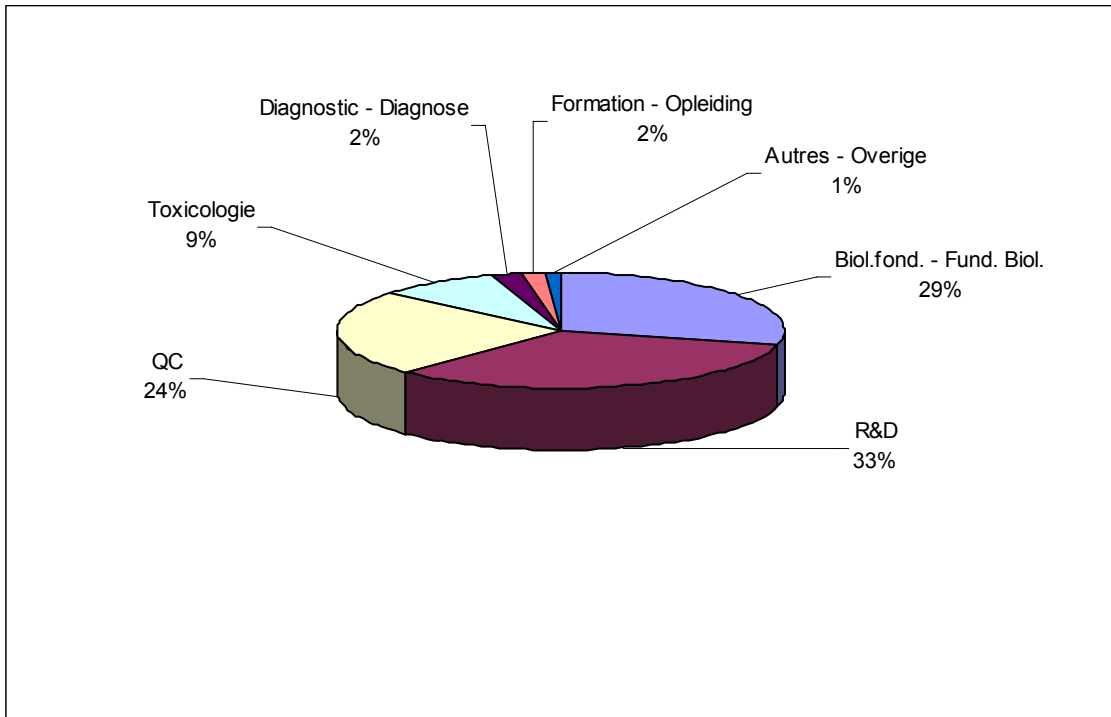


Figure 3: Breakdown of the experimental fields

Diagnostic – diagnostics; Formation – training; Autres – other; Biol. Fond. – basic biology; R&D – research and development; QC – quality control; Toxicologie – toxicology

The following diagram (Figure 4: Breakdown of experimental fields by the animals most used) shows that, of the animals most used, rats and mice are used mainly for basic research and the development of products and material for medicine (65%) and for safety tests (22%).

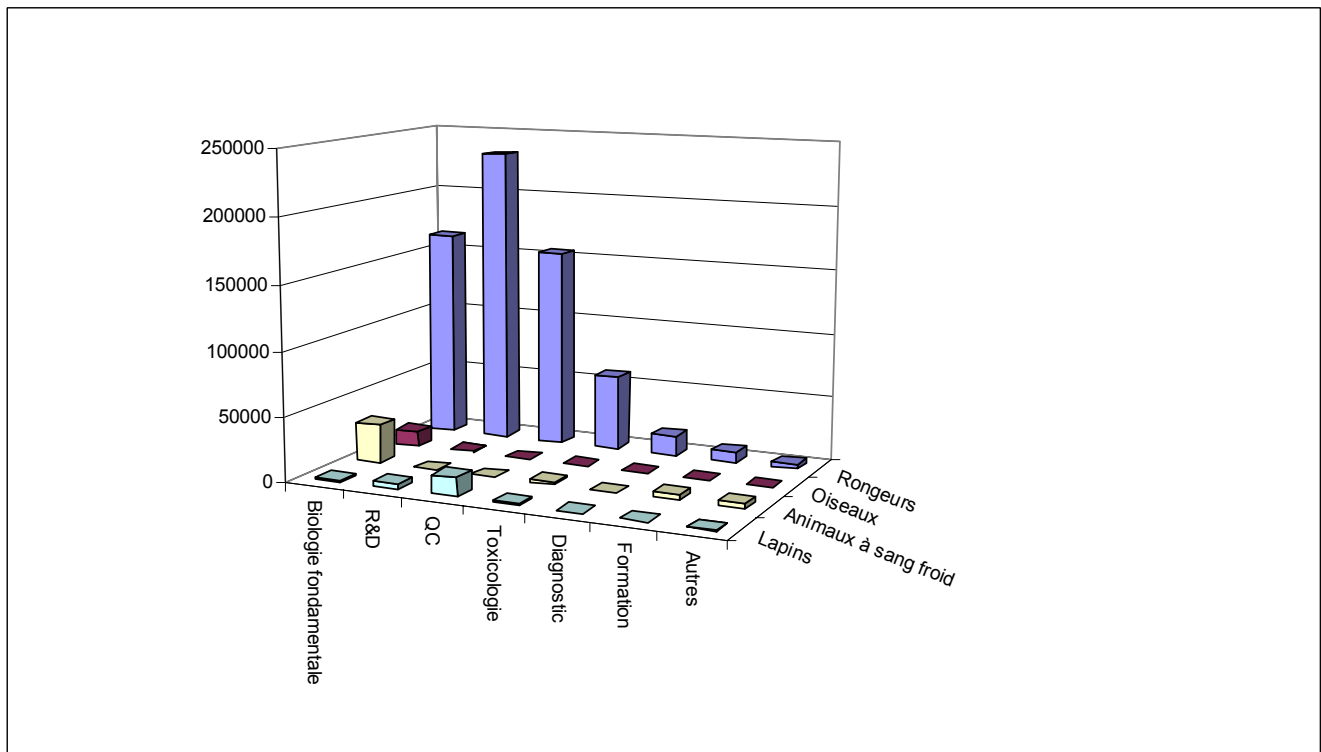


Figure 4: Breakdown of experimental fields by the animals most used

Biologie fondamentale – basic biology; R&D – research and development; QC – quality control; Toxicologie – toxicology; Diagnostic – diagnostics; Formation – training; Autres – other; Lapins – rabbits; Animaux à sang froid – cold-blooded animals; Oiseaux – birds; Rongeurs – rodents.

As regards the other species, 92% of primates and 78% of dogs were used in toxicology tests for safety.

The use of primates is still linked to the World Health Organisation programme to eradicate poliomyelitis worldwide, a programme for which the bulk of the oral polio vaccine is produced in Belgium. Primates have not been used to produce the vaccine since 2003 and neurovirulence tests on types of vaccine strain are now carried out solely on mice rather than primates, a method which recently became part of international law.

The fields where use has increased significantly since 2004 are training (by 5 166, 71%), medical diagnosis (by 7 475, 88%) and toxicology tests (by 15 026, 31%).

Toxicology and safety tests account for 9% of the animals used in experiments in 2005; 90% of the animals used in toxicology tests were used in safety trials required by laws and regulations (*Figure 5: Proportion of quality control and toxicology tests imposed by law*).

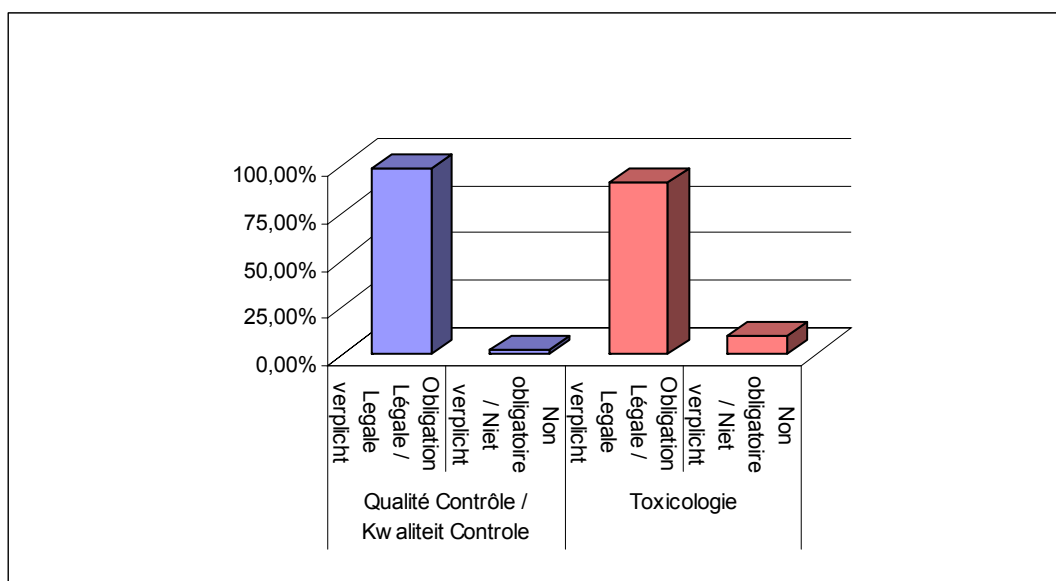


Figure 5: Proportion of quality control and toxicology tests imposed by law

Obligation légale – legal requirement; Non obligatoire – not compulsory; Qualité Contrôle – quality control; Toxicologie – toxicology.

4. Origin of animals used in experiments

The Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes lays down the list of animals which must come from specifically approved suppliers. In 2005, 91% of the animals used in experiments were on that list. Of these, 96% came from approved suppliers in Belgium, other countries of the European Union and members of the Council of Europe.

Animals belonging to agricultural species and other animals, including cold-blooded animals, do not appear on the list in the Royal Decree of 14 November 1993. They come from suppliers which meet the conditions laid down by the legislation in force for such establishments.

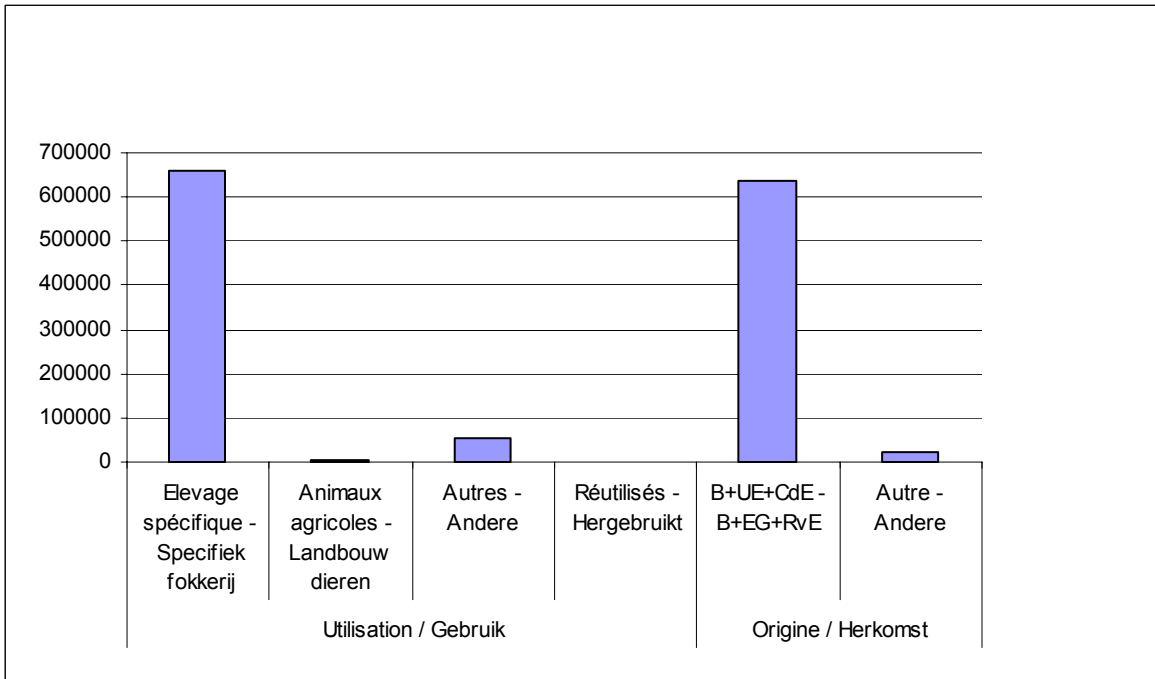


Figure 6: Origin of animals used in experiments

Elevage spécifique – specially bred; Animaux agricoles – agricultural animals; Autres – other; Réutilisés – re-used; B+UE+CdE – B+EU+CoE; Utilisation – use; Origine – origin

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	488125	166973	298054	1079	22019	
1.b. Rats (<i>Rattus norvegicus</i>)	106483	19125	80233	6535	590	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	39530	5352	34178	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	1874	69	1773	0	32	
1.e. Other Rodents (other <i>Rodentia</i>)	2260					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	21159	18347	2806	0	6	536
1.g. Cats (<i>Felis catus</i>)	81	49	32	0	0	78
1.h. Dogs (<i>Canis familiaris</i>)	1295	82	898	23	292	475
1.i. Ferrets (<i>Mustela putorius furo</i>)	154	0	154	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	108					
1.l. Pigs (<i>Sus</i>)	1876					
1.m. Goats (<i>Capra</i>)	157					
1.n. Sheep (<i>Ovis</i>)	445					
1.o. Cattle (<i>Bos</i>)	944					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	7
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	449	0	37	0	412	22
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	59					
1.u. Quail (<i>Coturnix coturnix</i>)	425	421	0	0	4	
1.v. Other birds (other <i>Aves</i>)	13266					
1.w. Reptiles (<i>Reptilia</i>)	144					
1.x. Amphibians (<i>Amphibia</i>)	6177					
1.y. Fish (<i>Pisces</i>)	33965					
1.z. TOTAL	718976					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	142620	168987	114435	6487	31740	15303	5518	3035	488125
2.b. Rats	20078	56836	13598	131	12960	487	1843	550	106483
2.c. Guinea-Pigs	247	5497	18039	1006	14190	26	525	0	39530
2.d. Hamsters	131	1	0	1660	0	0	34	48	1874
2.e. Other Rodents	411	1697	0	0	142	0	0	10	2260
2.f. Rabbits	1326	3888	14276	329	1095	0	84	161	21159
2.g. Cats	49	0	0	32	0	0	0	0	81
2.h. Dogs	115	104	0	38	1018	7	13	0	1295
2.i. Ferrets	0	154	0	0	0	0	0	0	154
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	28	27	15	2	0	1	31	4	108
2.l. Pigs	1197	144	21	187	95	16	113	103	1876
2.m. Goats	26	54	0	40	0	0	32	5	157
2.n. Sheep	177	123	0	34	24	0	2	85	445
2.o. Cattle	97	136	0	484	15	83	17	112	944
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	37	0	0	0	412	0	0	0	449
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	28	31	0	0	0	0	0	0	59
2.u. Quail	421	0	0	0	0	0	4	0	425
2.v. Other birds	11546	1269	165	36	238	0	2	10	13266
2.w. Reptiles	144	0	0	0	0	0	0	0	144
2.x. Amphibians	5071	0	0	0	0	30	1076	0	6177
2.y. Fish	25466	0	0	0	1769	0	3130	3600	33965
2.z. TOTAL	209215	238948	160549	10466	63698	15953	12424	7723	718976

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	30371	50	50	0	0	0	0	1254	15	31740
3.b. Rats	12260	0	0	0	0	0	0	0	700	12960
3.c. Guinea-Pigs	14190	0	0	0	0	0	0	0	0	14190
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	142	0	142
3.f. Rabbits	1095	0	0	0	0	0	0	0	0	1095
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	1018	0	0	0	0	0	0	0	0	1018
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	80	0	0	0	0	0	0	0	15	95
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	24	0	0	0	0	0	0	0	0	24
3.o. Cattle	0	0	0	0	0	0	0	0	15	15
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	412	0	0	0	0	0	0	0	0	412
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	118	0	0	0	0	0	0	120	0	238
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	275	510	0	0	0	0	0	444	540	1769
3.z. TOTAL	59843	560	50	0	0	0	0	1960	1285	63698

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	5754	62251	46356	193220	9749	317330
4.b. Rats	1845	29488	2602	41694	119	75748
4.c. Guinea-Pigs	233	2134	0	15491	5	17863
4.d. Hamsters	0	0	0	70	0	70
4.e. Other Rodents	36	585	0	846	198	1665
4.f. Rabbits	260	5	18	219	321	823
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	56	16	0	121	2	195
4.i. Ferrets	0	0	0	154	0	154
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	28	28
4.l. Pigs	71	0	0	116	286	473
4.m. Goats	0	0	0	60	0	60
4.n. Sheep	39	0	0	75	0	114
4.o. Cattle	4	0	0	0	136	140
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	25	0	25
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	6	0	3	25	0	34
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	211	1724	1935
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	9	0	0	3	0	12
4.y. Fish	0	0	0	0	1000	1000
4.z. TOTAL	8313	94479	48979	252330	13568	417669

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	26663	0	9365	83891	1003	120922
5.b. Rats	0	294	0	1385	9621	2429	13729
5.c. Guinea-Pigs	0	2534	0	4092	12410	9	19045
5.d. Hamsters	0	840	0	0	820	0	1660
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	81	0	219	14281	24	14605
5.g. Cats	0	26	0	0	6	0	32
5.h. Dogs	0	22	0	0	16	0	38
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	2	0	15	17
5.l. Pigs	0	82	0	0	105	21	208
5.m. Goats	0	0	0	0	40	0	40
5.n. Sheep	0	2	0	0	32	0	34
5.o. Cattle	0	484	0	0	0	0	484
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	201	0	0	0	0	201
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	0	31229	0	15063	121222	3501	171015

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	3234	0	3180	21142	4184	31740
6.b. Rats	0	0	0	640	11501	819	12960
6.c. Guinea-Pigs	0	40	0	403	13747	0	14190
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	142	142
6.f. Rabbits	0	12	0	0	1069	14	1095
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	1018	0	1018
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	80	0	0	0	15	95
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	24	0	0	0	0	24
6.o. Cattle	0	0	0	15	0	0	15
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	412	0	412
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	82	0	0	0	156	238
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	230	0	0	590	275	674	1769
6.z. TOTAL	230	3472	0	4828	49164	6004	63698

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1534	15	24673	0	0	0	1720	854	457	1611	100	0	776	31740
7.b. Rats	0	60	5297	0	0	0	1718	1604	1657	531	326	0	1767	12960
7.c. Guinea-Pigs	0	0	14030	0	160	0	0	0	0	0	0	0	0	14190
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	142	0	0	0	0	0	0	0	0	0	0	0	142
7.f. Rabbits	0	0	169	18	9	12	0	0	814	0	0	0	73	1095
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	474	0	0	0	215	0	0	0	0	0	329	1018
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	95	95
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	15	15
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	412	0	0	0	0	0	0	0	0	0	0	412
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	100	0	0	0	0	0	0	0	0	0	0	138	238
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	1298	0	0	0	0	0	76	0	0	0	0	0	395	1769
7.z. TOTAL	2832	317	45055	18	169	12	3729	2458	2928	2142	426	0	3612	63698

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	1534	0	43801	18	169	12	3013	2458	2622	2142	426	1669	1788	59652
8.b. Products/substances used or intended to be used mainly in agriculture	390	0	0	0	0	0	0	0	0	0	0	0	0	390
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	368	317	0	0	0	0	76	0	0	0	0	0	155	916
8.i. Other toxicological or safety evaluations	540	0	1254	0	0	0	640	0	306	0	0	0	0	2740
8.j. TOTAL	2832	317	45055	18	169	12	3729	2458	2928	2142	426	1669	1943	63698

CYPRUS

Statistical data submitted

The statistical data have been submitted by “Veterinary Services of the Republic of Cyprus”.

Remark: data are reported in table 1, 2 and 4 only.

Comments of the Cyprus authorities

The Director of the Veterinary Services of the Republic of Cyprus is empowered by Law to regulate all activities that relate to the use of experimental animals. At present, within the areas under the control of the Republic, only rodents (mice) are used in animal experimentation. These primarily include genetic models for various diseases or processes with main emphasis on Central Nervous System complications and development.

These activities began to take place in Cyprus in March 2003 and are all carried out in one research establishment, the Cyprus Institute of Neurology and Genetics (www.cing.ac.cy).

The Veterinary Services are satisfied that the animals are kept in a very rigorously monitored, pathogen-free environment (monitored according to FELASA guidelines). No outbreak of all pathogens tested has been observed. We are also satisfied that the principles of the three Rs are duly adhered to.

Dr. Giorgos Neophytou

Director of Veterinary Services

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	967	930	12		25	
1.b. Rats (<i>Rattus norvegicus</i>)	0					
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	0					
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	0					
1.g. Cats (<i>Felis catus</i>)	0					
1.h. Dogs (<i>Canis familiaris</i>)	0					
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)						
1.l. Pigs (<i>Sus</i>)						
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)						
1.o. Cattle (<i>Bos</i>)						
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)						
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	967					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	822						145		967
2.b. Rats									0
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits									0
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0

2.z. TOTAL	822	0	0	0	0	0	145	0	967
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TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice		792		175		967
4.b. Rats						0
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	792	0	175	0	967

CZECH REPUBLIC

Statistical data submitted

The statistical data have been submitted by the “Central Commission for Animal Welfare (*Ústřední komise pro ochranu zvířat*)”.

Comments of the Czech authorities

National comments for the preparation of the 5th Statistical report on the use of experimental animals - Czech Republic

Protection of animals and animal welfare in the Czech Republic is the responsibility of the Ministry of Agriculture, which provides the organisation background necessary for the activities performed by the Central Commission for Animal Welfare (*Ústřední komise pro ochranu zvířat*). The animal welfare activities are implemented pursuant to Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended. The supervision over these matters has been the responsibility of the Regional Veterinary Administrations' inspectors in 13 regions of the Czech Republic and the Municipal Veterinary Administration in Prague.

There were 93 inspections conducted in laboratory animal breeding establishments involving 120 067 animals, corrective measures were imposed in 3 cases and administrative procedure was initiated twice.

In 2005 a total of 330 933 animals were used for experimental and other scientific purposes in the CR. It shall be pointed out that 36.99 % of it is represented by ringed birds (122 422 birds) since pursuant to the relevant Czech legislation even bird ringing is an experiment.

Of the remaining 208 511 animals used for experimental and scientific purposes only 0.01 % were cats (29 cats), 0.13 % dogs (264 dogs), 0.02 % monkeys (51 monkeys), while no apes were used. Rodents and rabbits (62.16 %, i.e. 129 615 animals) and fish (33.29 %, i.e. 69 418 fish) represent the prevailing majority of animals used.

In the last couple of years the number of experimental animals used in the CR was approximately the same (approximately 220 000 animals excluding ringed birds). Fluctuations in numbers, if any, are caused by experiments using fish and poultry because these experiments are usually conducted on a large group of animals (a flock in houses or stock in water reservoirs).

The use of alternative methods to experiments on animals has been pushed through in the CR. Persons who manage, control and conduct experiments on animals are obliged to seek in the registers of validated alternative methods such methods which are applicable to their experiment. In the experimental project the applicant shall declare in writing that no validated alternative method can be applied for the given purpose.

The training courses for persons who manage, control and conduct experiments on animals comprise also teaching of alternative methods to experiments on animals.

Doc. MVDr. Richard S O V J Á K, CSc.

Chairman

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	82252	75473	4708	2071		
1.b. Rats (<i>Rattus norvegicus</i>)	31703	29924	1087	240	452	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	4075	4075				
1.d. Hamsters (<i>Mesocricetus</i>)	220	220				
1.e. Other Rodents (other <i>Rodentia</i>)	5798					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	5567	5567				119
1.g. Cats (<i>Felis catus</i>)	29	3			26	
1.h. Dogs (<i>Canis familiaris</i>)	264	264				24
1.i. Ferrets (<i>Mustela putorius furo</i>)	159	159				
1.j. Other Carnivores (other <i>Carnivora</i>)	7					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	314					
1.l. Pigs (<i>Sus</i>)	1392					
1.m. Goats (<i>Capra</i>)	56					
1.n. Sheep (<i>Ovis</i>)	720					
1.o. Cattle (<i>Bos</i>)	711					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	51	51				30
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)	188					
1.u. Quail (<i>Coturnix coturnix</i>)	30	30				
1.v. Other birds (other <i>Aves</i>)	126211					
1.w. Reptiles (<i>Reptilia</i>)	1475					
1.x. Amphibians (<i>Amphibia</i>)	293					
1.y. Fish (<i>Pisces</i>)	69418					
1.z. TOTAL	330933					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	33319	4698	8962	14401	2673	9320	3338	5541	82252
2.b. Rats	25532	2462	146	920	911	77	1655		31703
2.c. Guinea-Pigs	433	4	1575	1048	527	457	31		4075
2.d. Hamsters	115		55	40		10			220
2.e. Other Rodents	5449			187			162		5798
2.f. Rabbits	352	16	1351	2962	448	344	83	11	5567
2.g. Cats	3			26					29
2.h. Dogs	4		10	100	145	5			264
2.i. Ferrets		126	7			6	20		159
2.j. Other Carnivores	7								7
2.k. Horses, donkeys and cross breeds				208			100	6	314
2.l. Pigs	502			569		85	236		1392
2.m. Goats	56								56
2.n. Sheep	83			51			19	567	720
2.o. Cattle	152	241		40		12	84	182	711
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys					51				51
2.s. Apes									0
2.t. Other Mammals	188								188
2.u. Quail					30				30
2.v. Other birds	122422		42	2556		6	585	600	126211
2.w. Reptiles	755						720		1475
2.x. Amphibians	208						85		293
2.y. Fish	26935			1422	26693	870	11866	1632	69418

2.z. TOTAL	216515	7547	12148	24530	31478	11192	18984	8539	330933
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TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	2300		68				600	405		3373
3.b. Rats	663		248				150	200		1261
3.c. Guinea-Pigs	30	26	471							527
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	245	4	174					25		448
3.g. Cats										0
3.h. Dogs	145									145
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys	51									51
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail								25		25
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish	1468	90	2676					19523	1891	25648
3.z. TOTAL	4902	120	3637	0	0	0	750	20178	1891	31478

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	1473	1230	9036	15146	4672	31557
4.b. Rats	5697	2896	694	6104	136	15527
4.c. Guinea-Pigs	10			13	6	29
4.d. Hamsters				10	20	30
4.e. Other Rodents					361	361
4.f. Rabbits	167		3	161	72	403
4.g. Cats	3					3
4.h. Dogs	2					2
4.i. Ferrets	126			6		132
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	31		30	188	40	289
4.m. Goats					56	56
4.n. Sheep	29				28	57
4.o. Cattle					17	17
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail				5		5
4.v. Other birds				111	1093	1204
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					1430	1430
4.z. TOTAL	7538	4126	9763	21744	7931	51102

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	4422	17623				1368	23413
5.b. Rats	211	880		8		117	1216
5.c. Guinea-Pigs	3	2620					2623
5.d. Hamsters		95					95
5.e. Other Rodents					187		187
5.f. Rabbits	483	3433		11		386	4313
5.g. Cats		26					26
5.h. Dogs		110					110
5.i. Ferrets		7					7
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds	205	3					208
5.l. Pigs		556				13	569
5.m. Goats							0
5.n. Sheep		51					51
5.o. Cattle		40					40
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds		2543				55	2598
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish	1222						1222
5.z. TOTAL	6546	27987	0	19	187	1939	36678

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine**

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	278	2170				225	2673
6.b. Rats	224	663	24				911
6.c. Guinea-Pigs	351	106	70				527
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	182	257	9				448
6.g. Cats							0
6.h. Dogs		145					145
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys		51					51
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail						25	25
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	6476	15055	312			4855	26698
6.z. TOTAL	7511	18447	415	0	0	5105	31478

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.

Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1055				68		1115		120		90		225	2673
7.b. Rats	298						613							911
7.c. Guinea-Pigs				40	487									527
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				259		164				25				448
7.g. Cats														0
7.h. Dogs							145							145
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys							51							51
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail			25											25
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish	22501						155				1600	2442		26698
7.z. TOTAL	23854	0	25	299	555	164	2079	0	120	25	1690	2442	225	31478

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	1213			145	30	100	1924								3412
8.b. Products/substances used or intended to be used mainly in agriculture	90			12	18										120
8.c. Products/substances used or intended to be used mainly in industry	1450			142	507	64	100					1374			3637
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	19510		25						120	25	90	1068			20838
8.i. Other toxicological or safety evaluations	591											2655	225		3471
8.j. TOTAL	22854	0	25	299	555	164	2024	0	120	25	90	5097	225		31478

DENMARK

Statistical data submitted

The statistical data have been submitted by the “*Dyreforsøgstilsynet*” (Animal Experiments Inspectorate).

Comments of Danish authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	208375	109300	96573	0	2502	145
1.b. Rats (<i>Rattus norvegicus</i>)	85664	45960	37649	725	1330	71
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	5046	1204	3838	0	4	2
1.d. Hamsters (<i>Mesocricetus</i>)	402	402	0	0	0	0
1.e. Other Rodents (other <i>Rodentia</i>)	6381	0	0	0	0	0
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	5805	4288	1359	18	140	739
1.g. Cats (<i>Felis catus</i>)	16	4	0	4	8	0
1.h. Dogs (<i>Canis familiaris</i>)	566	10	514	0	42	84
1.i. Ferrets (<i>Mustela putorius furo</i>)	19	0	0	0	19	0
1.j. Other Carnivores (other <i>Carnivora</i>)	242	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	62	0	0	0	0	0
1.l. Pigs (<i>Sus</i>)	7697	0	0	0	0	0
1.m. Goats (<i>Capra</i>)	199	0	0	0	0	0
1.n. Sheep (<i>Ovis</i>)	156	0	0	0	0	0
1.o. Cattle (<i>Bos</i>)	489	0	0	0	0	0
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	0	0	0	0	0
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	185	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	7784	0	0	0	0	0
1.w. Reptiles (<i>Reptilia</i>)	54	0	0	0	0	0
1.x. Amphibians (<i>Amphibia</i>)	840	0	0	0	0	0
1.y. Fish (<i>Pisces</i>)	35958	0	0	0	0	0
1.z. TOTAL	365940	0	0	0	0	0

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	50339	128153	13842	165	3742	2524	1441	8169	208375
2.b. Rats	18795	54087	860	0	8786	703	1984	449	85664
2.c. Guinea-Pigs	393	850	1434	0	2303	66	0	0	5046
2.d. Hamsters	338	0	0	0	64	0	0	0	402
2.e. Other Rodents	0	6343	0	0	0	38	0	0	6381
2.f. Rabbits	247	700	882	82	556	3232	104	2	5805
2.g. Cats	12	0	0	0	0	0	4	0	16
2.h. Dogs	46	109	0	0	407	0	4	0	566
2.i. Ferrets	19	0	0	0	0	0	0	0	19
2.j. Other Carnivores	242	0	0	0	0	0	0	0	242
2.k. Horses, donkeys and cross breeds	39	0	12	0	0	0	11	0	62
2.l. Pigs	3992	1807	20	29	581	483	350	435	7697
2.m. Goats	26	3	0	0	0	163	1	6	199
2.n. Sheep	125	27	4	0	0	0	0	0	156
2.o. Cattle	444	30	0	2	0	0	13	0	489
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	137	48	0	0	0	0	0	0	185
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	2695	0	2	0	0	5087	0	0	7784
2.w. Reptiles	54	0	0	0	0	0	0	0	54
2.x. Amphibians	597	93	0	0	0	0	150	0	840
2.y. Fish	10284	23710	0	0	1480	0	84	400	35958
2.z. TOTAL	88824	215960	17056	278	17919	12296	4146	9461	365940

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	2733	0	556	51	0	0	0	25	377	3742
3.b. Rats	5453	2138	355	134	0	33	0	561	112	8786
3.c. Guinea-Pigs	2102	0	45	0	0	0	0	156	0	2303
3.d. Hamsters	64	0	0	0	0	0	0	0	0	64
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	407	0	9	0	0	135	0	0	5	556
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	407	0	0	0	0	0	0	0	0	407
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	581	0	0	0	0	0	0	0	0	581
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	1080	0	0	0	0	400	0	1480
3.z. TOTAL	11747	2138	2045	185	0	168	0	1142	494	17919

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	1902	92293	20255	30999	716	146165
4.b. Rats	3072	35360	332	27760	96	66620
4.c. Guinea-Pigs	65	629	0	281	24	999
4.d. Hamsters	171	0	0	0	0	171
4.e. Other Rodents	0	5923	0	420	0	6343
4.f. Rabbits	142	8	0	740	2	892
4.g. Cats	0	12	0	0	0	12
4.h. Dogs	0	17	0	92	42	151
4.i. Ferrets	0	19	0	0	0	19
4.j. Other Carnivores	0	0	0	0	102	102
4.k. Horses, donkeys and cross breeds	0	0	0	0	26	26
4.l. Pigs	254	172	0	1616	665	2707
4.m. Goats	0	0	0	29	0	29
4.n. Sheep	0	0	0	50	0	50
4.o. Cattle	0	0	0	0	10	10
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	0	3714	3714
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	127	0	0	0	127
4.y. Fish	0	0	0	0	2800	2800
4.z. TOTAL	5606	134560	20587	61987	8197	230937

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	86	517	0	0	12882	522	14007
5.b. Rats	96	0	0	0	764	0	860
5.c. Guinea-Pigs	0	0	0	0	1332	102	1434
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	7	0	0	30	397	530	964
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	12	12
5.l. Pigs	25	0	0	0	24	0	49
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	0	4	4
5.o. Cattle	0	0	0	0	2	0	2
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	0	0	2	0	0	2
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	214	517	0	32	15401	1170	17334

Examples:
 5.2 – France is testing due to a UK (or FR) specific requirement
 5.3 – UK is testing according to EC legislation
 5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes:
 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	223	0	0	0	2190	1329	3742
6.b. Rats	0	0	0	0	5850	2936	8786
6.c. Guinea-Pigs	0	0	0	0	2112	191	2303
6.d. Hamsters	0	0	0	0	64	0	64
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	416	140	556
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	407	0	407
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	581	0	581
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	0	0	0	1080	0	400	1480
6.z. TOTAL	223	0	0	1080	11620	4996	17919

Examples:
 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes:
 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	0	2363	0	30	0	216	0	0	325	14	0	794	3742
7.b. Rats	0	0	1244	0	0	0	4585	3	116	0	2612	0	226	8786
7.c. Guinea-Pigs	0	0	1177	0	801	0	169	0	0	0	0	0	156	2303
7.d. Hamsters	0	0	28	0	0	0	36	0	0	0	0	0	0	64
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	0	53	0	5	294	0	0	0	0	0	204	556
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	20	0	0	0	381	0	0	0	0	0	6	407
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	8	0	0	473	0	0	0	100	0	0	581
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	1080	0	0	0	0	0	0	0	0	0	0	400	0	1480
7.z. TOTAL	1080	0	4832	61	831	5	6154	3	116	325	2726	400	1386	17919

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	0	4654	43	786	5	5739	0	116	48	100	0	320	11811
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	8	0	0	0	0	0	0	2051	0	14	2073
8.c. Products/substances used or intended to be used mainly in industry	1080	0	105	9	45	0	350	0	0	0	0	400	456	2445
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	8	3	0	51	0	0	123	185
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	34	0	0	0	0	0	0	0	0	0	135	169
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	561	0	181	742
8.i. Other toxicological or safety evaluations	0	0	8	0	0	0	88	0	0	226	14	0	158	494
8.j. TOTAL	1080	0	4801	60	831	5	6185	3	116	325	2726	400	1387	17919

GERMANY

Statistical data submitted

The statistical data have been submitted by the "*Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft*" (Federal Ministry for Consumer protection, Food and Agriculture).

Comments of German authorities

Further to the German Government's communications of 27 July 2006 regarding statistical information on the use of animals for experimental purposes, I now inform you of the following:

The German Government seeks to reduce animal experiments and to support the development of alternative methods (point 8.6 paragraph 3 of the 11 November 2005 coalition agreement). For example, the volume of assistance for the support priority "methods to replace animal experiments" has been increased from €3.4 million in 2005 to €4 million in 2006 - an increase of almost 18%. Furthermore, for many years the Federal Ministry of Food, Agriculture and Consumer Protection has been awarding a "research prize to support work on methods aimed at restricting and replacing animal experiments"; the prize carries an award of €15 000. In 2006 the 25th animal protection research prize will be awarded.

Based at the Federal Institute for Risk Assessment, the Central Office for recording and assessing methods to replace animal experiments was established in 1989 as the first institution of its kind in the world. Its task is to promote potentially successful approaches to developing and validating replacement and complementary methods. The Central Office's budget for doing so was almost doubled between 1990 (€204 200) and 2005 (€375 000). High priority is accorded to replacing animal experiments in official registration and authorisation procedures in which animal experiments are stipulated. The scientists at the Federal Institute for Risk Assessment also undertake successful research work themselves. For example, the Central Office is heavily involved in EU research projects, undertakes research projects as part of major joint projects and takes part in validation studies and collaborative tests within the EU. Furthermore, for many years a database on methods to replace animal experiments has been maintained at the Federal Institute for Risk Assessment; the database is available free of charge to scientists from the research world and industry at <http://www.dimdi.de/static/en/db/dbinfo/dbkurz/zt00.htm>.

In 2005 in Germany 1 822 424 animals were used for experiments and other scientific purposes. That represents an increase of 20 971 animals or 1.2% compared with the previous year.

As in previous years, rodents are the largest group at 1 573 074 animals or 86%. It is striking that up to 2005 their share continually increased from 75% in 2001. The number of dogs and cats has increased by 581 and 395 respectively compared with the

previous year. The number of farm animals used has remained constant at around 20 000 a year.

Apes have not been used. In the case of old-world monkeys, new-world monkeys and prosimians, there has been an increase of 338 animals compared with the previous year. That is the second highest figure since 2000. Apes were last reported in Germany in 1991.

The decline by 92 270 or 59% in the number of fish used is encouraging. In particular, there has been a reduction by 64 083 fish within basic research and by 15 463 fish in toxicological tests to identify environmental risks.

Within biological basic research there has been a reduction by 42 014 animals (5.5%) and within toxicological investigations and tests by 1 562 (1.0%).

No uniform trend is discernible in the case of animals used in the diagnosis of diseases; while their number rose by 158% to 39 013 in 2004 compared with the previous year, it fell again to 13 661 in 2005 and was therefore lower than in 2004.

With regard to products or equipment for medicine, dentistry or veterinary medicine, their research and development saw a marked increase by 13 869 animals and their manufacture or quality control by 101 535 animals.

Of those animals, 58% were used to research diseases in humans or animals.

For legally stipulated experiments for the manufacture or quality control of products for medicine, dentistry or veterinary medicine, or for toxicological safety tests, 24.9% of the animals were used.

On behalf of the ministry,

Dr Polten

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	1 084 358	921 971	141 721	18 197	2 469	
1.b. Rats (<i>Rattus norvegicus</i>)	435 417	339 626	90 339	3 516	1 936	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	37 761	37 372	389	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	7 916	6 965	861	13	77	
1.e. Other Rodents (other <i>Rodentia</i>)	7 622					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	103 329	101 939	1 354	4	32	6 532
1.g. Cats (<i>Felis catus</i>)	1 023	569	316	0	138	262
1.h. Dogs (<i>Canis familiaris</i>)	4 868	2 923	671	0	1 274	1 056
1.i. Ferrets (<i>Mustela putorius furo</i>)	560	131	4	0	425	4
1.j. Other Carnivores (other <i>Carnivora</i>)	235					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	755					
1.l. Pigs (<i>Sus</i>)	13 166					
1.m. Goats (<i>Capra</i>)	275					
1.n. Sheep (<i>Ovis</i>)	3 517					
1.o. Cattle (<i>Bos</i>)	2 909					
1.p. Prosimians (<i>Prosimia</i>)	99	0	99	0	0	81
1.q. New World Monkeys (<i>Ceboidea</i>)	408	347	61	0	0	67
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	1 579	120	247	0	1 212	327
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	115					
1.u. Quail (<i>Coturnix coturnix</i>)	2 457	2 457	0	0	0	
1.v. Other birds (other <i>Aves</i>)	39 150					
1.w. Reptiles (<i>Reptilia</i>)	136					
1.x. Amphibians (<i>Amphibia</i>)	10 432					
1.y. Fish (<i>Pisces</i>)	64 337					
1.z. TOTAL	1 822 424					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	548 649	277 287	106 512	42 650	50 280	4 411	16 146	38 423	1 084 358
2.b. Rats	101 199	195 642	47 486	11 683	62 982	885	13 472	2 068	435 417
2.c. Guinea-Pigs	1 907	4 999	14 251	5 921	9 755	11	402	515	37 761
2.d. Hamsters	3 583	2 227	3	1 195	56	6	307	539	7 916
2.e. Other Rodents	3 161	3 901	0	0	0	6	186	368	7 622
2.f. Rabbits	2 600	7 083	81 097	5 204	4 568	1 188	194	1 395	103 329
2.g. Cats	293	490	35	38	128	3	13	23	1 023
2.h. Dogs	410	1 568	34	245	2 422	63	89	37	4 868
2.i. Ferrets	4	542	0	0	0	0	0	14	560
2.j. Other Carnivores	27	0	0	202	0	0	0	6	235
2.k. Horses, donkeys and cross breeds	385	202	0	2	10	54	102	0	755
2.l. Pigs	3 140	4 845	32	985	327	925	1 978	934	13 166
2.m. Goats	151	43	7	1	2	3	55	13	275
2.n. Sheep	882	583	54	101	2	359	104	1 432	3 517
2.o. Cattle	435	1 159	0	147	91	734	161	182	2 909
2.p. Prosimians	2	0	0	0	97	0	0	0	99
2.q. New World Monkeys	196	89	0	0	122	0	0	1	408
2.r. Old World Monkeys	51	158	0	0	1 299	0	8	63	1 579
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	107	7	0	0	0	0	1	0	115
2.u. Quail	0	0	0	0	2 447	0	0	10	2 457
2.v. Other birds	9 089	10 329	690	13 117	1 644	857	1 271	2 153	39 150
2.w. Reptiles	114	13	0	0	0	0	9	0	136
2.x. Amphibians	8 836	0	0	0	0	0	1 596	0	10 432
2.y. Fish	30 135	0	0	825	23 180	4 156	2 177	3 864	64 337
2.z. TOTAL	715 356	511 167	250 201	82 316	159 412	13 661	38 271	52 040	1 822 424

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	32 474	6 930	10 388	0	0	0	0	10	478	50 280
3.b. Rats	36 143	10 131	15 018	113	0	0	0	451	1 126	62 982
3.c. Guinea-Pigs	5 364	2 290	2 061	0	0	0	0	0	40	9 755
3.d. Hamsters	36	20	0	0	0	0	0	0	0	56
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	3 182	851	501	4	0	0	0	0	30	4 568
3.g. Cats	128	0	0	0	0	0	0	0	0	128
3.h. Dogs	2 135	184	103	0	0	0	0	0	0	2 422
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	10	0	0	0	0	0	0	0	0	10
3.l. Pigs	303	0	8	0	0	0	0	0	16	327
3.m. Goats	0	2	0	0	0	0	0	0	0	2
3.n. Sheep	2	0	0	0	0	0	0	0	0	2
3.o. Cattle	91	0	0	0	0	0	0	0	0	91
3.p. Prosimians	97	0	0	0	0	0	0	0	0	97
3.q. New World Monkeys	122	0	0	0	0	0	0	0	0	122
3.r. Old World Monkeys	1 299	0	0	0	0	0	0	0	0	1 299
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	2 447	0	0	0	0	0	0	0	2 447
3.v. Other birds	60	1 084	0	0	0	0	480	20	0	1 644
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	313	8 521	2 664	0	0	0	0	9 744	1 938	23 180
3.z. TOTAL	81 759	32 460	30 743	117	0	0	480	10 225	3 628	159 412

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	53 032	131 336	161 390	361 742	3 918	711 418
4.b. Rats	45 836	110 443	9 632	110 670	289	276 870
4.c. Guinea-Pigs	614	289	37	4 777	144	5 861
4.d. Hamsters	661	1 783	182	2 426	0	5 052
4.e. Other Rodents	10	1 006	362	3 615	634	5 627
4.f. Rabbits	4 559	221	124	2 725	480	8 109
4.g. Cats	0	60	0	28	360	448
4.h. Dogs	543	3	28	195	955	1 724
4.i. Ferrets	0	0	0	533	0	533
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	8	16	451	475
4.l. Pigs	2 156	172	118	1 677	2 368	6 491
4.m. Goats	15	1	3	6	12	37
4.n. Sheep	375	9	0	253	933	1 570
4.o. Cattle	0	43	0	142	1 884	2 069
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	16	105	2	129	0	252
4.r. Old World Monkeys	3	18	2	96	0	119
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	7	0	42	0	49
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	8	0	915	10 965	11 888
4.w. Reptiles	13	0	0	12	78	103
4.x. Amphibians	561	131	16	239	0	947
4.y. Fish	300	593	0	2 000	6 756	9 649
4.z. TOTAL	108 694	246 228	171 904	492 238	30 227	1 049 291

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	391	110 626	0	872	33 610	3 663	149 162
5.b. Rats	0	52 998	0	0	5 874	297	59 169
5.c. Guinea-Pigs	0	16 475	0	436	3 125	136	20 172
5.d. Hamsters	0	859	0	0	275	64	1 198
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	52 271	0	0	8 292	25 738	86 301
5.g. Cats	0	73	0	0	0	0	73
5.h. Dogs	0	245	0	0	34	0	279
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	202	0	0	0	0	202
5.k. Horses, donkeys and cross breeds	0	2	0	0	0	0	2
5.l. Pigs	15	948	0	0	0	54	1 017
5.m. Goats	0	4	0	0	1	3	8
5.n. Sheep	0	15	0	0	79	61	155
5.o. Cattle	0	128	0	0	17	2	147
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	863	1 931	0	0	10 963	50	13 807
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	825	0	0	0	0	825
5.z. TOTAL	1 269	237 602	0	1 308	62 270	30 068	332 517

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine**

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	33 677	0	4 357	10 625	1 621	50 280
6.b. Rats	374	35 528	0	584	24 122	2 374	62 982
6.c. Guinea-Pigs	0	7 055	0	20	2 487	193	9 755
6.d. Hamsters	0	56	0	0	0	0	56
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	3 484	0	0	1 034	50	4 568
6.g. Cats	102	22	0	0	4	0	128
6.h. Dogs	64	999	0	0	1 347	12	2 422
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	10	10
6.l. Pigs	0	139	0	0	172	16	327
6.m. Goats	0	2	0	0	0	0	2
6.n. Sheep	0	2	0	0	0	0	2
6.o. Cattle	0	91	0	0	0	0	91
6.p. Prosimians	0	97	0	0	0	0	97
6.q. New World Monkeys	0	0	0	0	122	0	122
6.r. Old World Monkeys	0	0	0	0	1 299	0	1 299
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	1 562	0	0	885	0	2 447
6.v. Other birds	0	1 213	0	0	351	80	1 644
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	4 770	5 653	0	0	9 865	2 892	23 180
6.z. TOTAL	5 310	89 580	0	4 961	52 313	7 248	159 412

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.

Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	33 677	0	4 357	10 625	1 621	50 280	0	33 677	0	4 357	10 625	1 621	50 280
7.b. Rats	374	35 528	0	584	24 122	2 374	62 982	374	35 528	0	584	24 122	2 374	62 982
7.c. Guinea-Pigs	0	7 055	0	20	2 487	193	9 755	0	7 055	0	20	2 487	193	9 755
7.d. Hamsters	0	56	0	0	0	0	56	0	56	0	0	0	0	56
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	3 484	0	0	1 034	50	4 568	0	3 484	0	0	1 034	50	4 568
7.g. Cats	102	22	0	0	4	0	128	102	22	0	0	4	0	128
7.h. Dogs	64	999	0	0	1 347	12	2 422	64	999	0	0	1 347	12	2 422
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	10	10	0	0	0	0	0	10	10
7.l. Pigs	0	139	0	0	172	16	327	0	139	0	0	172	16	327
7.m. Goats	0	2	0	0	0	0	2	0	2	0	0	0	0	2
7.n. Sheep	0	2	0	0	0	0	2	0	2	0	0	0	0	2
7.o. Cattle	0	91	0	0	0	0	91	0	91	0	0	0	0	91
7.p. Prosimians	0	97	0	0	0	0	97	0	97	0	0	0	0	97
7.q. New World Monkeys	0	0	0	0	122	0	122	0	0	0	0	122	0	122
7.r. Old World Monkeys	0	0	0	0	1 299	0	1 299	0	0	0	0	1 299	0	1 299
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	1 562	0	0	885	0	2 447	0	1 562	0	0	885	0	2 447
7.v. Other birds	0	1 213	0	0	351	80	1 644	0	1 213	0	0	351	80	1 644
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	4 770	5 653	0	0	9 865	2 892	23 180	4 770	5 653	0	0	9 865	2 892	23 180
7.z. TOTAL	5 310	89 580	0	4 961	52 313	7 248	159 412	5 310	89 580	0	4 961	52 313	7 248	159 412

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	33 677	0	4 357	10 625	1 621	50 280	0	33 677	0	4 357	10 625	1 621	50 280
8.b. Products/substances used or intended to be used mainly in agriculture	374	35 528	0	584	24 122	2 374	62 982	374	35 528	0	584	24 122	2 374	62 982
8.c. Products/substances used or intended to be used mainly in industry	0	7 055	0	20	2 487	193	9 755	0	7 055	0	20	2 487	193	9 755
8.d. Products/substances used or intended to be used mainly in the household	0	56	0	0	0	0	56	0	56	0	0	0	0	56
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	3 484	0	0	1 034	50	4 568	0	3 484	0	0	1 034	50	4 568
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	102	22	0	0	4	0	128	102	22	0	0	4	0	128
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	64	999	0	0	1 347	12	2 422	64	999	0	0	1 347	12	2 422
8.i. Other toxicological or safety evaluations	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.j. TOTAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ESTONIA

Statistical data submitted

The statistical data have been submitted by anneli.harmson@agri.ee

Remark: data were reported in table 1, 2 and 4 only.

Comments of Estonian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	4350	510	3460	0	380	
1.b. Rats (<i>Rattus norvegicus</i>)	484	0	484	0	0	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	0					
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)	0					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	66	0	66	0	0	0
1.g. Cats (<i>Felis catus</i>)	0					
1.h. Dogs (<i>Canis familiaris</i>)	0					
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0					
1.l. Pigs (<i>Sus</i>)						
1.m. Goats (<i>Capra</i>)	0					
1.n. Sheep (<i>Ovis</i>)						
1.o. Cattle (<i>Bos</i>)	0					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)						
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	4900					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	200	4150							4350
2.b. Rats		484							484
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits		66							66
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0

2.z. TOTAL	200	4700	0	0	0	0	0	0	4900
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TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	340	2300	1070	640		4350
4.b. Rats	14	320		150		484
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	66					66
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	420	2620	1070	790	0	4900

GREECE

Statistical data submitted

The statistical data have been submitted by the “ΥΠΟΥΡΓΕΙΟ ΓΕΩΡΓΙΑΣ ΓΕΝΙΚΗ Δ/ΝΣΗ ΚΤΗΝΙΑΤΡΙΚΗΣ” (Ministry of Rural Development and Food, Directorate for Veterinary Care, Drugs & Practice).

Comments of Greek authorities

The legal basis for the collection of statistics on the number and use of vertebrate animals for experimental and other scientific purposes in Greece is provided by:

- Presidential Decree No 160/91 (Government Gazette I 64) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC, and
- Law No 2015/92 (Government Gazette I 30) approving the European Convention on the protection of animals used for experimental and other scientific purposes.

For the collection of statistics relating to the year 2005, the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 of 24.6.1997 were used. The Ministry of Rural Development and Food, Directorate-General for Veterinary Affairs, Directorate for Veterinary Care, Drugs & Practice sent them directly to the educational establishments (universities and technological colleges), research centres, healthcare institutions and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. These documents were not sent to cosmetics manufacturers for the year in question, as our department was informed that no cosmetics company uses animals for experimental purposes in Greece.

The total number of animals used in experiments in Greece in 2005 was 926 094.

Of these, 97.32% (901 300 animals) were **fish**, of which 0.14% were used to study fundamental biological characteristics and 99.86% for research and development of medical, dental and veterinary products and appliances (not including toxicological studies).

A further 2.374% (21 978 animals) were **rodents** (15 340 mice – accounting for 69.79%, 6 024 rats - accounting for 27.4%, 574 guinea pigs – accounting for 2.61% and 40 other rodents – accounting for 0.18%), 36.95% of which were used to study fundamental biological characteristics, 18.48% for research and development of medical, dental and veterinary products and appliances, 0.59% to control the production and quality of medical and dental products and appliances, 25.2% for toxicological and other safety studies (exclusively rats in this case), 14.84% for diagnosing illnesses, 0.01% for education and training purposes and, finally, 0.019% for other purposes.

Rabbits accounted for 0.13% of the animals used: (1 255 animals, of which 10 had already been used to take blood samples for the purpose of isolating platelets for further laboratory trials) 48.44% were used to study fundamental biological characteristics, 2.78% for research and development of medical, dental and veterinary products and appliances, 1.59% to control the production and quality of medical and dental products and appliances, 9.32% to control

the production and quality of veterinary products and appliances, 0.95% for toxicological and other safety studies, 2.23% for the diagnosis of illnesses, 16.09% for education and training purposes and, finally, 18.56% for other purposes.

Dogs accounted for 0.0015% (14 animals), of which 71.42% were used for research and development of medical, dental and veterinary products and appliances and 28.58% for education and training purposes.

Pigs accounted for 0.048% of the animals used (448 animals), of which 25.67% were used to study fundamental biological characteristics, 11.16% for research and development of medical, dental and veterinary products and appliances, 59.37% for education and training purposes and, finally, 3.79% for other purposes.

Sheep accounted for 0.001% of the animals used (99 animals), of which 20.2% were used to study fundamental biological characteristics, 54.54% for the diagnosis of illnesses, 24.24% for education and training purposes and 1.01% for other purposes.

Three Old World Apes were used to study fundamental biological characteristics, of which two can be reused according to the research institution's statement.

Hens accounted for 0.002% (21 animals), of which 71.42% were used for the diagnosis of diseases and 28.58% for education and training purposes.

Amphibians accounted for 0.105% (975 animals), of which 100% were used for education and training purposes.

Finally, only one (1) equid was used for education and training purposes.

It is apparent from the above data that the two main categories of experiments conducted in Greece are on the one hand, research and development of medical, dental and veterinary products and appliances and on the other, the study of fundamental biological characteristics.

More specifically, vertebrate animals are principally used:

- for research programmes in Greece's Higher Education Institutions and research centres. In particular, a high percentage of fish endemic to the waters of the Mediterranean Sea are used (the main source of the large number of fish referred to above).
- to study each species' fundamental biological characteristics, for which mainly rodents (mice and rats) and rabbits are used.

HEAD OF THE DIRECTORATE FOR VETERINARY CARE, DRUGS & PRACTICE

I. PAPADOPOULOS

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	15340	14050	80		1210	
1.b. Rats (<i>Rattus norvegicus</i>)	6024	5892			132	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	574	324			250	
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)	40					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	1255	1255				10
1.g. Cats (<i>Felis catus</i>)	0					
1.h. Dogs (<i>Canis familiaris</i>)	14	6	8			
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	1					
1.l. Pigs (<i>Sus</i>)	448					
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)	99					
1.o. Cattle (<i>Bos</i>)						
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	1		1			2
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	21					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	975					
1.y. Fish (<i>Pisces</i>)	901300					
1.z. TOTAL	926092					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	3279	3382	50		5324	2956	138	211	15340
2.b. Rats	4629	641	80		144	37	280	213	6024
2.c. Guinea-Pigs	215				85	270	4		574
2.d. Hamsters									0
2.e. Other Rodents		40							40
2.f. Rabbits	608	35	20	117	12	28	202	233	1255
2.g. Cats									0
2.h. Dogs		10					4		14
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds							1		1
2.l. Pigs	115	50					266	17	448
2.m. Goats									0
2.n. Sheep	20					54	24	1	99
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys	1								1
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds						15	6		21
2.w. Reptiles									0
2.x. Amphibians							975		975
2.y. Fish	1300	900000							901300
2.z. TOTAL	10167	904158	150	117	5565	3360	1900	675	926092

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	105								5219	5324
3.b. Rats		84	60							144
3.c. Guinea-Pigs	85									85
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits									12	12
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	190	84	60	0	0	0	0	0	5231	5565

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	95	1458	410	2950	300	5213
4.b. Rats	65	102		814		981
4.c. Guinea-Pigs					270	270
4.d. Hamsters						0
4.e. Other Rodents			40			40
4.f. Rabbits	162			321	28	511
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	36			79		115
4.m. Goats						0
4.n. Sheep					54	54
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds					15	15
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					900000	900000
4.z. TOTAL	358	1560	450	4164	900667	907199

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice						50	50
5.b. Rats	80						80
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		117				20	137
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	80	117	0	0	0	70	267

Examples:
 5.2 – France is testing due to a UK (or FR) specific requirement
 5.3 - UK is testing according to EC legislation
 5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes:
 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		105			5219		5324
6.b. Rats	89	55					144
6.c. Guinea-Pigs		85					85
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits						12	12
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	89	245	0	0	5219	12	5565

Examples:
 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes:
 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		5219											105	5324
7.b. Rats			34				60			50				144
7.c. Guinea-Pigs													85	85
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													12	12
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	5219	34	0	0	0	60	0	0	50	0	0	202	5565

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine														202	202
8.b. Products/substances used or intended to be used mainly in agriculture			84												84
8.c. Products/substances used or intended to be used mainly in industry							60								60
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations		5219													5219
8.j. TOTAL	0	5219	84	0	0	0	60	0	0	0	0	0	0	202	5565

SPAIN

Statistical data submitted

The Statistical data have been provided by the: "*Ministerio de Agricultura, Pesca y Alimentación, Subdirección General de Ordenación de explotaciones*" (Ministry of Agriculture, Fisheries and Food, Sub-directorate of Management of Developments).

Comments of Spanish authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	393217	357390	31627	22	4178	
1.b. Rats (<i>Rattus norvegicus</i>)	125754	113623	10478	0	1653	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	16780	14321	2459	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	908	877	31	0	0	
1.e. Other Rodents (other <i>Rodentia</i>)	294					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	11878	11111	767	0	0	0
1.g. Cats (<i>Felis catus</i>)	168	84		0	84	0
1.h. Dogs (<i>Canis familiaris</i>)	685	525	151	0	9	0
1.i. Ferrets (<i>Mustela putorius furo</i>)	237	155	82	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	42					
1.l. Pigs (<i>Sus</i>)	4818					
1.m. Goats (<i>Capra</i>)	119					
1.n. Sheep (<i>Ovis</i>)	821					
1.o. Cattle (<i>Bos</i>)	294					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	1	0	1	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	81	52	29	0	0	0
1.s. Apes (<i>Hominoidea</i>)	2	2	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	60					
1.u. Quail (<i>Coturnix coturnix</i>)	1	1	0	0	0	
1.v. Other birds (other <i>Aves</i>)	8424					
1.w. Reptiles (<i>Reptilia</i>)	10					
1.x. Amphibians (<i>Amphibia</i>)	419					
1.y. Fish (<i>Pisces</i>)	30584					
1.z. TOTAL	595597	498141	45625	22	5924	0

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	130339	115641	6680	17599	62528	51405	8325	11300	403817
2.b. Rats	51885	39077	2204	810	8379	5252	5085	2843	115535
2.c. Guinea-Pigs	342	8343	1142	3310	3510	92	28	13	16780
2.d. Hamsters	493	52	0	264	0	87	12	0	908
2.e. Other Rodents	100	166	0	0	0	0	28	0	294
2.f. Rabbits	854	2674	30	2106	5026	51	1008	90	11839
2.g. Cats	76	3	13	0	0	0	3	73	168
2.h. Dogs	44	81	6	0	272	5	18	0	426
2.i. Ferrets	17	220	0	0	0	0	0	0	237
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	0	0	0	42	0	0	0	0	42
2.l. Pigs	288	1531	0	921	368	40	1200	387	4735
2.m. Goats	16	7	0	0	24	0	0	72	119
2.n. Sheep	17	94	0	571	62	0	75	2	821
2.o. Cattle	0	104	0	190	0	0	0	0	294
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	1	0	0	0	0	0	0	0	1
2.r. Old World Monkeys	23	21	0	0	37	0	0	0	81
2.s. Apes	2	0	0	0	0	0	0	0	2
2.t. Other Mammals	0	0	0	60	0	0	0	0	60
2.u. Quail	1	0	0	0	0	0	0	0	1
2.v. Other birds	94	2682	0	4343	40	15	50	1200	8424
2.w. Reptiles	10	0	0	0	0	0	0	0	10
2.x. Amphibians	351	0	0	0	0	0	0	68	419
2.y. Fish	28349	700	0	0	1269	0	266	0	30584
2.z. TOTAL	213302	171396	10075	30216	81515	56947	16098	16048	595597

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	21400	24	0	0	0	0	725	1285	40597	64031
3.b. Rats	3870	359	768	0	0	0	0	230	1375	6602
3.c. Guinea-Pigs	3287	0	63	0	0	0	0	0	160	3510
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	5187	0	111	0	75	0	0	0	45	5418
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	179	0	0	0	0	0	0	0	77	256
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	251	0	0	0	0	0	0	0	15	266
3.m. Goats	24	0	0	0	0	0	0	0	0	24
3.n. Sheep	62	0	0	0	0	0	0	0	0	62
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	37	0	0	0	0	0	0	0	0	37
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	40	0	0	0	0	0	0	0	0	40
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	100	237	0	560	0	0	0	372	0	1269
3.z. TOTAL	34437	620	942	560	75	0	725	1887	42269	81515

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	5844	13808	87612	80515	3839	191618
4.b. Rats	5938	15263	1538	36055	579	59373
4.c. Guinea-Pigs	44	286	110	637	325	1402
4.d. Hamsters	0	87	52	46	143	328
4.e. Other Rodents	0	120	0	74	448	642
4.f. Rabbits	180	3	66	803	474	1526
4.g. Cats	0	18	0	3	0	21
4.h. Dogs	27	2	3	135	12	179
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	17	0	0	0	17
4.l. Pigs	273	0	21	468	420	1182
4.m. Goats	40	24	0	7	0	71
4.n. Sheep	0	0	0	45	55	100
4.o. Cattle	0	0	0	0	14	14
4.p. Prosimians	0	1	0	0	0	1
4.q. New World Monkeys	0	3	0	0	0	3
4.r. Old World Monkeys	0	0	0	28	0	28
4.s. Apes	0	0	0	2	0	2
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	57	0	0	0	57
4.v. Other birds	0	0	0	0	1300	1300
4.w. Reptiles	0	45	0	0	0	45
4.x. Amphibians	0	192	50	50	0	292
4.y. Fish	0	0	200	300	3966	4466
4.z. TOTAL	12346	29926	89652	119168	11575	262667

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	66	21771	0	0	5	2437	24279
5.b. Rats	0	1342	0	1672	0	0	3014
5.c. Guinea-Pigs	0	3340	0	1058	0	54	4452
5.d. Hamsters	0	0	0	0	0	264	264
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	2	1563	0	0	0	571	2136
5.g. Cats	0	0	0	13	0	0	13
5.h. Dogs	0	0	0	0	0	6	6
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	42	0	0	0	0	42
5.l. Pigs	22	553	0	0	20	326	921
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	571	0	0	0	0	571
5.o. Cattle	0	190	0	0	0	0	190
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	60	0	0	0	0	60
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	3349	0	681	0	313	4343
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	90	32781	0	3424	25	3971	40291

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	308	13299	0	441	46381	3602	64031
6.b. Rats	96	1195	0	1509	2391	1411	6602
6.c. Guinea-Pigs	41	703	0	287	2479	0	3510
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	133	194	0	175	4760	156	5418
6.g. Cats	0	0	0	0	0	23	23
6.h. Dogs	0	67	0	10	156	0	233
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	6	244	0	0	16	0	266
6.m. Goats	0	24	0	0	0	0	24
6.n. Sheep	2	42	0	0	0	18	62
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	32	5	37
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	40	40
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	0	0	0	72	1197	0	1269
6.z. TOTAL	586	15768	0	2494	57412	5255	81515

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	9430	35486	1016	0	40	0	0	674	0	24	0	0	17361	64031
7.b. Rats	831	365	601	135	0	0	1057	96	0	0	567	0	2956	6608
7.c. Guinea-Pigs	0	399	12	16	463	0	0	0	0	0	0	0	2614	3504
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	6	16	24	282	0	64	6	0	113	0	0	0	4907	5418
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	156	0	0	0	0	0	100	256
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	266	266
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	62	62
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	37	0	0	0	0	0	0	37
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	40	40
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	287	0	0	0	0	0	860	0	50	0	72	0	0	1269
7.z. TOTAL	10554	36266	1653	433	503	64	2116	770	163	24	639	0	28330	81515

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	2563	2749	1633	281	445	24	897	0	163	0	567	0	25115	34437
8.b. Products/substances used or intended to be used mainly in agriculture	237	0	0	0	0	0	359	0	0	24	0	0	0	620
8.c. Products/substances used or intended to be used mainly in industry	601	71	0	90	58	21	0	96	0	0	0	0	5	942
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	560	0	0	0	0	0	0	560
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	56	0	19	0	0	0	0	0	0	0	75
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	725	0	0	0	0	0	0	0	0	0	0	0	725
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	473	812	6	0	0	0	300	0	0	0	72	0	224	1887
8.i. Other toxicological or safety evaluations	6680	33075	14	6	0	0	0	674	0	0	0	0	1820	42269
8.j. TOTAL	10554	37432	1653	433	503	64	2116	770	163	24	639	0	27164	81515

FRANCE

Statistical data submitted

The statistical data have been submitted by the “*Ministère de la Recherche et des Nouvelles Technologies*” (Ministry for Research and New Technologies).

Comments of the French authorities

This study was realized by the *EFICOM Markétudes* Company for the Research and University Education Ministry.

The number of animals used in France since 1999 is steady and about 2.2 billion. It represents a decrease of 40 % in comparison with the figures of the first study in 1990. In 2004, a slight increasing tendency could have been observed which led the figures to their 1999 rounded values. Since 1999, the amount of rodents used is steady (2.1 billion); and even if some animal groups are more often used (the amount of fishes and amphibian has doubled), there is a reversal tendency for other species (the amount of horses and oxen decreased by 50 %, and cats by 25 %). In return, the use of primates becomes more and more significant and is certainly not going to weak because of their scientific interests.

Concerning the study results, when significant differences were revealed between the 2001 and the 2004 figures, some verification were done in order to know what was the origin of these sudden evolutions. Each time these differences were explained by either new activity, for example the obtainment of therapeutic antibodies for rabbits increased by 74 %, or the closure of laboratories. They could be explained too by mistakes typed in the 2001 study report (concerning reptiles for example). The other variations are not significant and support the figures provided by experimental centres and laboratories.

This study allows estimating that public sector uses a third of the total amount of animals, of which 65 % is for basic research and education. On the other hand, private sector uses the remaining two third, of which 37 % are dedicated to research and development, 46 % to production and control, and 11 % to toxicological evaluations.

This study allows showing too that centres for animal experimentation are about 450 (it can vary depending on juridical conventions that link laboratories to these centres). It represents a third of the figure established in 1990. This decrease of the amount of experimental centres shows that henceforth laboratories are regrouped in order to dispose of centralized installations and competent staff. The « disappearance » of 900 experimental animal houses shows the pressure brought by the associations and the concerned authorities for fifteen years. It was engendered by very significant investments to come up to the current sanitary, ethic and scientific expectances. Of course, this diminution did not obviously drive to a decrease of the amount of animals with the same proportion, but it set practices that assure respect and well-being to animals.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	1 510 334	1 409 076	21 809	2 383	77 066	
1.b. Rats (<i>Rattus norvegicus</i>)	424 387	411 068	2 128	25	11 166	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	79 350	56 862	16 679	0	5 809	
1.d. Hamsters (<i>Mesocricetus</i>)	8 691	7 672	75	0	944	
1.e. Other Rodents (other <i>Rodentia</i>)	12 683					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	93 282	92 897	10	0	375	1 542
1.g. Cats (<i>Felis catus</i>)	1 313	622	9	0	682	408
1.h. Dogs (<i>Canis familiaris</i>)	5 539	3 662	20	0	1 857	690
1.i. Ferrets (<i>Mustela putorius furo</i>)	155	85	0	0	70	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	223					
1.l. Pigs (<i>Sus</i>)	6 587					
1.m. Goats (<i>Capra</i>)	442					
1.n. Sheep (<i>Ovis</i>)	4 992					
1.o. Cattle (<i>Bos</i>)	1 296					
1.p. Prosimians (<i>Prosimia</i>)	578	578	0	0	0	30
1.q. New World Monkeys (<i>Ceboidea</i>)	433	340	20	13	60	96
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	2 778	809	38	0	1 931	427
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0					
1.u. Quail (<i>Coturnix coturnix</i>)	4 023	3 983	0	0	40	0
1.v. Other birds (other <i>Aves</i>)	102 240					
1.w. Reptiles (<i>Reptilia</i>)	0					
1.x. Amphibians (<i>Amphibia</i>)	15 675					
1.y. Fish (<i>Pisces</i>)	50 397					
1.z. TOTAL	2 325 398					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	351 428	404 603	475 247	59 199	71 036	66 658	41 988	40 175	1 510 334
2.b. Rats	73 253	205 258	19 913	14 031	69 933	497	15 714	25 788	424 387
2.c. Guinea-Pigs	1 404	6 127	50 991	6 373	13 122	7	417	909	79 350
2.d. Hamsters	2 043	3 320	151	2 103	144	910	12	8	8 691
2.e. Other Rodents	745	10 645	0	0	0	27	0	1 266	12 683
2.f. Rabbits	1 246	9 686	61 349	3 334	10 328	1 123	1 689	4 527	93 282
2.g. Cats	53	396	0	458	24	0	9	373	1 313
2.h. Dogs	106	1 062	148	491	3 427	0	32	273	5 539
2.i. Ferrets	30	55	29	0	41	0	0	0	155
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	0	21	87	8	0	0	91	16	223
2.l. Pigs	159	2 421	4	1 407	1 002	1	350	1 243	6 587
2.m. Goats	26	106	77	0	10	0	23	200	442
2.n. Sheep	731	936	3 062	0	10	26	111	116	4 992
2.o. Cattle	56	461	1	11	92	20	141	514	1 296
2.p. Prosimians	382	0	0	0	0	0	0	196	578
2.q. New World Monkeys	24	121	35	0	168	0	5	80	433
2.r. Old World Monkeys	238	216	326	0	1 874	0	29	95	2 778
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	0	0
2.u. Quail	20	0	0	0	0	0	100	3 903	4 023
2.v. Other birds	3 768	10 718	10 857	37 069	36 332	435	1 209	1 852	102 240
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	4 760	53	0	0	500	0	9 362	1 000	15 675
2.y. Fish	41 140	0	0	0	4 948	0	1 439	2 870	50 397
2.z. TOTAL	481 612	656 205	622 277	124 484	212 991	69 704	72 721	85 404	2 325 398

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	39 549	7 321	5 868	0	1 797	516	123	2 438	13 424	71 036
3.b. Rats	44 318	3 177	5 693	16	2 226	229	0	1 565	12 709	69 933
3.c. Guinea-Pigs	4 353	445	3 832	177	940	27	0	0	3 348	13 122
3.d. Hamsters	142	0	2	0	0	0	0	0	0	144
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	4 796	696	1 319	106	533	0	0	0	2 878	10 328
3.g. Cats	24	0	0	0	0	0	0	0	0	24
3.h. Dogs	2 623	134	108	0	0	0	0	0	562	3 427
3.i. Ferrets	41	0	0	0	0	0	0	0	0	41
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	303	0	39	0	0	0	444	83	133	1 002
3.m. Goats	0	0	0	0	0	0	0	10	0	10
3.n. Sheep	0	0	0	0	0	0	10	0	0	10
3.o. Cattle	67	0	0	0	0	0	25	0	0	92
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	168	0	0	0	0	0	0	0	0	168
3.r. Old World Monkeys	970	0	6	0	0	0	0	0	898	1 874
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	262	0	98	0	0	0	30 519	366	5 087	36 332
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	400	0	0	0	0	100	0	0	500
3.y. Fish	0	2 848	2 000	0	0	0	0	100	0	4 948
3.z. TOTAL	97 616	15 021	18 965	299	5 496	772	31 221	4 562	39 039	212 991

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	69 470	226 646	154 806	307 007	64 760	822 689
4.b. Rats	47 369	112 450	17 732	99 236	2 221	279 008
4.c. Guinea-Pigs	1 719	924	149	2 980	1 766	7 538
4.d. Hamsters	1 078	1 117	0	2 031	2 047	6 273
4.e. Other Rodents	0	10 633	0	114	670	11 417
4.f. Rabbits	3 349	0	93	4 504	4 109	12 055
4.g. Cats	0	14	0	127	308	449
4.h. Dogs	130	36	11	654	337	1 168
4.i. Ferrets	0	0	0	85	0	85
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	21	21
4.l. Pigs	830	1	6	245	1 499	2 581
4.m. Goats	9	0	0	1	122	132
4.n. Sheep	152	40	0	116	1 385	1 693
4.o. Cattle	1	0	0	0	536	537
4.p. Prosimians	0	382	0	0	0	382
4.q. New World Monkeys	9	29	0	107	0	145
4.r. Old World Monkeys	9	69	52	315	9	454
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	20	0	20
4.v. Other birds	5	0	0	0	14 916	14 921
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	649	2 018	1 869	277	4 813
4.y. Fish	0	0	0	32 809	8 331	41 140
4.z. TOTAL	124 130	352 990	174 867	452 220	103 314	1 207 521

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	5 219	92 021	0	500	428 624	8 082	534 446
5.b. Rats	4 608	13 371	0	14 938	1 027	0	33 944
5.c. Guinea-Pigs	0	9 411	0	0	47 947	6	57 364
5.d. Hamsters	0	2 254	0	0	0	0	2 254
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	6	7 978	0	0	56 680	19	64 683
5.g. Cats	0	458	0	0	0	0	458
5.h. Dogs	0	639	0	0	0	0	639
5.i. Ferrets	0	23	0	0	6	0	29
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	95	0	95
5.l. Pigs	0	1 342	0	0	4	65	1 411
5.m. Goats	0	0	0	0	77	0	77
5.n. Sheep	0	0	0	0	3 062	0	3 062
5.o. Cattle	0	11	0	0	1	0	12
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	35	0	0	0	0	35
5.r. Old World Monkeys	0	6	0	0	320	0	326
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	37 117	152	0	10 657	0	47 926
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	9 833	164 666	152	15 438	548 500	8 172	746 761

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	7 381	17 787	22	3 586	34 457	7 803	71 036
6.b. Rats	568	8 729	0	5 966	48 339	6 331	69 933
6.c. Guinea-Pigs	414	9 751	0	323	2 107	527	13 122
6.d. Hamsters	0	78	0	0	64	2	144
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	502	1 631	0	1 726	4 669	1 800	10 328
6.g. Cats	0	24	0	0	0	0	24
6.h. Dogs	0	231	0	510	2 547	139	3 427
6.i. Ferrets	0	0	0	0	41	0	41
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	31	187	0	132	512	140	1 002
6.m. Goats	0	0	0	0	0	10	10
6.n. Sheep	0	0	0	0	10	0	10
6.o. Cattle	0	67	0	0	25	0	92
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	168	0	168
6.r. Old World Monkeys	0	253	0	488	1 035	98	1 874
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	629	98	0	0	35 605	0	36 332
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	500	0	0	0	0	0	500
6.y. Fish	0	3 000	0	0	33	1 915	4 948
6.z. TOTAL	10 025	41 836	22	12 731	129 612	18 765	212 991

Examples:
 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes:
 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	2 005	17 724	9 119	2 493	8 033	0	12 909	5 105	912	1 001	315	0	11 420	71 036
7.b. Rats	1 881	8 642	5 955	0	0	142	20 645	6 386	5 301	4 573	6 247	0	10 161	69 933
7.c. Guinea-Pigs	0	92	282	1 919	8 239	0	352	0	0	0	0	0	2 238	13 122
7.d. Hamsters	0	64	0	0	0	0	2	0	0	0	0	0	78	144
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	15	1 289	1 494	0	1 647	1 026	0	2 544	0	1 254	0	1 059	10 328
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.h. Dogs	0	166	599	0	0	0	2 429	0	0	0	0	0	233	3 427
7.i. Ferrets	0	0	41	0	0	0	0	0	0	0	0	0	0	41
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	49	0	0	0	0	262	0	89	0	0	0	602	1 002
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	10	10
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	10	10
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	92	92
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	72	78	0	0	0	18	0	0	0	0	0	0	168
7.r. Old World Monkeys	0	0	259	0	0	33	1 556	0	0	0	0	0	26	1 874
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	5 087	0	0	0	98	0	0	0	0	0	31 147	36 332
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	500	500
7.y. Fish	1 178	0	1 000	0	0	0	2 170	0	0	0	0	500	100	4 948
7.z. TOTAL	5 064	26 824	23 709	5 906	16 272	1 822	41 467	11 491	8 846	5 574	7 816	500	57 700	212 991

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	2 016	13 462	15 447	1 216	6 197	792	18 681	5 623	3 485	5 016	5 643	0	20 038	97 616
8.b. Products/substances used or intended to be used mainly in agriculture	2 111	1 683	1 865	102	230	56	5 896	1 723	666	0	134	555	0	15 021
8.c. Products/substances used or intended to be used mainly in industry	568	1 080	1 218	2 455	972	119	9 156	2 488	873	2	0	0	34	18 965
8.d. Products/substances used or intended to be used mainly in the household	0	18	0	36	133	67	0	0	0	0	0	0	45	299
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	349	684	413	2 222	281	966	0	368	213	0	0	0	5 496
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	123	0	19	0	467	0	0	8	0	0	155	772
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	185	0	0	0	0	24	0	0	0	0	31 012	31 221
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	1 289	287	0	0	0	1 350	0	0	0	592	0	1 044	4 562
8.i. Other toxicological or safety evaluations	409	6 943	1 779	372	2 096	367	18 251	473	2 298	2 042	1 180	0	2 829	39 039
8.j. TOTAL	5 104	24 824	21 588	4 594	11 869	1 682	54 767	10 331	7 690	7 281	7 549	555	55 157	212 991

HUNGARY

Statistical data submitted

The statistical data have been submitted by the Ministry of Agriculture and Rural Development.

Comments of the Hungarian authorities

2005 was the first year when Hungarian user establishments furnished data on the number of animals used for experimental and other scientific purposes in the harmonized eight table version of statistical reporting format. Furthermore, the data in this format were supplied on a voluntary basis. (The Hungarian law in force prescribes the use of the former 5-table version for statistical reporting.) This situation resulted in two consequences.

1. It is very difficult to compare the data of 2005 with those of the previous years when the former 5-table version had been in use.
2. The novelty and unfamiliarity of the tables and lack of sufficient guidance on the meaning of the new columns may have had a negative impact on the accuracy and coherence of data. (For example, in Tables 5 and 6 the non mutually exclusive classification of regulatory requirements may have corrupted the precision of the breakdown of the total figures.)

All the above circumstances warrant caution in interpreting the data.

Comments relating to the number of animals used

The total number of animals used for experimental and other scientific purposes in 2005 was 297.209 which represents 19% decrease compared to the same figure of 2004. (It is worth to note that the total number of animals had been relatively stable (365-377 thousand) in the period of 2001-2004). The decrease was 25% in the number of mice, 7% in case of rats, 28% for guinea-pigs, 66% in other rodents and 47% within birds. The number of used dogs and cats practically did not change. In contrast to the general decreasing tendency the use of fish more than doubled (+138%) while the number of rabbits increased by 9%.

Despite the considerable reduction in the number of rodents from year 2004 to year 2005 (~59.000 animals) this group kept its proportion (86.4%) within the total number of animals. Notable changes can be observed in the proportion of birds (a drop from 8.9% to 5.9%) and that of fish (an increase from 1.1% to 3%).

Due to the limiting conditions described above, however, it cannot be fairly judged whether these changes represent the beginning of a longer-term tendency or just reflect natural variation of the data.

When analysed by the purposes of the use of animals a slight increase can be observed in the fundamental biological research segment (3.7%) while the number of animals substantially decreased in education (51%), in diagnosis of disease and toxicological evaluations (32% each) and in the human and veterinary medicine field (21%) including research, development, production and quality control. However, in absolute numbers the latter decrease (48.671) accounts for more than two thirds of the total decrease (68.008).

Compared to 2004 the proportion of fundamental research in overall usage augmented from 21% to 27% while that of medicine related use decreased from 62% to 60%. Toxicological and safety investigations form the third largest part (10%) of animal usage.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	138312	106993	29067	0	2252	
1.b. Rats (<i>Rattus norvegicus</i>)	109479	102798	6681	0	0	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	8360	4688	3672	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	137	137	0	0	0	
1.e. Other Rodents (other <i>Rodentia</i>)	381					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	9152	8640	0	0	512	0
1.g. Cats (<i>Felis catus</i>)	124	121	0	0	3	0
1.h. Dogs (<i>Canis familiaris</i>)	1206	966	104	0	136	0
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	6					
1.l. Pigs (<i>Sus</i>)	882					
1.m. Goats (<i>Capra</i>)	2					
1.n. Sheep (<i>Ovis</i>)	381					
1.o. Cattle (<i>Bos</i>)	32					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	6	3	0	0	3	0
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0					
1.u. Quail (<i>Coturnix coturnix</i>)	283	93	0	0	190	
1.v. Other birds (other <i>Aves</i>)	17151					
1.w. Reptiles (<i>Reptilia</i>)	25					
1.x. Amphibians (<i>Amphibia</i>)	1709					
1.y. Fish (<i>Pisces</i>)	9581					
1.z. TOTAL	297209					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	31950	67452	22717	0	8125	7050	988	30	138312
2.b. Rats	35834	64523	0	0	7625	0	1497	0	109479
2.c. Guinea-Pigs	771	2417	2562	0	2554	16	22	18	8360
2.d. Hamsters	137	0	0	0	0	0	0	0	137
2.e. Other Rodents	0	81	0	0	300	0	0	0	381
2.f. Rabbits	1146	3995	3011	24	702	105	167	2	9152
2.g. Cats	109	0	0	0	0	0	15	0	124
2.h. Dogs	273	92	0	0	633	0	208	0	1206
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	6	0	6
2.l. Pigs	173	261	0	0	26	55	82	285	882
2.m. Goats	0	0	0	0	0	0	2	0	2
2.n. Sheep	19	189	0	24	4	3	2	140	381
2.o. Cattle	6	12	0	0	8	0	6	0	32
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	6	0	0	0	0	0	0	0	6
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	0	0
2.u. Quail	93	0	0	0	190	0	0	0	283
2.v. Other birds	3068	8070	132	3165	2244	360	109	3	17151
2.w. Reptiles	25	0	0	0	0	0	0	0	25
2.x. Amphibians	458	0	0	0	0	0	1251	0	1709
2.y. Fish	5365	0	0	0	3330	0	386	500	9581

2.z. TOTAL	79433	147092	28422	3213	25741	7589	4741	978	297209
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TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	2994	321	0	0	0	0	0	556	4254	8125
3.b. Rats	1556	1317	13	0	0	52	0	394	4293	7625
3.c. Guinea-Pigs	208	2	0	0	0	0	0	0	2344	2554
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	300	0	0	0	0	0	0	0	0	300
3.f. Rabbits	55	18	0	0	0	0	0	0	629	702
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	296	0	0	0	0	0	0	0	337	633
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	6	0	0	0	0	0	0	20	0	26
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	4	0	0	0	0	0	0	0	0	4
3.o. Cattle	8	0	0	0	0	0	0	0	0	8
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	190	0	0	0	0	0	0	0	190
3.v. Other birds	1444	0	0	0	0	0	0	800	0	2244
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	1000	430	0	0	0	0	0	1000	900	3330
3.z. TOTAL	7871	2278	13	0	0	52	0	2770	12757	25741

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	2146	55622	7607	13195	5982	84552
4.b. Rats	3601	54589	1003	6056	15	65264
4.c. Guinea-Pigs	59	93	0	2167	301	2620
4.d. Hamsters	0	0	0	0	0	0
4.e. Other Rodents	0	75	0	6	0	81
4.f. Rabbits	350	2753	0	196	707	4006
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	165	9	0	18	43	235
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	0	0
4.l. Pigs	61	0	0	14	189	264
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	3	277	280
4.o. Cattle	0	0	0	0	20	20
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	818	0	10	9906	10734
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	0	0	0	300	300
4.z. TOTAL	6382	113959	8610	21665	17740	168356

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	17952	0	0	4340	425	22717
5.b. Rats	0	0	0	0	0	0	0
5.c. Guinea-Pigs	0	1317	0	0	1157	88	2562
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	24	2981	0	0	30	0	3035
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	0	0	0
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	24	0	0	0	0	0	24
5.o. Cattle	0	0	0	0	0	0	0
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	100	3065	0	0	130	2	3297
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	148	25315	0	0	5657	515	31635

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine**

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	2779	1839	148	0	3359	0	8125
6.b. Rats	945	900	646	0	5121	13	7625
6.c. Guinea-Pigs	0	946	0	0	1608	0	2554
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	300	0	0	0	0	300
6.f. Rabbits	6	76	0	0	620	0	702
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	242	60	0	0	331	0	633
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	6	0	0	0	20	26
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	4	0	0	0	0	4
6.o. Cattle	0	8	0	0	0	0	8
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	190	0	0	0	0	190
6.v. Other birds	0	1182	0	0	0	1062	2244
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	1000	1430	0	0	900	0	3330
6.z. TOTAL	4972	6941	794	0	11939	1095	25741

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.

Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1781	427	2282	0	0	0	40	0	6	1068	0	0	2521	8125
7.b. Rats	160	529	2915	0	0	0	1129	47	6	13	773	0	2053	7625
7.c. Guinea-Pigs	368	0	419	0	1091	0	0	0	0	0	0	0	676	2554
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	300	0	0	0	0	0	0	0	0	0	0	300
7.f. Rabbits	0	0	64	143	0	111	0	0	0	0	252	0	132	702
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	311	0	0	0	200	0	0	0	0	0	122	633
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	6	0	0	0	0	0	0	0	0	0	20	26
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	4	0	0	0	0	0	0	0	0	0	0	4
7.o. Cattle	0	0	8	0	0	0	0	0	0	0	0	0	0	8
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	110	80	0	0	0	0	0	0	0	0	0	0	190
7.v. Other birds	0	0	1008	0	0	0	0	0	0	0	0	0	1236	2244
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	2330	0	900	0	0	0	0	0	100	0	0	0	0	3330
7.z. TOTAL	4639	1066	8297	143	1091	111	1369	47	112	1081	1025	0	6760	25741

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	2778	24	2924	9	0	0	0	0	100	0	0	0	2036	7871
8.b. Products/substances used or intended to be used mainly in agriculture	490	110	1425	12	0	111	80	0	0	0	0	0	158	2386
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	13	0	0	0	13
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	52	0	0	0	0	0	0	0	0	0	0	52
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	1000	0	760	0	0	0	0	47	12	0	131	0	820	2770
8.i. Other toxicological or safety evaluations	371	932	3136	122	1091	0	1289	0	0	1068	894	0	3746	12649
8.j. TOTAL	4639	1066	8297	143	1091	111	1369	47	112	1081	1025	0	6760	25741

IRELAND

Statistical data submitted

The statistical data for Ireland have been provided by the Department of Health and Children.

Comments of Irish authorities

General

-A total of 37,940 animals were used. This represents a reduction of 27% compared to 2002 (the last published figures).

- There were 539 valid licences during the period 1 January 2005 – 31 December 2005.

- 171 new licences were issued in 2005. This is an increase of 13% compared to 2002.

- Rodents accounted for 67% of all animals used.

- No primates were used. This was in accordance with Ireland's policy not to licence for the use of primates.

- Of the animals used, 39% (14,779) were bred in registered breeding establishments in Ireland.

- Universities and Colleges accounted for 76% (28,904) of all animals used in scientific procedures.

- 58% of all procedures (21,929) used no anaesthesia (Certificate A). Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.

- 20% of animals (7,557) were used in procedures involving anaesthesia with permitted recovery (Certificate B).

- 3,336 genetically modified animals were used in experimental activity. This represents approximately 9% of the total numbers used.

Animals Used for Selected Purposes

- 9% of animals (3,472) were involved in studies specific to animal diseases.

- Of the 382 pigs used in 2005, 69% (263) were involved in studies on human and animal diseases.

- 119 cats were used, 64 of which were used in toxicology and other safety evaluations.

- 167 dogs were used, a reduction of 14% since 2002.

- Education and training accounted for 2% (688) of the animals used.

- Of the 2,024 other birds, 95% (1,914) were used in behavioural studies.

- 82% (313) of the rabbits used were for the study of human cardiovascular diseases.
- 189 horses were used, an increase of 170 since 2002. 91% of the horses used were for EC legislation including European Pharmacopoeia requirements. 117 of the horses were used with a Certificate A. Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.

Toxicological and other Safety Evaluations

- No animals were used in the testing of cosmetic products.
- Toxicological and other safety evaluations accounted for 18% (6,869) of animals used.
- 98% of the animals used in toxicological and other safety evaluations were mice.
- 875 mice were used in LD₅₀ and LC₅₀ testing, a reduction of 33% since 2002.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 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 (<i>Mus musculus</i>)	17 776	8 767	8 532		477	
1.b. Rats (<i>Rattus norvegicus</i>)	7 722	5 733	1 864	60	65	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	4	4				
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)	0					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	379	19	360			
1.g. Cats (<i>Felis catus</i>)	119	119				60
1.h. Dogs (<i>Canis familiaris</i>)	167	137	30			92
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	189					
1.l. Pigs (<i>Sus</i>)	382					
1.m. Goats (<i>Capra</i>)	0					
1.n. Sheep (<i>Ovis</i>)	601					
1.o. Cattle (<i>Bos</i>)	2 109					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)	48					
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	2024					
1.w. Reptiles (<i>Reptilia</i>)	0					
1.x. Amphibians (<i>Amphibia</i>)	0					
1.y. Fish (<i>Pisces</i>)	6 420					
1.z. TOTAL	37940					

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 the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental 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 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	9 922	603			6703	158	15	375	17776
2.b. Rats	6 367	1209				76	26	44	7722
2.c. Guinea-Pigs		4							4
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	61	304						14	379
2.g. Cats		10	45		64				119
2.h. Dogs		38	42		87				167
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds				172			5	12	189
2.l. Pigs	130	123				10	99	20	382
2.m. Goats									0
2.n. Sheep	62	1		72		3	463		601
2.o. Cattle	1417	15		329	15		20	313	2109
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	4	44							48
2.u. Quail									0
2.v. Other birds		7				110	60	1847	2024
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish	6408							12	6420

2.z. TOTAL	24371	2358	87	573	6869	357	688	2637	37940
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TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	150								6553	6703
3.b. Rats										0
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits										0
3.g. Cats	64									64
3.h. Dogs	87									87
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle	15									15
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	316	0	0	0	0	0	0	0	6553	6869

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	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
4.a. Mice	675	1927	1155	6768	158	10683
4.b. Rats	1386	5379		887		7652
4.c. Guinea-Pigs		4				4
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	313	2		50		365
4.g. Cats	10					10
4.h. Dogs				38		38
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	101			56	106	263
4.m. Goats						0
4.n. Sheep	1			38	27	66
4.o. Cattle					1432	1432
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals	4				44	48
4.u. Quail						0
4.v. Other birds	7				110	117
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish		23		4790	1595	6408
4.z. TOTAL	2497	7335	1155	12627	3472	27086

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats					45		45
5.h. Dogs					42		42
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds		172					172
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep		72					72
5.o. Cattle		286				43	329
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	530	0	0	87	43	660

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 – Spain is testing due to a Hungarian 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)

Note: columns 5.2 - 5.5 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.
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine**

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		5238			1465		6703
6.b. Rats							0
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits							0
6.g. Cats	64						64
6.h. Dogs	87						87
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle						15	15
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	151	5238	0	0	1465	15	6869

Examples: 6.2 – France is testing due to a UK (or FR) specific 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)

Note: 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.
Example: a test required by French legislation and carried out in 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.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total	
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods												
7.a. Mice	875	4363					1465								6703
7.b. Rats															0
7.c. Guinea-Pigs															0
7.d. Hamsters															0
7.e. Other Rodents															0
7.f. Rabbits															0
7.g. Cats														64	64
7.h. Dogs														87	87
7.i. Ferrets															0
7.j. Other Carnivores															0
7.k. Horses, donkeys and cross breeds															0
7.l. Pigs															0
7.m. Goats															0
7.n. Sheep															0
7.o. Cattle			15												15
7.p. Prosimians															0
7.q. New World Monkeys															0
7.r. Old World Monkeys															0
7.s. Apes															0
7.t. Other Mammals															0
7.u. Quail															0
7.v. Other birds															0
7.w. Reptiles															0
7.x. Amphibians															0
7.y. Fish															0
7.z. TOTAL	875	4363	15	0	0	0	1465	0	0	0	0	0	151	6869	

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	875	4363	15										1465	151	6869
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations															0
8.j. TOTAL	875	4363	15	0	0	0	0	0	0	0	0	0	1465	151	6869