EUROPEAN COMMISSION

Brussels, 30.9.2010
SEC(2010) 1107 final

VOL B - Part III ([I], [II], [IV])

COMMISSION STAFF WORKING DOCUMENT

DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES

Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

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

COM(2010) 511 final

Important notice

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VOL B - Part III: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES

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Statistical data submitted

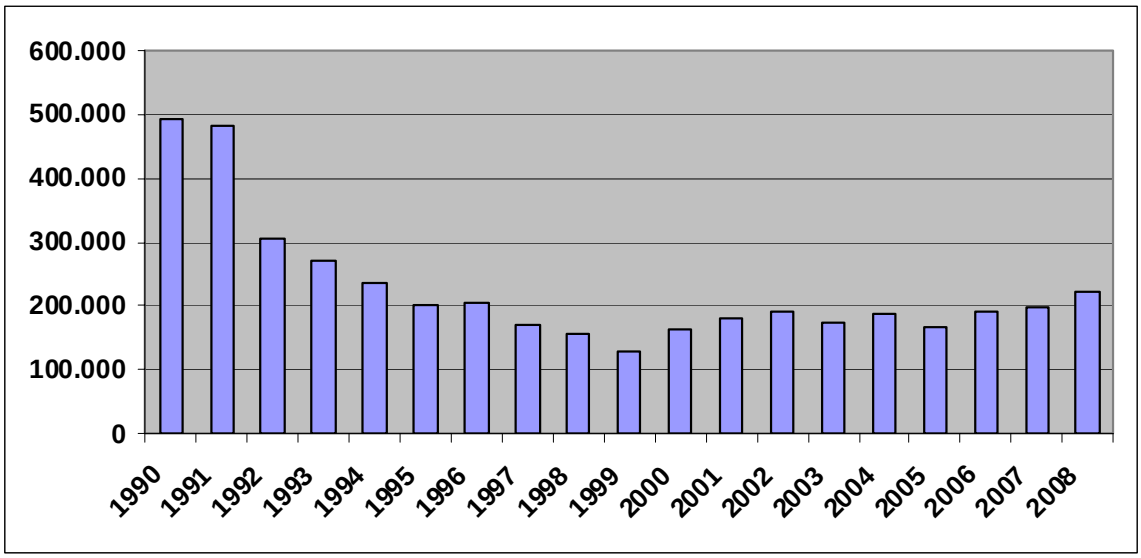
The statistical data have been submitted by the "*Bundesministerien für Gesundheit und Frauen-Land und Forstwirtshaft, Umwelt und Wasserwirtschaft – Wirtschaft und Arbeit - Bildung, Wissenschaft und Kultur*" (Federal Ministries for Health and Women -Agriculture Forestry, the Environment and Water Mangement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

Comments from the Austrian authorities

The number of animals used in procedures in Austria during 2008 has risen by 11,4% as compared to 2007. However, relative to international figures the Austrian number still remains low. The animal use statistics for 2008 show that in total 220,456 animals were used in procedures in Austria.

Compared to previous years, this total number lies within the range of variation of the last years, yet is still well below the number of the earliest years. Relative to 1990 (the year statistics were recorded for the first time, in which year 482,166 animals were used in procedures) the number of animals is reduced by about 55%. No great apes were used in 2008. No animals have been used for cosmetics testing. The statistics have been presented in the EU-wide standardized format.

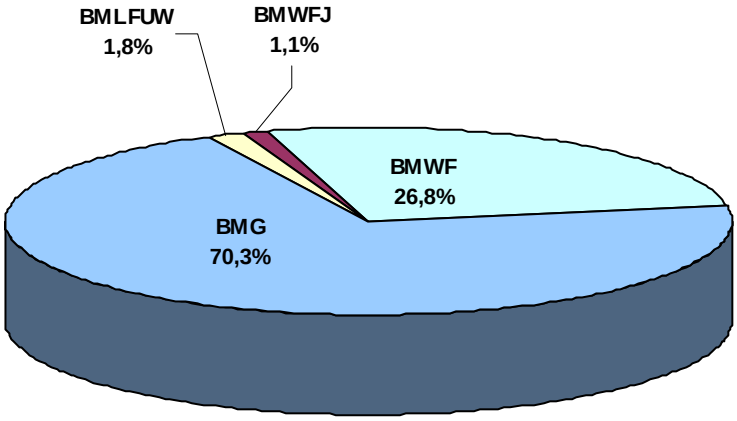
Development of the numbers of animals used since 1990



Breakdown according to areas of competence

A breakdown of the numbers according to areas of competence for administration of the Animal Experiments Law ranks them as follows:

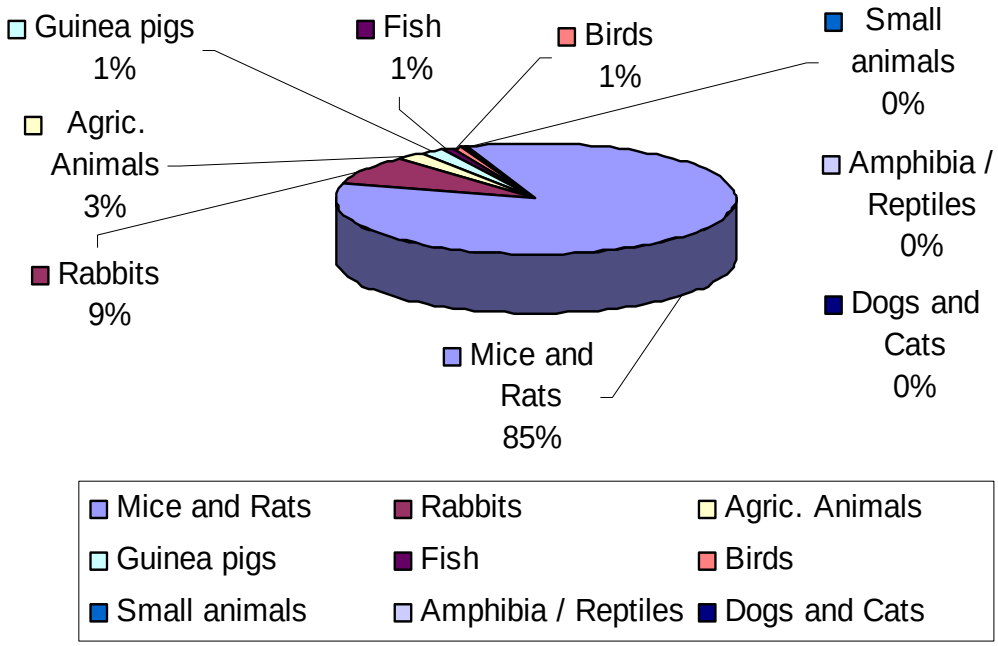
Health (BMG: Federal Ministry of Health - primarily R&D for pharmaceuticals, production and quality control of pharmaceuticals and medicinal products, animal health products) is placed first with 155,161 (70,3%) animals. Second is Science and Research (BMWF: Federal Ministry of Science and Research: universities, Austrian Academy of Sciences, etc. - primarily basic research, in particular health related research) with 58,971 (26,8%) animals. Environmental Protection and Agriculture (BMLFUW: Federal Ministry of Agriculture, Forestry, Environment and Water Management - primarily safety testing of chemicals and protection of the environment) follows with 3,872 (1,8%) animals and Industry (BMWFJ: Federal Ministry of Economy, Family and Youth - primarily basic research) is last with 2,452 (1,1%) animals used.



Predominantly mice and rats are used as experimental animals

Of the total number of 220,456 animals used in procedures in Austria during 2008 were:

187.472	85,0%	mice and rats
18.761	8,5%	rabbits
3.284	1,5%	guinea pigs
5.888	2,7%	agricultural animals
1.381	0,6%	birds
2.579	1,2%	fish
754	0,3%	small animals (hamsters, ferrets, other rodents)
294	0,1%	amphibia and reptiles
41		dogs
2		cats


Guinea pigs 1%
Fish 1%
Birds 1%
Small animals 0%
Agric. Animals 3%
Amphibia / Reptiles 0%
Rabbits 9%
Dogs and Cats 0%
Mice and Rats 85%
Mice and Rats
Rabbits
Agric. Animals
Guinea pigs
Fish
Birds
Small animals
Amphibia / Reptiles
Dogs and Cats

Animal Tests for Humans and Animals

The number of animals used in procedures in 2008 - with 85% (187,472) predominantly mice and rats – is generally due to increased biomedical research in Austria as well as businesses active in biomedical, pharmaceutical and biological research and production. This research and development was directed to production and quality control of human and veterinary pharmaceuticals and medicinal products manufactured for the international market and for combating severe diseases such as cancer or cardiovascular diseases.

A significant part was also devoted to the development, production and quality control of vaccines for the international market, in particular vaccines for which there was a demand from health authorities all over the world.

In scientific and basic research the aims were *inter alia* improvement of the knowledge in the area of cancer research and development of effective therapies with reduced side effects or stress for the patients. Fundamental and applied research was conducted on cardiovascular diseases (myocardial infarction and its consequences) and neurological disorders (Alzheimer, Parkinson and prion-related diseases).

Increased biomedical research as well as the development of pharmaceuticals and medicinal products requires animal tests - as a first step and precondition for clinical testing on humans – in the interest of health and safety of humans and animals. The same is also true for quality control of pharmaceuticals and medicinal products.

Last but not least, animal tests are also required for animal health, meaning that for the development of veterinary pharmaceuticals it is necessary to conduct clinical studies on animal patients, and animal tests are similarly necessary for the development of diagnostic and therapeutic measures for animals.

Animal Test with Minimal Pain on Healthy Cattle for the Health of Agricultural Animals

An example of the fact that animal tests with minimal pain are sometimes necessary to improve the health of animals is provided by the number of cattle which appear in the 2008 Statistics due to a research project of the Federal Ministry of Agriculture, Forestry, Environment and Water Management dealing with “Full pastoral farming of dairy cattle under alpine production conditions”. In this research project merely blood samples were taken from healthy cows in agricultural productions units in order to investigate how the conversion to low-input pastoral farming affects fertility and animal health, milk production and quality and to find out which consequences for the output of the farm and for the environment might arise from the conversion.

No animal experiments for cosmetics

In accordance with the legal prohibition of animal experiments for cosmetics (§ 3 Abs. 5 Tierversuchsgesetz) in force since 1999 there were naturally no animal experiments carried out for cosmetics.

No great apes used

It is particularly gratifying that in 2008 in Austria no animal experiments on great apes were carried out, in accordance with the legal prohibition of animal experiments on great apes which has been in force since January 1, 2006 (BGBl. I, Nr. 162/2005). This also reflects a general trend in Europe to

restrict such experiments as far as possible and to avoid them altogether according to the best available science.

Statistics in EU-wide standardized format

In accordance with the amended Animal Experiments Law (BGBl. I, Nr. 169/1999) and the Ordinance on Animal Use Statistics (BGBl. II Nr. 199/2000) the Animal Use Statistics 2008 requires the use of eight statistical tables which should contain data in a standardized format and give details on, *inter alia*, the origin of the animals, the purposes for which they were used (basic research, R&D for medicines and medicinal products, for quality control, etc.).

Internationally Compared Low Animal Numbers in Austria

The number of animals used in procedures in Austria contributed less than 1,5% to the total number of 12.1 million vertebrate animals used in Europe, as can be seen from the EU-wide animal use statistics for 2005 (the last year for which the European Commission compiled such a statistical report). When comparing at an international level, the figures of animal numbers in Austrian still remain low. These comparatively low numbers of animals are due to at least three interconnected developments in relation to animals experiments:

1. **Application of „3R“**

Firstly, scientists, researchers and users themselves apply the principles of the „3R“(Replacement, Reduction, Refinement) - which also guide the Austrian Animal Experiments Law - to the widest possible extent, as well as using alternatives.

2. **Restrictive authorization practice for projects**

Second, all authorities issue permits for projects very restrictively in accordance with the strict provisions of the Animal Experiments Law and the Ordinance on Animal Experiments, which allow animal experiments only under very restrictive conditions and stipulate that projects may only be permitted, if no other satisfactory methods are available to achieve the aim without using live animals.

3. Support for research on Alternative Methods to Animal Testing

Finally, public financial support for developing and promoting alternative methods contributes to motivation of users and researches:

3.1. Financial support for research projects aimed at developing alternative methods, totalling more than 2,562m EUR for 29 projects, as well as promoting the use of alternative methods nationally and internationally,

3.2. National Award for Alternative Methods, i.e. a specific award publicly recognizing scientific achievements in the area of alternative methods.

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 (*Mus musculus*)	177544	41.468	133.479	116	2.481	61
1.b. Rats (*Rattus norvegicus*)	9928	4.140	5.652	0	136	20
1.c. Guinea-Pigs (*Cavia porcellus*)	3284	737	2.547	0	0	0
1.d. Hamsters (*Mesocricetus*)	693	0	693	0	0	0
1.e. Other Rodents (other *Rodentia*)	47	0	20	0	27	0
1.f. Rabbits (*Oryctolagus cuniculus*)	18761	14.886	3.857	0	18	0
1.g. Cats (*Felis catus*)	2	0	2	0	0	0
1.h. Dogs (*Canis familiaris*)	41	6	13	0	22	22
1.i. Ferrets (*Mustela putorius furo*)	14	0	0	0	14	0
1.j. Other Carnivores (other *Carnivora*)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breds (*Equidae*)	47	16	20	0	11	20
1.l. Pigs (*Sus*)	5086	4889	6	0	191	0
1.m. Goats (*Capra*)	39	35	0	0	4	0
1.n. Sheep (*Ovis)*	142	98	0	0	44	23
1.o. Cattle (*Bos*)	574	539	14	0	21	4
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	0
1.r. Old World Monkeys (*Cercopithecoidea*)	0	0	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	0	0	0	0	0	0
1.u. Quail (*Coturnix coturnix)*	14	14	0	0	0	0
1.v. Other birds (other *Aves*)	1367	548	119	0	700	77
1.w. Reptiles (*Reptilia*)	17	0	0	0	17	0
1.x. Amphibians (*Amphibia*)	277	19	0	0	258	20
1.y. Fish (*Pisces*)	2579	1880	65	0	634	0
1.z. TOTAL	220456					

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	44.234	76.102	51.086	0	3.420	1.083	713	906	177544
2.b. Rats	4.106	3.036	68	0	2.352	0	366	0	9928
2.c. Guinea-Pigs	211	522	1.618	0	925	0	8	0	3284
2.d. Hamsters	0	185	358	0	150	0	0	0	693
2.e. Other Rodents	47	0	0	0	0	0	0	0	47
2.f. Rabbits	143	520	17.276	14	726	0	82	0	18761
2.g. Cats	2	0	0	0	0	0	0	0	2
2.h. Dogs	0	14	0	0	0	0	12	15	41
2.i. Ferrets	0	14	0	0	0	0	0	0	14
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	35	0	0	0	0	12	0	0	47
2.l. Pigs	1.730	2.665	0	0	63	125	382	121	5086
2.m. Goats	0	1	3	0	0	0	35	0	39
2.n. Sheep	46	17	5	0	0	0	74	0	142
2.o. Cattle	334	14	0	0	0	5	176	45	574
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	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	1.174	84	14	0	0	12	83	0	1367
2.w. Reptiles	17	0	0	0	0	0	0	0	17
2.x. Amphibians	277	0	0	0	0	0	0	0	277
2.y. Fish	2.053	0	0	0	416	60	0	50	2579
2.z. TOTAL	54423	83174	70428	14	8052	1297	1931	1137	220456

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	2.720	0	0	0	0	0	0	0	700	3420
3.b. Rats	824	0	0	0	0	0	0	0	1.528	2352
3.c. Guinea-Pigs	250	0	0	0	0	0	0	0	675	925
3.d. Hamsters	150	0	0	0	0	0	0	0	0	150
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	580	0	0	0	0	0	0	0	146	726
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	63	0	0	0	0	0	0	0	0	63
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	0	0	0	0	0	132	284	416
3.z. TOTAL	4587	0	0	0	0	0	0	132	3333	8052

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	3.871	4.726	21.735	48.038	103	78473
4.b. Rats	893	598	1.683	3.482	27	6683
4.c. Guinea-Pigs	108	92	0	546	0	746
4.d. Hamsters	0	358	0	185	0	543
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	94	14	2	841	0	951
4.g. Cats	0	0	0	0	2	2
4.h. Dogs	0	0	0	0	35	35
4.i. Ferrets	0	0	0	14	0	14
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	24	24
4.l. Pigs	275	10	0	200	154	639
4.m. Goats	0	0	0	1	0	1
4.n. Sheep	9	0	0	38	4	51
4.o. Cattle	0	0	0	0	344	344
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	149	541	690
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	7	6	6	0	0	19
4.y. Fish	1.794	0	0	0	60	1854
4.z. TOTAL	7051	5804	23426	53494	1294	91069

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	7.019	0	0	44.067	0	51086
5.b. Rats	60	8	0	0	0	0	68
5.c. Guinea-Pigs	0	236	0	0	1.382	0	1618
5.d. Hamsters	0	0	0	358	0	0	358
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	26	11.078	0	0	6.172	14	17290
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 breds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	0	0	0
5.m. Goats	0	0	0	3	0	0	3
5.n. Sheep	0	0	0	5	0	0	5
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	4	0	0	10	0	0	14
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	18.341	0	376	51.621	14	70442

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 Norwegian requirement
5.5 – Poland is testing due to a US specific requirement
5.6 – Germany is testing due to a Swiss 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, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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	2596	0	0	824	0	3420
6.b. Rats	0	212	0	0	2045	95	2352
6.c. Guinea-Pigs	0	104	0	0	821	0	925
6.d. Hamsters	0	0	0	0	150	0	150
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	20	271	0	0	435	0	726
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 breds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	63	63
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	132	0	0	0	284	0	416
6.z. TOTAL	152	3183	0	0	4559	158	8052

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 Norwegian requirement
6.5 – Poland is testing due to a US specific requirement
6.6 – Germany is testing due to a Swiss 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, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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	36	1670	0	522	0	0	0	0	266	0	0	926	3420
7.b. Rats	0	1124	136	12	0	0	629	0	0	0	0	0	451	2352
7.c. Guinea-Pigs	0	0	80	0	695	0	126	0	0	0	0	0	24	925
7.d. Hamsters	0	0	0	0	0	0	150	0	0	0	0	0	0	150
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	20	18	74	0	89	75	0	0	0	0	0	450	726
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 breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	63	0	0	0	0	0	0	0	0	0	63
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	0	0	0	0	0	0	0	0	0	0	0	416	0	416
7.z. TOTAL	0	1180	1904	149	1217	89	980	0	0	266	0	416	1851	8052

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	224	1.904	63	20	17	420	0	0	88	0	0	1.851	4587	224
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	956	0	86	1.197	72	560	0	0	178	0	284	0	3333
8.j.	TOTAL	0	1180	1904	149	1217	89	980	0	0	266	0	416	1851	8052

POLAND

Statistical data submitted

The statistical data have been submitted by the Ministry of Science and Higher Education Warsaw.

Comments of the Polish 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 (*Mus musculus*)	123897	122068	705	227	897	
1.b. Rats (*Rattus norvegicus*)	45824	44646	61	150	967	
1.c. Guinea-Pigs (*Cavia porcellus*)	6495	6495	0	0	0	
1.d. Hamsters (*Mesocricetus*)	312	280	0	0	32	
1.e. Other Rodents (other *Rodentia*)	11966					
1.f. Rabbits (*Oryctolagus cuniculus*)	3086	2804	0	0	282	137
1.g. Cats (*Felis catus*)	83	21	0	0	62	0
1.h. Dogs (*Canis familiaris*)	230	9	0	0	221	18
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	520					
1.k. Horses, donkeys and cross breds (*Equidae*)	529					
1.l. Pigs (*Sus*)	11742					
1.m. Goats (*Capra*)	300					
1.n. Sheep (*Ovis)*	2217					
1.o. Cattle (*Bos*)	7540					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	0
1.r. Old World Monkeys (*Cercopithecoidea*)	0	0	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	1246					
1.u. Quail (*Coturnix coturnix)*	5100	5100	0	0	0	
1.v. Other birds (other *Aves*)	27391					
1.w. Reptiles (*Reptilia*)	248					
1.x. Amphibians (*Amphibia*)	1221					
1.y. Fish (*Pisces*)	25941					
1.z. TOTAL	275888					

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	61614	2649	12230	4911	7243	2855	1620	30775	123897
2.b. Rats	33700	1277	1703	0	4845	2519	891	889	45824
2.c. Guinea-Pigs	26	0	5309	323	815	0	9	13	6495
2.d. Hamsters	186	100	0	0	0	10	6	10	312
2.e. Other Rodents	11526	0	0	0	204	50	106	80	11966
2.f. Rabbits	718	167	853	587	358	65	171	167	3086
2.g. Cats	0	0	13	0	1	9	0	60	83
2.h. Dogs	25	0	0	0	0	180	0	25	230
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	510	0	0	0	0	0	0	10	520
2.k. Horses, donkeys and cross breds	309	0	0	0	0	130	65	25	529
2.l. Pigs	3118	16	10	0	20	40	107	8431	11742
2.m. Goats	147	0	48	0	0	0	33	72	300
2.n. Sheep	1374	0	0	0	0	0	244	599	2217
2.o. Cattle	6380	0	60	0	0	0	1070	30	7540
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	1238	0	0	0	0	0	8	0	1246
2.u. Quail	4730	0	0	0	360	0	10	0	5100
2.v. Other birds	21006	88	524	0	97	222	650	4804	27391
2.w. Reptiles	246	0	0	0	0	0	2	0	248
2.x. Amphibians	697	0	0	0	0	0	524	0	1221
2.y. Fish	11022	0	0	0	3748	168	33	10970	25941
2.z. TOTAL	158572	4297	20750	5821	17691	6248	5549	56960	275888

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	2571	347	0	0	0	0	0	0	4325	7243
3.b. Rats	1397	472	230	0	0	920	0	897	929	4845
3.c. Guinea-Pigs	489	280	46	0	0	0	0	0	0	815
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	204	0	204
3.f. Rabbits	177	129	44	8	0	0	0	0	0	358
3.g. Cats	1	0	0	0	0	0	0	0	0	1
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	20	0	0	0	0	0	0	0	20
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	60	300	0	0	0	0	0	0	0	360
3.v. Other birds	0	0	0	0	0	0	0	97	0	97
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	1127	2260	169	52	0	0	0	140	0	3748
3.z. TOTAL	5822	3808	489	60	0	920	0	1338	5254	17691

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	1041	44644	7545	7020	1703	61953
4.b. Rats	1985	7400	493	7393	30	17301
4.c. Guinea-Pigs	0	0	0	0	0	0
4.d. Hamsters	0	0	176	40	0	216
4.e. Other Rodents	154	440	0	50	70	714
4.f. Rabbits	0	0	0	455	0	455
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	0	0	9	0	180	189
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 breds	0	0	0	0	130	130
4.l. Pigs	40	0	0	87	0	127
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	24	0	24
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	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	1800	0	12	292	2104
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	260	260
4.z. TOTAL	3220	54284	8223	15081	2665	83473

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	7974	5575	0	590	257	2745	17141
5.b. Rats	549	1062	0	60	32	0	1703
5.c. Guinea-Pigs	745	4658	0	195	0	34	5632
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	305	348	0	0	647	140	1440
5.g. Cats	12	1	0	0	0	0	13
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 breds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	10	0	10
5.m. Goats	48	0	0	0	0	0	48
5.n. Sheep	0	0	0	0	0	0	0
5.o. Cattle	60	0	0	0	0	0	60
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	524	0	0	0	0	0	524
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	10217	11644	0	845	946	2919	26571

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 Norwegian requirement
5.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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	2445	3920	0	0	0	878	7243
6.b. Rats	2135	2462	0	0	70	178	4845
6.c. Guinea-Pigs	66	749	0	0	0	0	815
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	204	0	0	0	0	0	204
6.f. Rabbits	30	298	0	0	0	30	358
6.g. Cats	0	1	0	0	0	0	1
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 breds	0	0	0	0	0	0	0
6.l. Pigs	20	0	0	0	0	0	20
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	360	0	0	0	0	360
6.v. Other birds	0	0	0	0	0	97	97
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	100	2598	0	0	0	1050	3748
6.z. TOTAL	5000	10388	0	0	70	2233	17691

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 Norwegian requirement
6.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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 Carcinogenicity	7.8 Developmental toxicity	7.9 Mutagenicity	7.10 Reproductive toxicity	7.11 Toxicity to aquatic vertebrates 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	280	0	664	0	0	0	384	0	0	0	0	0	5915	7243
7.b. Rats	584	0	881	0	0	0	859	0	1692	0	545	0	284	4845
7.c. Guinea-Pigs	0	0	0	0	546	0	0	0	0	0	0	0	269	815
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	204	0	0	0	0	0	0	204
7.f. Rabbits	0	0	15	182	0	86	0	0	25	0	0	0	50	358
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	1	1
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 breds	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	20	20
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	360	0	0	0	0	0	0	0	0	0	0	0	0	360
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	97	97
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	3326	0	0	0	0	0	0	0	0	0	100	232	90	3748
7.z. TOTAL	4550	0	1560	182	546	86	1447	0	1717	0	645	232	6726	17691

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 Carcinogenicity	8.8 Developmental toxicity	8.9 Mutagenicity	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebrates 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	1307	0	1078	53	274	6	381	0	447	0	391	367	1518	5822
8.b. Products/substances used or intended to be used mainly in agriculture	2670	0	0	62	251	56	241	0	146	0	283	0	99	3808
8.c. Products/substances used or intended to be used mainly in industry	139	0	47	18	16	10	101	0	34	0	88	0	36	489
8.d. Products/substances used or intended to be used mainly in the household	52	0	0	4	0	4	0	0	0	0	0	0	0	60
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	106	0	814	0	0	0	0	920
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	381	0	0	0	0	860	0	0	0	0	0	97	1338
8.i. Other toxicological or safety evaluations	577	0	743	84	0	0	556	0	0	187	0	0	3107	5254
8.j. TOTAL	4745	381	1868	221	541	76	2245	0	1441	187	762	367	4857	17691

PORTUGAL

Statistical data submitted

The statistical data have been submitted by the "Ministério da Agricultura, Desenvolvimento Rural e das Pescas – Direcção Geral de Veterinária – Direcção de Serviços de Saúde e Protecção Animal" (Ministry of Agriculture, Rural Development and Fisheries – General Direction of Veterinary – Directorate for Animal Health and Protection)

Comments of the Portuguese authorities

1. Total number of animals used by species

In 2008, the total number of animals used for experimental and other scientific purposes in Portugal was 50,888.

Compared to the data of 2005, where the total number of used animals was 41,621, it means that with regard to 2008 there was an increase in the use of animals of 22,26%.

Mice are the most commonly used species representing 78,23% of the total number of animals.

The second most used group of animals was Rats (12,91%).

The third most used group is represented by the Cold-blooded animals (7,47%) and the fourth by the group of Artio and Perissodactyla with 0,52%.

Rodents with Rabbits represent 91,69% of the total number of animals used.

The Carnivors were not used in 2008 and, as in other previous reports, in Portugal, Non-human primates continued to not being used.

Comparison with the data of the previous report (data of 2005)

The percentages of classes of animals used in 2005 (41,621 animals) and in 2008 (50,888 animals) are represented in the following table:

Class of animals (%)	**2005**	**2008**
Mice	68,04	78,23
Rats	16,32	12,91
Guinea-pigs	0,91	0,30
Hamsters and other rodents	0,31	0,06

Rabbits	1,43	0,19
Cold-blooded animals	11,53	7,47
Quail and other birds	0,27	0,31
Artio Perissodactyla	1,11	0,52
Carnivors	0,09	0,00

In 2008, looking at the data by groups of animals, the percentage of all of them decreased. However the largest increase occurred, again, in mice and a slight increase in the Birds group (quail and other birds). The biggest decrease occurred in the use of cold-blooded animals (4,06%) followed in descending order, by the use of rats (3.41%) and in rabbits (1,24%).

Within the group of cold-blooded animals, fish were the only animals used.

Within the Artiodactyla, Pigs were the most used animals (61,67%).

2. Number of animals used by purposes of experiments

In 2008, the percentage of animals (total 50,888) used by purposes of experiments was the following:

- 83,82% of animals were used in “Fundamental biology”;
- 9,74% in “Research and development for human medicine, veterinary medicine, dentistry”;
- 0% in “Production and quality control of products and devices in human medicine and dentistry and veterinary medicine”;
- 0,61% in “Toxicological and other safety evaluation”;
- 1,44% in “Diagnosis of disease”;
- 1,83% in “Education and training”;
- 2,55% in “Other purposes”;

Referring to the use of species versus experimental purposes, the highest amount of use of mice and of rats is in “fundamental biology” and in “research and development for human medicine, veterinary medicine, dentistry”.

Comparison with the data of the previous report (data of 2005)

The most significant increase in 2008 is the number of animals that were used for "Fundamental biology", which increased from 78,78%, in 2005, to 83,82%, in 2008.

The other increases that occurred were in the percentage of animals used in "Research and development for human medicine, veterinary medicine, dentistry" which increased from 6,78%, in 2005, to 9,74%, in 2008, and in "Other purposes" which increased from 1,39% in 2005, to 2,55% in 2008.

The use of animals in the rest of the other categories decreased, for example:

The percentage of animals used for "Production and quality control of products and devices in human medicine and dentistry and veterinary medicine" was the biggest decrease in 2008 as no animal was used for this purpose, compared to 2005 in which 5,09% of all animals were used to this same purpose.

The percentage of animals used for "Toxicological and other safety evaluation" decreased from 2,26% to 0,61%.

The percentage of animals used for "Education and training" decreased from 3,02% to 0,61%.

3. Number of animals used for "Toxicological and safety evaluation" by type of products

In 2008, the use of animals in "Toxicological and other safety evaluation" represents only 0,61%, which only refers to 310 animals (mice), of a total of 50,888 animals that were used for experimental purposes in Portugal.

"Potential or actual contaminants in the general environment which do not appear in other columns" represents 61,30% of the animals used for "Toxicological and other safety evaluation" and "Other toxicological or safety evaluations" represent 38,70%.

Comparison with the data of the previous report (data of 2005)

Compared to the data of 2005, in 2008 there was a decrease in the use of animals in "Toxicological and other safety evaluation".

The percentage of animals used for "Toxicological and other safety evaluation" decreased from 2,26% to 0,61% (from 939 to 310 animals).

The data of 2008 refers to the same category of products that had been tested in 2005, except for the category of "Products/substances or devices for human medicine and dentistry and for veterinary medicine" where no animals were used in 2008.

"Potential or actual contaminants in the general environment which do not appear in other columns" represented, in 2005, 21,29% of the animals used for "Toxicological and other safety evaluation" and, in 2008, 61,30%; "Other toxicological or safety evaluations" represented 26,62% in 2005 while, in 2008, 38,70%, which means that there was an increase in 2008.

As in 2005, in 2008 the other groups of products/substances were not tested which means that, for example, there were no animals used for the purpose of evaluating the safety of cosmetics or additives in food for animal consumption.

4. Number of animals used for the study of diseases

In 2008, the number of animals used for the "Studies on human and animal diseases" was 14,753, which represents 29% of the total number of animals (50,888 animals) that were used.

The percentages of animals per type of diseases were:

- 2,70% in "Human cardiovascular diseases";
- 15,66% in "Human nervous and mental disorders";
- 2,22% in "Human cancer (excl. evaluation of carcino hazards)";
- 75,57% in "Other human diseases";
- 3,85% in "Specific animal diseases".

The percentage of the number of animals used for studies of human diseases represents 96,15% (14,185 animals) of the total number of animals used for all studies of diseases (14,753 animals).

In 2008, the number of animals used to study animal diseases was only 568 (3.85%) while in 2005, that number had been 271 (1.40%), which means that in 2008, there was an increase on the use of animals for the study of animal diseases.

5. Number of animals used for "Toxicological and other safety evaluations" by the types of tests

As referred previously, in 2008, the use of animals in "Toxicological and other safety evaluation" represents only 0,61%, which only refers to 310 animals, of a total of 50,888 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2005)

The percentages of animals used in toxicity tests for "Toxicological and other safety evaluation" in 2005 (939 animals) and in 2008 (310 animals) are represented in the following table:

Type of tests (%)	**2005**	**2008**
Acute and sub-acute toxicity testing methods (including limit test)	37,6	0

Irritation/sensitization tests	27,8	0
Sub-chronic and chronic toxicity	0	0
Mutagenicity and Carcinogenicity	32	38,71
Reproductive and developmental toxicity	0	0
Toxicity of aquatic vertebrates not included in other columns	0	0
Other tests	2,7	61,29

In 2008, the uses of animals in toxicity tests only fell into the categories of "Carcinogenicity" and "Other tests" which means that there was a decrease in the other uses of tests compared to data of 2005, i.e., "Acute and sub-acute toxicity testing methods (including the 'limit test')" and "Irritation/sensitization tests" the percentage of which decreased to 0%.

6. Type of toxicity tests carried out for "Toxicological and other safety evaluations" of products

As pointed out previously, in 2008, the use of animals in "Toxicological and other safety evaluation" represents only 0,61%, which only refers to 310 animals, of a total of 50,888 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2005)

The numbers of animals used for "Toxicological and other safety evaluation" per types of products in 2005 (939 animals) and in 2008 (310 animals) are represented in the following tables:

Types of products **(%)**	**2005**	**2008**
Products/substances or devices for human medicine and dentistry and for veterinary medicine	689	120
Potential or actual contaminants in the general environment which do not appear in othe columns	0	190
Other toxicological or safety evaluations	250	0

In 2008, the number of animals used to test “Products/substances or devices for human medicine and dentistry and for veterinary medicine” were 120 animals in “Carcinogenicity” (in 2005, they were 200 animals);

In 2008, in comparision to 2005, there was an increase of the number of animals used to test “Potential or actual contaminants in the general environment which do not appear in other columns” from zero animals, in 2005, to 190, in 2008.

In 2008, there were no animals used to fill the category “Other toxicological or safety evaluations” which represent a decrease compared to 2005.

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 (*Mus musculus*)	39811	29109	9094		1608	60
1.b. Rats (*Rattus norvegicus*)	6571	1463	4819		289	24
1.c. Guinea-Pigs (*Cavia porcellus*)	152	137	15			8
1.d. Hamsters (*Mesocricetus*)	29	27	2			
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	99	94	5			
1.g. Cats (*Felis catus*)						
1.h. Dogs (*Canis familiaris*)						10
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	6					
1.l. Pigs (*Sus*)	222					
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*	28					
1.o. Cattle (*Bos*)	10					
1.p. Prosimians (*Prosimia*)						
1.q. New World Monkeys (*Ceboidea*)						
1.r. Old World Monkeys (*Cercopithecoidea*)						
1.s. Apes (*Hominoidea*)						
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*						
1.v. Other birds (other *Aves*)	160					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)	3800					
1.z. TOTAL	50888					

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	33487	4272			310	646	196	900	39811
2.b. Rats	5255	665				89	492	70	6571
2.c. Guinea-Pigs		15					8	129	152
2.d. Hamsters	20							9	29
2.e. Other Rodents									0
2.f. Rabbits	69	3					15	12	99
2.g. Cats									
2.h. Dogs									
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							6		6
2.l. Pigs	4						198	20	222
2.m. Goats									
2.n. Sheep	20						8		28
2.o. Cattle							10		10
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals									
2.u. Quail									
2.v. Other birds								160	160
2.w. Reptiles									
2.x. Amphibians									
2.y. Fish	3800								3800
2.z. TOTAL	42655	4955	0	0	310	735	933	1300	50888

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								190	120	310
3.b. Rats										
3.c. Guinea-Pigs										
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits										
3.g. Cats										
3.h. Dogs										
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breds										
3.l. Pigs										
3.m. Goats										
3.n. Sheep										
3.o. Cattle										
3.p. Prosimians										
3.q. New World Monkeys										
3.r. Old World Monkeys										
3.s. Apes										
3.t. Other Mammals										
3.u. Quail										
3.v. Other birds										
3.w. Reptiles										
3.x. Amphibians										
3.y. Fish										
3.z. TOTAL								190	120	310

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	31	1443	262	10022	568	12326
4.b. Rats	327	868	65	928		2188
4.c. Guinea-Pigs				129		129
4.d. Hamsters				27		27
4.e. Other Rodents						0
4.f. Rabbits	40			41		81
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs				2		2
4.m. Goats						
4.n. Sheep						
4.o. Cattle						
4.p. Prosimians						
4.q. New World Monkeys						
4.r. Old World Monkeys						
4.s. Apes						
4.t. Other Mammals						
4.u. Quail						
4.v. Other birds						
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	398	2311	327	11149	568	14753

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.b. Rats							
5.c. Guinea-Pigs							
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits							
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breds							
5.l. Pigs							
5.m. Goats							
5.n. Sheep							
5.o. Cattle							
5.p. Prosimians							
5.q. New World Monkeys							
5.r. Old World Monkeys							
5.s. Apes							
5.t. Other Mammals							
5.u. Quail							
5.v. Other birds							
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL							

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 Norwegian requirement
5.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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		190			120		310
6.b. Rats							
6.c. Guinea-Pigs							
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits							
6.g. Cats							
6.h. Dogs							
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breds							
6.l. Pigs							
6.m. Goats							
6.n. Sheep							
6.o. Cattle							
6.p. Prosimians							
6.q. New World Monkeys							
6.r. Old World Monkeys							
6.s. Apes							
6.t. Other Mammals							
6.u. Quail							
6.v. Other birds							
6.w. Reptiles							
6.x. Amphibians							
6.y. Fish							
6.z. TOTAL		190			120		310

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 Norwegian requirement
6.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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								120					190	310
7.b. Rats														
7.c. Guinea-Pigs														
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits														
7.g. Cats														
7.h. Dogs														
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breds														
7.l. Pigs														
7.m. Goats														
7.n. Sheep														
7.o. Cattle														
7.p. Prosimians														
7.q. New World Monkeys														
7.r. Old World Monkeys														
7.s. Apes														
7.t. Other Mammals														
7.u. Quail														
7.v. Other birds														
7.w. Reptiles														
7.x. Amphibians														
7.y. Fish														
7.z. TOTAL								120					190	310

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								120						120
8.b. Products/substances used or intended to be used mainly in agriculture														
8.c. Products/substances used or intended to be used mainly in industry														
8.d. Products/substances used or intended to be used mainly in the household														
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h. Potential or actual contaminants in the general environment which do not appear in other columns													190	190
8.i. Other toxicological or safety evaluations														
8.j. TOTAL								120					190	310

ROMANIA

Statistical data submitted

International Relations and Community Programme Directorate, National Sanitary Veterinary and Food Safety Authority

Comments of Romania 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 (*Mus musculus*)	44585	44349			236	1483
1.b. Rats (*Rattus norvegicus*)	5171	4834			337	
1.c. Guinea-Pigs (*Cavia porcellus*)	6607	6060			547	824
1.d. Hamsters (*Mesocricetus*)	263	263				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	2205	1755			450	444
1.g. Cats (*Felis catus*)	0					
1.h. Dogs (*Canis familiaris*)	0					
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	14	14				
1.l. Pigs (*Sus*)	2	2				
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*	131	131				11
1.o. Cattle (*Bos*)	3	3				
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	0					
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*	9	9				
1.v. Other birds (other *Aves*)	1196	943			253	12
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)						
1.z. TOTAL	60186					

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	1448	2620	8243	8008	5378	17559	140	1189	44585
2.b. Rats	952	263			540	3266	150		5171
2.c. Guinea-Pigs		56	2622	148	671	1447	1663		6607
2.d. Hamsters	263								263
2.e. Other Rodents									0
2.f. Rabbits		65	1409	80	79	526	5	41	2205
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds		2	9	3					14
2.l. Pigs				2					2
2.m. Goats									0
2.n. Sheep			112	2				17	131
2.o. Cattle			3						3
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						9			9
2.v. Other birds		66		747		286		97	1196
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	2663	3072	12398	8990	6668	23093	1958	1344	60186

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	4808		50	170	50				300	5378
3.b. Rats	50	370	50	20	50					540
3.c. Guinea-Pigs	671									671
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	79									79
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										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	5608	370	100	190	100	0	0	0	300	6668

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	259	236	300	443	1620	2858
4.b. Rats	56	430	250	221		957
4.c. Guinea-Pigs				25	4	29
4.d. Hamsters	103	40		120		263
4.e. Other Rodents						0
4.f. Rabbits	3				1	4
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						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	421	706	550	809	1625	4111

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						16251	16251
5.b. Rats							0
5.c. Guinea-Pigs						2770	2770
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits						1489	1489
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds						12	12
5.l. Pigs						2	2
5.m. Goats							0
5.n. Sheep						114	114
5.o. Cattle						3	3
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						747	747
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	0	21388	21388

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 Norwegian requirement
5.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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						5378	5378
6.b. Rats						540	540
6.c. Guinea-Pigs						671	671
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits						79	79
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							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	0	0	0	0	0	6668	6668

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 Norwegian requirement
6.5 – Poland 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, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, 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	40	1842	82	30	30	30	1682						1642	5378
7.b. Rats	370	20					5						145	540
7.c. Guinea-Pigs					669		2							671
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													79	79
7.g. Cats														0
7.h. Dogs														0
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														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	410	1862	82	30	699	30	1689	0	0	0	0	0	1866	6668

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	320	50	70	30	30	30	50						5028	5608
8.b. Products/substances used or intended to be used mainly in agriculture													370	370
8.c. Products/substances used or intended to be used mainly in industry	50		50											100
8.d. Products/substances used or intended to be used mainly in the household													190	190
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	40	5	55											100
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													300	300
8.j. TOTAL	410	55	175	30	30	30	50	0	0	0	0	0	5888	6668