EUROPEAN
COMMISSION

Brussels, 5.12.2013
SWD(2013) 497 final

PART 5/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT
Seventh 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(2013) 859 final}

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT
Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union

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

TABLE OF CONTENTS

AUSTRIA

Statistical data submitted

The statistical data were submitted by the *'Bundesministerium für Wissenschaft und Forschung'* (Federal Ministry of Science and Research).

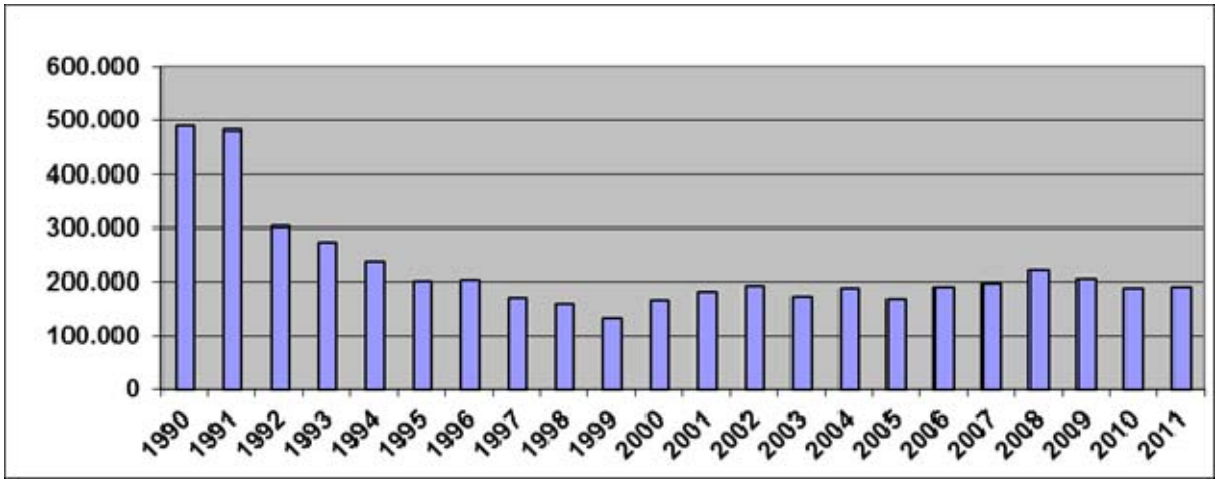
Comments of the Austrian authorities

- Slight increase of animal numbers by 2.1% compared to previous year. 85% of animals used are mice and rats.
- Internationally Compared Low Animal Numbers in Austria.
- Rise in animal numbers primarily for R&D and production and quality control of pharmaceuticals.
- No great apes used, No animal experiments for cosmetics.
- In long term comparison reduction in animal numbers of 61% since 1990.
- Statistics in EU-wide standardized form.

After 2 years of decrease, the number of animals used in procedures in Austria during 2011 has risen again for the first time. The increase in 2011 is 2.1% as compared to 2010, however the numbers are still lower than in previous years (7,9 % lower than in 2009 and 13,2 % lower than in 2008). The animal use statistics for 2011 shows that in total 191,288 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 61%.

Development of the numbers of animals used since 1990.



Breakdown according to areas of competence.

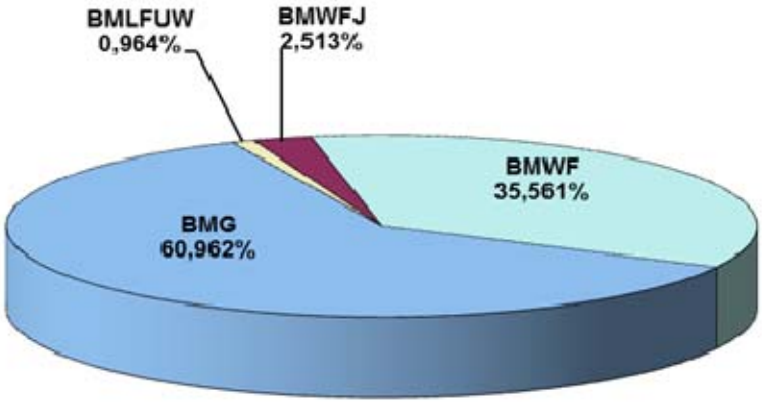
A breakdown of the numbers according to areas of competence for administration of the Animal Experiments Law ranks them as follows:

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 116,613 (61 %) animals, before

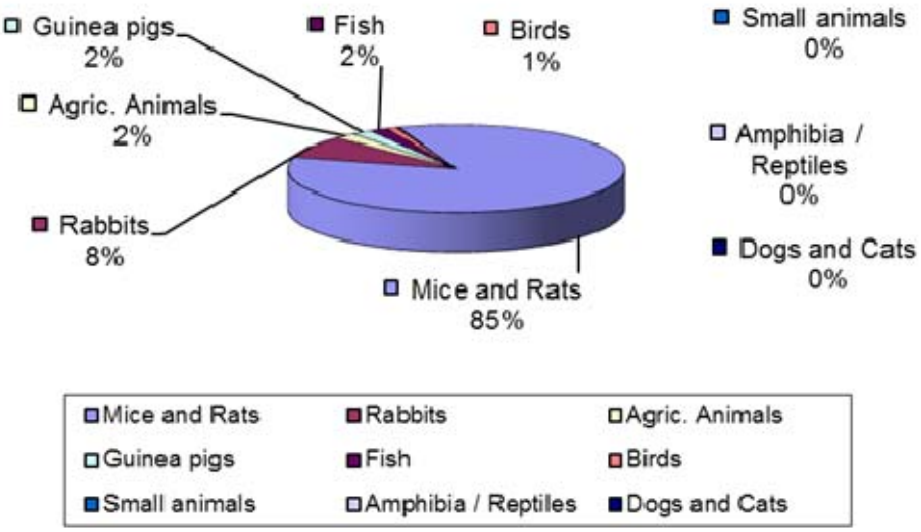
Science and Research (BMWF: Federal Ministry of Science and Research: universities, Austrian Academy of Sciences, etc. - primarily basic research, in particular health related research) which is second with 68.024 (35 %) animals,

Industry (BMWFJ: Federal Ministry of Economy, Family and Youth - primarily basic research) comes in third with 4.807 (3 %) animals and

Environmental Protection and Agriculture (BMLFUW: Federal Ministry of Agriculture, Forestry, Environment and Water Management - primarily safety testing of chemicals and protection of the environment) is last with 1.884 (1 %) animals used.



162.179	84,78%	mice and rats
15.633	8,17%	rabbits
4.006	2,09%	guinea pigs
3.797	1,98%	agricultural animals
3.267	1,71%	birds
1.940	1,01%	fish
201	0,11%	small animals (hamsters, ferrets, other rodents)
176	0,09%	amphibia and reptiles
89	0,05%	dogs and cats



Animal Tests for Humans and Animals

The number of animals used in procedures in 2011 - with 85% (162,179) 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 (testing of charges) for which there was a demand from health authorities all over the world. The major part of rabbits and guinea pigs was used for these purposes.

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 (e.g. 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. The major part of agricultural animals was used for these purposes.

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 2011 in Austria no animal experiments on great apes were carried out, in accordance with the legal prohibition of animal experiments on great apes which is 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 form

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 2011 provides the statistical data in a standardized form and gives details about 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 1.9 % to the total number of 12.0 million vertebrate animals used in Europe, as can be seen from the EU-wide animal use statistics for 2008 (the last year for which the European Commission compiled such a statistics). In international comparison, the figures of animal numbers in Austria 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“(Reduction, Refinement, Replacement) - 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 2,562 Mio. 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*)	153153	43464	106502	44	3143	
1.b. Rats (*Rattus norvegicus*)	9026	4593	4433	0	0	
1.c. Guinea-Pigs (*Cavia porcellus*)	3797	1432	2365	0	0	
1.d. Hamsters (*Mesocricetus*)	125	0	125	0	0	
1.e. Other Rodents (other *Rodentia*)	64					
1.f. Rabbits (*Oryctolagus cuniculus*)	15633	12718	2899	0	16	20
1.g. Cats (*Felis catus*)	14	12	2	0	0	8
1.h. Dogs (*Canis familiaris*)	75	0	0	0	75	0
1.i. Ferrets (*Mustela putorius furo*)	12	0	12	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	128					
1.l. Pigs (*Sus*)	1553					
1.m. Goats (*Capra*)	60					
1.n. Sheep (*Ovis)*	683					
1.o. Cattle (*Bos*)	1582					
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					
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)	1940					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	176					
1.y. Fish (*Pisces*)	3267					
1.z. TOTAL	191288					

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	58092	44836	45925	0	1523	1186	969	622	153153
2.b. Rats	4977	2656	144	0	966	18	215	50	9026
2.c. Guinea-Pigs	31	293	2331	0	1142	0	0	0	3797
2.d. Hamsters	49	0	76	0	0	0	0	0	125
2.e. Other Rodents	64	0	0	0	0	0	0	0	64
2.f. Rabbits	100	331	14539	6	624	0	27	6	15633
2.g. Cats	0	2	0	0	0	0	0	12	14
2.h. Dogs	20	0	0	0	0	6	19	30	75
2.i. Ferrets	0	12	0	0	0	0	0	0	12
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	118	0	0	0	0	0	0	10	128
2.l. Pigs	301	979	0	0	28	29	216	0	1553
2.m. Goats	18	2	0	0	0	0	0	40	60
2.n. Sheep	109	2	0	0	0	70	50	452	683
2.o. Cattle	180	4	0	0	0	44	140	1214	1582
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	0	0	0	0	0	0	0	0	0
2.v. Other birds	1192	602	4	0	0	6	136	0	1940
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	176	0	0	0	0	0	0	0	176
2.y. Fish	3008	0	0	0	221	0	38	0	3267
2.z. TOTAL	68435	49719	63019	6	4504	1359	1810	2436	191288

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	1099	0	0	0	0	0	0	0	424	1523
3.b. Rats	242	0	0	0	0	0	0	0	724	966
3.c. Guinea-Pigs	128	0	0	0	0	0	0	0	1014	1142
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	474	0	0	0	0	0	0	0	150	624
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	28	0	0	0	0	0	0	0	0	28
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	123	98	221
3.z. TOTAL	1971	0	0	0	0	0	0	123	2410	4504

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	4578	8013	22611	49401	24	84627
4.b. Rats	378	1586	1269	3624	4	6861
4.c. Guinea-Pigs	6	5	0	363	0	374
4.d. Hamsters	49	0	0	76	0	125
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	18	27	1	820	8	874
4.g. Cats	0	0	0	0	14	14
4.h. Dogs	0	0	0	0	11	11
4.i. Ferrets	0	0	0	12	0	12
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	0	0
4.l. Pigs	180	0	1	349	474	1004
4.m. Goats	0	0	0	2	0	2
4.n. Sheep	18	0	0	16	9	43
4.o. Cattle	4	0	0	0	204	208
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	30	1570	1600
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	10	0	0	0	10
4.y. Fish	1152	0	0	1115	210	2477
4.z. TOTAL	6383	9641	23882	55808	2528	98242

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	5706	0	0	40219	0	45925
5.b. Rats	104	0	0	0	0	40	144
5.c. Guinea-Pigs	0	181	0	0	2125	25	2331
5.d. Hamsters	0	0	0	0	76	0	76
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	7459	0	0	6912	174	14545
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	0	0	0	0
5.n. Sheep	0	0	0	0	0	0	0
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	0	0	0	0	4	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	104	13346	0	0	49336	239	63025

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	1045	0	0	478	0	1523
6.b. Rats	0	32	0	0	934	0	966
6.c. Guinea-Pigs	0	54	0	0	1088	0	1142
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	260	0	7	357	0	624
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	28	28
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	0	221	0	221
6.z. TOTAL	0	1391	0	7	3078	28	4504

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	0	945	0	0	0	34	0	0	424	0	0	120	1523
7.b. Rats	0	532	32	0	0	0	402	0	0	0	0	0	0	966
7.c. Guinea-Pigs	0	0	54	0	1088	0	0	0	0	0	0	0	0	1142
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	23	107	30	0	108	22	0	0	0	0	0	334	624
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	28	0	0	0	0	0	0	0	0	0	28
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	98	0	0	0	0	0	0	0	0	0	123	0	221
7.z. TOTAL	0	653	1138	58	1088	108	458	0	0	424	0	123	454	4504

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	23	1138	28	74	0	266	0	0	0	0	0	442	1971
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	123	0	123
8.i. Other toxicological or safety evaluations	0	630	0	30	1014	108	192	0	0	424	0	0	12	2410
8.j. TOTAL	0	653	1138	58	1088	108	458	0	0	424	0	123	454	4504

POLAND

Statistical data submitted

The statistical data were submitted by the Ministry of Science and Higher Education, Warsaw.

Comments of the Polish authorities

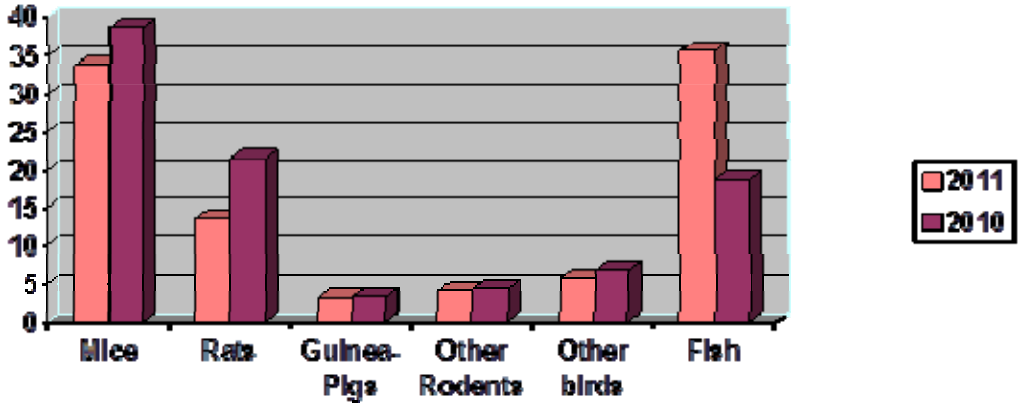
In Poland the Ministry of Science and Higher Education is responsible for gathering the statistical data on the use of animals for scientific purposes and sending the to the European Commission.

The first report on number of animals used for scientific purposes in Poland passed to EC concerned 2005. Since then, the number of animals used for scientific purposes is maintained at a stable level – an average of about 250,000 animals per year.

In 2011 282,160 animals were used for scientific purposes in Poland. Report on number of animals used for scientific purposes was submitted in 2012 to the Ministry of Science and Higher Education by 94 authorized experimental units. The largest group of animals used for research constitutes fish, mice and rats.

The following table and graph present a comparison of the species of animals used for scientific purposes in 2011 compared to 2010.

2011			2010		
Species	Number	Percentage	Species	Number	Percentage
Mice	**95 115**	**33,70 %**	Mice	**88 040**	**38,66 %**
Rats	**38 171**	**13,53 %**	Rats	**49 050**	**21,54 %**
Guinea-Pigs	**8943**	**3,17 %**	Guinea-Pigs	**7 626**	**3,35 %**
Other Rodents	**11 710**	**4,15 %**	Other Rodents	**10 069**	**4,42 %**
Other birds	**13 615**	**5,88 %**	Other birds	**16 151**	**7 %**
Fish	**100 275**	**35,54 %**	Fish	**42 467**	**18,65 %**
Other animals	**13 899**	**4,92 %**	Other animals	**14 274**	**6,26 %**



The increase in 2011 of used fish, mice and rats for scientific purposes is due to increased number of experiments carried out on animals in Poland. It is correlated with establishing in 2011 new financing research agency (National Centre for Research) funding research grants for basic research.

The primary purpose for which animals were used in experiments in 2011 is biological studies of fundamental nature. For this kind of research 72.91 % of animals were used from all animals used for scientific purposes in 2011. A large group of animals used for scientific purposes in 2011 constitutes animals used in projects for research and development of products and devices for human medicine and density and for veterinary medicine (9.7% of all animals used for scientific purposes in 2011) and concerning production and quality control of products and devices for human medicine and density (5.8 % of animals used for scientific purposes in 2011). For other categories of research 9.85 % of animals were used. For the purposes of education and training 4,877 animals were used in 2011 representing 1.73%.

The below graph shows the usage of animals in 2011 in Poland by a particular purpose of research.

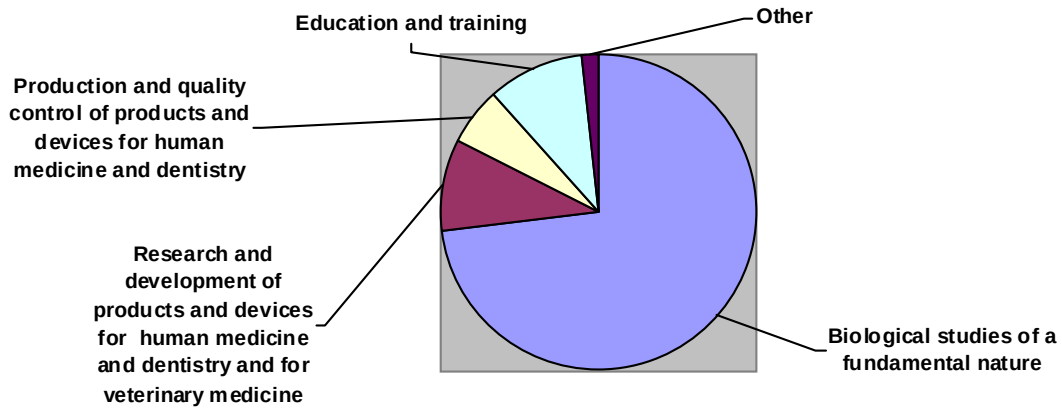

Education and training
Other
Production and quality control of products and devices for human medicine and dentistry
Research and development of products and devices for human medicine and dentistry and for veterinary medicine
Biological studies of a fundamental nature

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*)	95 115	91577	1551	1319	668	
1.b. Rats (*Rattus norvegicus*)	38 171	30451	522	7173	25	
1.c. Guinea-Pigs (*Cavia porcellus*)	8943	8839	104	0	0	
1.d. Hamsters (*Mesocricetus*)	278	278	0	0	0	
1.e. Other Rodents (other *Rodentia*)	11710					
1.f. Rabbits (*Oryctolagus cuniculus*)	2198	2186	0	0	12	527
1.g. Cats (*Felis catus*)	480	480	0	0	0	0
1.h. Dogs (*Canis familiaris*)	229	187	0	0	42	0
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	2149					
1.k. Horses, donkeys and cross breds (*Equidae*)	766					
1.l. Pigs (*Sus*)	1147					
1.m. Goats (*Capra*)	396					
1.n. Sheep (*Ovis)*	379					
1.o. Cattle (*Bos*)	3489					
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*)	594					
1.u. Quail (*Coturnix coturnix)*	1247	1247	0	0	0	
1.v. Other birds (other *Aves*)	13615					
1.w. Reptiles (*Reptilia*)	15					
1.x. Amphibians (*Amphibia*)	964					
1.y. Fish (*Pisces*)	100275					
1.z. TOTAL	282160					

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	57785	15787	9500	2529	3611	4340	1222	341	95115
2.b. Rats	23112	8013	1342	400	3288	1523	307	186	38171
2.c. Guinea-Pigs	86	2248	4453	932	916	300	0	8	8943
2.d. Hamsters	272	0	0	0	0	0	6	0	278
2.e. Other Rodents	11264	0	0	0	0	230	216	0	11710
2.f. Rabbits	501	465	757	26	255	25	155	14	2198
2.g. Cats	23	4	0	0	0	390	63	0	480
2.h. Dogs	72	0	0	0	0	97	60	0	229
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	1142	0	0	0	0	457	550	0	2149
2.k. Horses, donkeys and cross breds	738	0	0	0	0	13	15	0	766
2.l. Pigs	661	136	0	62	149	84	55	0	1147
2.m. Goats	250	0	0	0	0	0	106	40	396
2.n. Sheep	277	67	0	0	0	15	20	0	379
2.o. Cattle	2658	64	0	110	0	412	215	30	3489
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	541	0	0	0	0	53	0	0	594
2.u. Quail	453	0	0	0	10	0	4	780	1247
2.v. Other birds	9195	580	334	2176	0	535	449	346	13615
2.w. Reptiles	12	0	0	0	0	0	3	0	15
2.x. Amphibians	214	0	0	0	0	0	750	0	964
2.y. Fish	96484	0	0	0	1630	1000	681	480	100275
2.z. TOTAL	205740	27364	16386	6235	9859	9474	4877	2225	282160

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	757	160	0	0	0	110	0	0	2584	3611
3.b. Rats	433	458	33	0	0	680	0	150	1534	3288
3.c. Guinea-Pigs	489	266	33	0	0	0	0	0	128	916
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	173	46	36	0	0	0	0	0	0	255
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	0	0	0	0	0	0	0	149	0	149
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	10	0	0	0	0	0	0	0	10
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	1207	423	0	0	0	0	0	0	1630
3.z. TOTAL	1852	2147	525	0	0	790	0	299	4246	9859

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	1408	29588	7893	8254	1830	48973
4.b.	Rats	1748	13374	824	4663	295	20904
4.c.	Guinea-Pigs	33	72	0	28	0	133
4.d.	Hamsters	0	0	62	0	300	362
4.e.	Other Rodents	0	286	0	30	0	316
4.f.	Rabbits	0	12	40	305	5	362
4.g.	Cats	0	0	4	0	56	60
4.h.	Dogs	0	0	7	0	110	117
4.i.	Ferrets	0	0	0	0	0	0
4.j.	Other Carnivores	0	0	0	0	941	941
4.k.	Horses, donkeys and cross breds	0	0	0	0	24	24
4.l.	Pigs	66	0	0	82	50	198
4.m.	Goats	0	0	0	100	0	100
4.n.	Sheep	0	0	21	30	21	72
4.o.	Cattle	0	0	0	40	140	180
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	118	118
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	640	0	0	360	1000
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	1058	1058
4.z.	TOTAL	3255	43972	8851	13532	5308	74918

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	2292	2692	0	505	0	6540	12029
5.b. Rats	165	506	0	716	0	355	1742
5.c. Guinea-Pigs	194	5101	0	90	0	0	5385
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	580	110	0	0	0	93	783
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	2	60	0	0	0	0	62
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	0	0	0
5.o. Cattle	0	0	0	0	0	110	110
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	334	1136	0	0	0	1040	2510
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
5.z. TOTAL	3567	9605	0	1311	0	8138	22621

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	108	1757	30	390	0	1326	3611
6.b. Rats	0	1032	736	525	0	995	3288
6.c. Guinea-Pigs	0	916	0	0	0	0	916
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	255	0	0	0	0	255
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	149	0	0	149
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	10	0	0	0	0	10
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	0	1630	0	1630
6.z. TOTAL	108	3970	766	1064	1630	2321	9859

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	153	0	876	0	0	0	558	0	0	0	0	0	2024	3611
7.b. Rats	160	0	737	549	0	0	1125	0	256	0	0	0	461	3288
7.c. Guinea-Pigs	0	340	0	0	570	0	0	0	0	0	0	0	6	916
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	0	154	0	39	0	0	0	0	0	0	62	255
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	0	0	0	0	0	0	0	0	0	149	149
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	10	0	0	0	0	0	0	0	0	0	0	0	0	10
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	1238	0	0	0	0	0	313	0	0	0	0	79	0	1630
7.z. TOTAL	1561	340	1613	703	570	39	1996	0	256	0	0	79	2702	9859

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 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	96	0	628	360	242	0	8	0	0	0	0	0	518	1852
8.b. Products/substances used or intended to be used mainly in agriculture	994	0	42	82	266	23	371	0	160	0	0	0	209	2147
8.c. Products/substances used or intended to be used mainly in industry	390	0	11	22	54	16	0	0	0	0	0	0	32	525
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	640	0	0	0	0	0	150	790
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	290	7	2	0	0	0	0	0	0	0	0	0	299
8.i. Other toxicological or safety evaluations	81	50	925	237	8	0	977	0	96	0	0	79	1793	4246
8.j. TOTAL	1561	340	1613	703	570	39	1996	0	256	0	0	79	2702	9859

PORTUGAL

Statistical data submitted

The statistical data were submitted by the *'Ministério da Agricultura, Desenvolvimento, Mar, Ambiente e Ordenamento do Território – Direcção Geral de Alimentação e Veterinária – Direcção de Serviços de Protecção Animal'* (Ministry of Agriculture, Sea, Environment and Spatial Planning – General Direction of Feed and Veterinary – Directorate for Animal Protection).

Comments of the Portuguese authorities

1. Total number of animals used by species

In 2011, the total number of animals used for experimental and other scientific purposes in Portugal was 46,556.

Compared to the data of 2008, where the total number of used animals was 50888, it means that with regard to 2008 it was a decrease on the use of animals of 8,51%.

Mice are the most commonly used species representing 52,41% of the total number of animals.

The second most used group of animals was Rats (24,25%).

The third most used group is represented by the Cold-blooded animals (20,68%) and the fourth by the group of Artio and Perissodactyla with 1,29%.

Rodents with Rabbits represent 77,06% of the total number of animals used.

Non-human primates, as it has been used to happen in Portugal, continued to not being used.

Comparison with the data of the previous report (data of 2008)

The percentages of classes of animals used in 2008 (50,888 animals) and in 2011 (46,556 animals) are represented in the following table:

Class of animals	2008 (%)	2011 (%)
Mice	78,23	52,41
Rats	12,91	24,25
Guinea-pigs	0,30	0,009
Hamsters and other rodents	0,06	0,17
Rabbits	0,19	0,22
Cold-blooded animals	7,47	20,68
Quail and other birds	0,31	0,93
Artio Perissodactyla	0,52	1,29
Carnivors	0,00	0,043

In 2011, looking at the data by groups of animals, the percentage of rodents and rabbits suffered a decrease, from 91,69% in 2008 to 77,06% in 2011 due to a decrease on mouse use. The noticed decrease on mouse use was the reflection of two circumstances:

1. several institutions were improving their establishments or moved to new facilities that had been built and therefore the use of animals was stopped.
2. there was a substantial increase on the use of cold-blooded animals, from 7,47% in 2008, to 20,68% in 2011, mainly due to the increase on the use of fish models.

Among the group of the Cold-blooded animals, Fish were the most used animals to being used followed by the use of amphibians.

Within the Artiodactyla, Pigs were once again the most used animals (78,74%).

2. Number of animals used by purposes of experiments

In 2011, the percentage of animals (total 46,556) used by purposes of experiments was the following:

- 87,92% of animals were used in "*Fundamental biology*";
- 2,39% in "Research and development for human medicine, veterinary medicine, dentistry";
- 0,21% in "Production and quality control of products and devices in human medicine and dentistry and veterinary medicine";
- 2,32% in "Toxicological and other safety evaluation";
- 2,80% in "Diagnosis of disease";
- 3,22% in "Education and training";
- 1,14% in "Other purposes".

Referring to the use of species versus experimental purposes, the highest amount of use of Mice, Rats and Fish is in "*Fundamental biology*" and the highest second amount of use of Fish is in "*Toxicological and other safety evaluation*".

Comparison with the data of the previous report (data of 2008)

From 2008 to 2011, there was only a decrease in the percentage of animals in two categories: "*Research and development for human medicine, veterinary medicine, dentistry*" and "*Other purposes*", with the most significant decrease of 7,35% in the percentage of animals that were used for "*Research and development for human medicine, veterinary medicine, dentistry*".

The percentage of animals used in the rest of the other categories increased, for example:

The most significant increase in 2011 was in the percentage of animals that were used for "*Fundamental biology*" which increased 4,1% (from 83,82%, in 2008, to 87,92%, in 2011).

The percentage of animals used for "*Toxicological and other safety evaluation*" increased from 0,61% to 2,32% and the percentage of animals used for "*Education and training*" increased from 1,83% to 3,22%.

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

In 2011, the use of animals in "*Toxicological and other safety evaluation*" represents only 2,32%, which only refers to 1079 animals (28 mice, 102 rats and 949 fish), from the total of 46,556 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 53,29% of all the animals used for "*Toxicological and other safety evaluation*". The other percentages of uses in this category are the following:

- "Products/substances or devices for human medicine and dentistry and for veterinary medicine" represent 13,35%.
- "Products/substances used or intended to be used mainly in agriculture" represent 18,63%.
- "Other toxicological or safety evaluations" represent 14,74%.

Comparison with the data of the previous report (data of 2008)

Compared to the data of 2008, in 2011 there was an increase on the use of animals in "*Toxicological and other safety evaluation*".

The percentage of animals used for "*Toxicological and other safety evaluation*" increased from 0,61% to 2,32% (from 310 to 1,079 animals).

The data of 2011 refers to more two categories of products than the ones that had been tested in 2008.

Animals used to test "*Products/substances or devices for human medicine and dentistry and for veterinary medicine*" and "*Products/substances used or intended to be used mainly in agriculture*" were represented in 2011 but not in 2008.

"*Potential or actual contaminants in the general environment which do not appear in other columns*" represented, in 2008, 61,29% of the animals used for "*Toxicological and other safety evaluation*" and, in 2011, 53,29%;

"*Other toxicological or safety evaluations*" represented 38,71% in 2008 while, in 2011, 14,74%, which means that there was a decrease in 2011.

As in 2008, in 2011 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 2011, the number of animals used for the "*Studies on humans and animals diseases*" was 20,973, which represents 45,05% of the total number of animals (46,556 animals) that were used.

The percentages of animals per type of diseases were:

- 1,79% in “Human cardiovascular diseases”;
- 25,50% in “Human nervous and mental disorder's;
- 5,63% in “Human cancer (excl. evaluation of carcino hazards)”;
- 65,72% in “Other human diseases”;
- 1,36% in “Specific animal diseases”.

The percentage of the number of animals used for studies of human diseases represents 98,64% (20,687 animals) of the total number of animals used for all studies of diseases (20,973 animals).

In 2011, the number of animals used to study animal diseases was only 286 (1,36%) while in 2008, that number had been 568 (3,85%), which means that in 2011, there was decrease in 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 2011, the use of animals in “*Toxicological and other safety evaluation*” represents only 2,32%, which only refers to 1,079 animals, of a total of 46,556 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2008)

The percentages of animals used in toxicity tests for “*Toxicological and other safety evaluation*” in 2008 (310 animals) and in 2011 (1,079 animals) are represented in the following table:

Type of tests	2008 (%)	2011 (%)
Acute and sub-acute toxicity testing methods (including limit test)	0	35,87
Irritation/sensitization tests	0	0
Sub-chronic and chronic toxicity	0	0
Mutagenicity and Carcinogenicity	38,71	14,74
Reproductive and developmental toxicity	0	0
Toxicity of aquatic vertebrates not included in other columns	0	49,40

Other tests	61,29	0

In 2011 there was an increase on the uses of tests compared to data of 2008, and the biggest increase (49,40%) occurred on the uses of "*Toxicity of aquatic vertebrates not included in other columns*".

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

As pointed out previously, in 2011, the use of animals in "*Toxicological and other safety evaluation*" represents only 2,32%, which only refers to 1,079 animals, of a total of 46,556 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2008)

The numbers of animals used for "*Toxicological and other safety evaluation*" per types of products in 2008 (310 animals) and in 2011 (1079 animals) are represented in the following tables:

Types of products	2008 (%)	2011 (%)
Products/substances or devices for human medicine and dentistry and for veterinary medicine	38,71	13,35
Products/ substances used or intended to be used mainly in agriculture	0	18,63
Potential or actual contaminants in the general environment which do not appear in other columns	61,29	53,29
Other toxicological or safety evaluations	0	14,74

In 2011, the number of animals used to test "*Products/substances or devices for human medicine and dentistry and for veterinary medicine*" were 144 animals distributed in "*LD50, LC50*" and in "*Other lethal methods*".

In 2011, in comparision to 2008, there was an increase of the number of animals used to test "*Products/substances used or intended to be used mainly in agriculture*" from 0% in 2008, to 18,63%, in 2011. All the animals were used in "*Non lethal clinical signs methods*".

Related to the "*Potential or actual contaminants in the general environment which do not appear in other columns*", in 2011 there was a decrease of 8%, compared the 2008, from 61,29%, in 2008, to 53,29%, in 2011. The tests that were performed in this category, were "*Other lethal methods*" and "*Toxicity to aquatic vertebrates not included in other columns*".

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*)	24399	17341	5023		2035	60
1.b. Rats (*Rattus norvegicus*)	11290	6784	4153		353	24
1.c. Guinea-Pigs (*Cavia porcellus*)	4		4			4
1.d. Hamsters (*Mesocricetus*)	6		6			
1.e. Other Rodents (other *Rodentia*)	74				24	
1.f. Rabbits (*Oryctolagus cuniculus*)	102	90			12	
1.g. Cats (*Felis catus*)						
1.h. Dogs (*Canis familiaris*)	20	20				
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)						
1.l. Pigs (*Sus*)	474					
1.m. Goats (*Capra*)	99					
1.n. Sheep (*Ovis)*	29					
1.o. Cattle (*Bos*)						
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*)	433					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	25					
1.y. Fish (*Pisces*)	9601					
1.z. TOTAL	46556					

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	22005	558			28	1217	518	73	24399
2.b. Rats	10081	453			102	88	543	23	11290
2.c. Guinea-Pigs							4		4
2.d. Hamsters								6	6
2.e. Other Rodents	74								74
2.f. Rabbits	16						21	65	102
2.g. Cats									
2.h. Dogs		20							20
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds									
2.l. Pigs		60					370	44	474
2.m. Goats			99						99
2.n. Sheep		24					5		29
2.o. Cattle									
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	113							320	433
2.w. Reptiles									
2.x. Amphibians	25								25
2.y. Fish	8616				949		36		9601
2.z. TOTAL	40930	1115	99	0	1079	1305	1497	531	46556

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									28	28
3.b. Rats									102	102
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	144	201						575	29	949
3.z. TOTAL	144	201						575	159	1079

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		2335	856	12162	202	15555
4.b. Rats	372	2989	324	1597	12	5294
4.c. Guinea-Pigs						
4.d. Hamsters						
4.e. Other Rodents		24				24
4.f. Rabbits	4				12	16
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs					60	60
4.m. Goats				24		24
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	376	5348	1180	13783	286	20973

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		99					99
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		99					99

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		28					28
6.b. Rats		102					102
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		949					949
6.z. TOTAL		1079					1079

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								28						28
7.b. Rats								102						102
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	96	90	201							29		533		949
7.z. TOTAL	96	90	201					130		29		533		1079

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	96	48												144
8.b. Products/substances used or intended to be used mainly in agriculture			201											201
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		42										533		575
8.i. Other toxicological or safety evaluations								130		29				159
8.j. TOTAL	96	90	201					130		29		533		1079

ROMANIA

Statistical data submitted

The data were submitted by the 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*)	44575	44575				1483
1.b. Rats (*Rattus norvegicus*)	5161	5161				
1.c. Guinea-Pigs (*Cavia porcellus*)	6607	6607				824
1.d. Hamsters (*Mesocricetus*)	263	263				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	2195	2195				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	1196				12
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)						
1.z. TOTAL	60156					

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	5358	17559	140	1189	44565
2.b. Rats	952	263			345	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	69	526	5	41	2195
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	6443	23093	1958	1344	60156

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	4783		35	40	40	25			295	5218
3.b. Rats	50	80		115	10	25			205	485
3.c. Guinea-Pigs	671									671
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	69									69
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	5573	80	35	155	50	50	0	0	500	6443

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	30		120		253
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	696	550	809	1625	4101

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							
5.c. Guinea-Pigs						2770	2770
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits						1489	1489
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breds						12	12
5.l. Pigs						2	2
5.m. Goats							
5.n. Sheep						114	114
5.o. Cattle						3	3
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						747	747
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
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						5358	5358
6.b. Rats						345	345
6.c. Guinea-Pigs						671	671
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits						69	69
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	0	0	0	0	0	6443	6443

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	480	161	70	30	30	30	38						4510	5349
7.b. Rats	90	105					4						145	344
7.c. Guinea-Pigs							12						669	681
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													69	69
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	570	266	70	30	30	30	54	0	0	0	0	0	5393	6443

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	25	70	30	30	30	50						5028	5583
8.b. Products/substances used or intended to be used mainly in agriculture	80													80
8.c. Products/substances used or intended to be used mainly in industry	15	20												35
8.d. Products/substances used or intended to be used mainly in the household	40	115												155
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	25	25												50
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	25	25												50
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	65	56					4						365	490
8.j. TOTAL	570	266	70	30	30	30	54	0	0	0	0	0	5393	6443

SLOVENIA

Statistical data submitted

The statistical data were submitted by the Veterinary Administration of the Republic of Slovenia (VARS).

Comments of Slovenian authorities

Commentary to the Annual Report on the Use of Animals in Procedures in 2011.

Veterinary Administration of the Republic of Slovenia (VARS) is the competent authority in the Republic of Slovenia for drawing up the Annual Report on the Use of Animals in Procedures, based on the Animal Protection Act (ZZZiv-UPB2, UL RS 43/2007). Procedures may be performed by establishments only, which have been authorised by VARS (25 user establishments) for conducting procedures on animals. Each user establishment designates an animal welfare expert, who collects data on the annual use of animals within the establishment in the form of 8 EU tables, which are submitted to VARS. VARS prepares a collective Annual Report on the Use of Animals in Procedures, which is made accessible to the public as information of public character.

As procedure on animals shall be regarded the use of animals for the experimental or other scientific purposes, which may cause pain, suffering, distress or lasting harm to the animals, and other measures, which may lead to or bring about a birth of an animal under such circumstances. In the Republic of Slovenia, procedures on animals are prohibited for the ethically unacceptable targets, as testing of weapons of war, cosmetic preparations, tobacco or alcohol products, or for procedures where the musculature paralysing agents are used without the appropriate anaesthesia. Use of animals for the educational purposes has been restricted, as procedures may be conducted only in the form of presentations to the students of veterinary medicine and of human medicine, provided that no alternative teaching aid (film, image, model, preparation etc) is at disposal.

In 2011, a total of 11,874 animals were used in procedures, which is by 4.54 % less animals as compared to 2008, where a total of 12,438 animals were used. A major portion constitute the laboratory rodents with 97.47 %, followed by rabbits with 1.97 %, fish with 0.35 %, and other animals (pigs, horses, sheep) with 0.20 % .

Laboratory rodents and rabbits originate from the Slovenian approved breeding establishments (28.07 %) and from the other EU Member States (the remaining portion). Other animals – rearing animals - originate from the agricultural holdings, where the animal owners give their consent in writing to the use of such animals in procedures.

Most animals were used in the applied research for the development, generation and control of quality of products and means intended for use in human medicine, dentistry and veterinary medicine, and to a lesser extent, for the assessment of toxicity (90.67 %). Only 8.00 % of the animals were used in baseline research studies, 0.60 % for the education and training purposes, 0.08 % for diagnosing diseases, and the remaining 0.65 % for other non-defined purposes of use.

Rabbits were reused in series of procedures within the applicable procedures for the identification of quality of products intended for use in human medicine, dentistry and veterinary medicine.

Pigs were used in the education of students of veterinary medicine and in the training of surgeons in human medicine. Seven horses were used in the research study of identifying the impacts of Vitamin E and Coenzyme Q10 on the oxidative stress within a certain physical activity of the recreational horses, 4 castrated male ovine animals were used in obtaining the ruminal fluid (juice) by operative insertion of a fistula for the nutritional research purposes, and 42 fish in their natural habitat were used for the telemetric monitoring purposes in the Sava River basin.

By the adoption of relevant legislation, and taking into account the 3R principle, and through an implemented control system, the use of animals in procedures has decreased over the recent five years, on the average to around 12,700 animals, where the laboratory rodents with over 95.00 % constitute a major portion. Non-human primates are not used in procedures, and neither the carnivores within the recent five years. Through the well-qualified staff involved in procedures on animals within the past 5-year period in Slovenia, the responsibility for and attitude towards the animals of the researchers have improved, which is reflected in the accurate keeping of procedure protocols, the careful selection of methods and in the subsequent precise implementation of procedures. In decreasing the number of animals used in procedures, in pharmaceutical industry in particular, the validated alternative methods and/or the use of cell cultures and tissues have had an important role.

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*)	11133	3004	8129			
1.b. Rats (*Rattus norvegicus*)	393	250	143			
1.c. Guinea-Pigs (*Cavia porcellus*)	48	48				
1.d. Hamsters (*Mesocricetus*)	0					
1.e. Other Rodents (other *Rodentia*)	0					
1.f. Rabbits (*Oryctolagus cuniculus*)	234	13	221			209
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*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	7					
1.l. Pigs (*Sus*)	13					
1.m. Goats (*Capra*)	0					
1.n. Sheep (*Ovis)*	4					
1.o. Cattle (*Bos*)	0					
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*)	0					
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)	0					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	0					
1.y. Fish (*Pisces*)	42					
1.z. TOTAL	11874					

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	664	1962	7957	195		10	30	28	10846
2.b. Rats	232	247			183		18		680
2.c. Guinea-Pigs	48								48
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits			222				12		234
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds								7	7
2.l. Pigs	2						11		13
2.m. Goats									0
2.n. Sheep	4								4
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								42	42
2.z. TOTAL	950	2209	8179	195	183	10	71	77	11874

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										0
3.b. Rats	183									183
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits										0
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	183	0	0	0	0	0	0	0	0	183

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		253	1842	224		2319
4.b. Rats	18	55		342		415
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 breds						0
4.l. Pigs				2		2
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	18	308	1842	568	0	2736

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		8152					8152
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		222					222
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							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	0	8374	0	0	0	0	8374

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							0
6.b. Rats		183					183
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits							0
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	183	0	0	0	0	183

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														0
7.b. Rats		40								143				183
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits														0
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	0	40	0	0	0	0	0	0	0	143	0	0	0	183

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		40								143				183
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	0	40	0	0	0	0	0	0	0	143	0	0	0	183

SLOVAKIA

Statistical data submitted

The statistical data were submitted by the State Veterinary and Food Administration of the Slovak Republic.

Comments of Slovakian authorities

The State Veterinary and Food Administration of the Slovak Republic (hereinafter referred to as the „SVFA SR“) is a competent authority of the Slovak Republic in the matter of protection of animals used for experimental purposes. The SVFA SR approves in compliance with Article 6 paragraph 2 letter i) point 2 and 3 of Act No 39/2007 Coll. on Veterinary Care as amended (hereinafter referred to as „Act 39/2007 Coll“.), the performance of experiments on animals and breeding, supplying and experimental establishments. The original Ordinance of the Government of the Slovak Republic No 289/2003 Coll. by which the Directive 86/609/EEC was transposed into the legal order of the Slovak Republic, was amended in compliance with Commission recommendations 2007/526/EC of 18.06.2007, that concerned the accommodation and care of animals used for experimental and other scientific purposes. On 1 February 2009 a new Ordinance of the Government of the Slovak Republic No 23/2009 Coll. entered into force (hereinafter referred to as the „Ordinance of the Government of the SR No 23/2009 Coll“.), in which the requirements for the protection of animals used for experimental or other scientific purposes are specified in detail. In this Ordinance the transitional period for harmonizing the requirements in respect of accommodation and care of animals from the year 2009 till 31.12.2013 was indicated.

The SVFA SR manages, directs, coordinates and controls **40** District Veterinary and Food Administrations (hereinafter referred to as the „DVFA“). All employees of the veterinary administration working in the field of animal protection are veterinarians participating in execution of controls in establishments. The controls are performed based on the methodical instructions and checklists worked out by the competent authority in compliance with requirements laid down in Ordinance of the Government of the SR No 23/2009 Coll. and in Act No 39/2007 Coll.

Approval of establishments:

All kinds of establishments are approved by the SVFA SR based on the application submitted by applicants and results from the control carried out directly in the establishment. By the control performed in the establishment the compliance with the observance of requirements laid down in Ordinance of the Government of the SR No 23/2009 Coll. are judged. In the establishment, mainly the control of applicant´s documents, control of records kept by an applicant and physical control of the establishment are performed.

All controls performed in establishments are non-discriminatory. They are performed for the purpose of approval of the establishment, control of already approved establishments carried out for the purpose of compliance with requirements laid down in Ordinance of the Government of SR No 23/2009 Coll. or a control is performed on an impulse.

Totally, **24** establishments asked the **SVFA SR** for the approval of its establishment for keeping animals and performance of experiments on animals according to

requirements laid down in Ordinance of the Government of the SR No 23/2009 Coll. In one approved establishment an additional approval of new premises– quarantine was carried out. One establishment fulfilled the requirements laid down in Ordinance of the Government of SR No 23/2009 Coll. during the execution of the control, for this reason it was not necessary to carry out the subsequent control.

Kinds and numbers of controls performed in establishments for the year 2011 in the Slovak Republic

Kind of the control	Number of controls
Judgement of suitability of the establishment for carrying out experiments	25
Subsequent control	23
Totally performed controls	**48**

The SVFA SR after having issued the decision on approval of the establishment shall issue an official number to the respective establishment under which the establishment is kept in the lists of approved supplying, breeding and user establishments in the Slovak Republic on the website of the SVFA SR **www.svssr.sk**. In compliance with paragraph 11 Article 39 of Act No 39/2007 Coll. In the Slovak Republic is possible to breed the animals for the purpose of their usage in experiments only in approved breeding and supplying establishments. According to the Act, it is possible to perform the experiments on animals only in approved experimental establishments.

In the year 2011, the SVFA SR registered totally 66 approved establishments. Out of this, there were 53 experimental establishments, 10 experimental establishments bred animals for their own need, 2 breeding establishments and 1 supplying establishment. Compared to the year 2008, in which the report was given for individual Member States, the number of approved establishments was changed. Out of the total number of 75 approved establishments, the number decreased to 66 approved establishments. The changes concern mainly the number of experimental and breeding establishments. Since the year 2009, several establishments submitted an application for cancellation of its approval. It was due to the cancellation of the establishment itself, or change in respect of activity of the establishment. Many establishments were not able to fulfil the requirements concerning the care and accommodation of animals laid down in Ordinance of the Government of the SR No 23/2009 Coll. In the year 2011, some establishments e.g. of the Slovak Academy of Sciences divided according to kept animal species. It means, that one establishment has also 3 official numbers of approval according to animal species used in experiments.

Total number of approved establishments in the Slovak Republic in the year 2011.

Kind of establishment	Number of establishments
Experimental establishment	53
Experimental establishment with breeding of animals for own use	10
Breeding establishment	2
Supplying establishment	1
Total	**66**

Approval of experiments:

In the Slovak Republic it is possible to use the animals only in approved experiments in approved experimental establishment.

The SVFA SR approves the experiments performed on animals based on the application for approval of an experiment, submitted by an applicant– approved experimental establishment. An application must be completed by the applicant in compliance with Article 8 of Ordinance of the Government of the SR No 23/2009. It must contain all the prescribed data concerning the used animals, mainly their species, number and origin, manner of their marking in the experiment, used anaesthesia within an experiment, performance of the experiment with indication of the aim, purpose of the experiment and expected results. In an application the name of a contracting veterinarian, a person submitting an experiment and person responsible for the care of animals are indicated. The document on the existence of the relevant alternative method to the submitted experiment shall be attached to each experiment. The applicant shall find out and search in internationally checked registers of alternative method the relevant alternative to the submitted experiment. A detailed specification of the manner of observance of principles 3R shall be attached to the application. An applicant shall submit the experiment first for the assessment to the ethic commission which shall be established according to the Act in each experimental establishment. The ethic commission is comprised of minimum 5 members, out of which 1/3 must not be dependent from the experimental establishment. The ethic commission on the submitted project of an experiment, shall assess the observance of principles 3R, existence of alternative method contrary to the submitted experiment, justification of each experiment, purpose and its aim, use of the animals in the experiment, caused pain. An applicant may submit his/her project of an experiment for approval by the SVFA SR only after recommendation for submission, issued by the ethic commission.

The SVFA SR has in compliance with Act No. 71/1967 Coll. on Administrative Proceedings (Administrative Codex) minimum 30 days for assessment of an application for approval of the experiment. The SVFA SR, as a competent authority, may by the DECISION APPROVE, REFUSE, SUSPEND the performance of the experiment or may STOP an ADMINISTRATIVE PROCEEDINGS. The SVFA SR upon approval of experiments must observe the rules of the personal data protection and protection of data with signs of trade secret or intellectual property indicated in an application for approval of the experiment.

Since 01.01.2011, the SVFA SR approved experiments only to those establishments which were approved in compliance with requirements laid down in Ordinance of the Government of the SR No 23/2009 Coll. Therefore, the number of approved experiments for the year 2011 decreased, because not all registered establishments were still approved in compliance with new requirements laid down in Ordinance of the Government of the SR No 23/2009 Coll.

Survey on the number of approved experiments and on the number of interruptions of administrative proceedings:

Year	2009	2010	2011	
Approval of experiment	115	176	103	
Appeal for removal of deficiencies	48	25	34	

Commentary to completed tables:

To the Table 1 Most of used animals originate from domestic approved breeding establishments or approved experimental establishments with breeding of animals for own use. The animals which originated from foreign suppliers or breeders originated from the EU Member States, mainly from the Czech Republic, Hungary, Germany, Poland or France. An increased number of animals repeatedly used in experiments (domestic rabbit 82 animals, 150 domestic fowl) is for the reason of an increased performance of experiments to order for the purpose of manufacture, development of substances intended for disease diagnostics. The hyperimmune sera from which the antibodies were purified, were obtained from immunized animals.

To the Table 2 The SVFA SR approved **103** experiments using experimental animals, stopped 34 administrative proceedings within experiment approval for the year 2011. The total number of animals used in experiments does not represent entirely the number of used animals for the year 2011. It is for the reason that into the indicated number of used animals in the year 2011 also animals are included, which were used from experiments approved already in the year 2009, 2010, 2011. In the Slovak Republic, the experiments are approved for the period of 3 years. In the

column 2.8. the number of animals are indicated which were used within preparation of exepriments - so called pilot studies for performance of the experiment. The animals were used for the introduction of new surgical methods being used in the course of performance of experiments concerning demanding surgical interventions and other handling of animals. The pilot studies were approved by the competent authority as experiments. The usage of animals to obtain the necessary skills of persons performing the experiments – training of persons – the SVFA SR approved as a pre-experiment within the performance of the experiment. In the column 2.9 the numbers of animals used as a live collection for maintenance of viruses, parasites and breeding of ticks or animals used for preparation of primocultures are indiated. Each preparation of a collection was approved as a separate experiment.

To the Table 3. In the column 3.2 the animals were used for evaluation of products and substances for human medicine (testing of new medicines, medical devices, surgical supplies – suitability of new polymers in treatment of hernia). In the column 3.4 the numbers of animals are indicated which are used for the control of various chemical substances and substances e.g. for evaluation of human risk of amines, NH3, aldehydes, amides, alkylamides, nitrosamines as independent substances and their combinations, substances used as additive for slowing down or stopping the growth of microorganisms in paint substances, in fibres from plastic products or substances which are a part of fuel oils, lubricants and substances used in rubber industry. The orders for re-testing of the same substance produced in various batches were done in several establishments. In some cases, whole series of standard toxicological safety tests were carried out with the same substance, based on the EU legislation e.g. REACH. In the column 3.8 the animals were used for the purpose of testing the substance used in food industry as a supplement of food in a form of enterosolvent pellets of microcrystalline cellulose, either independent or enriched by lactose, or an influence of chosen feed additives was controlled. In the column 3.10 the numbers of animals are indicated with the aim to validate in in vivo experiments on animals findings of alternative in vitro experiments characterizing the toxicological profile of nanoelemens which will be perspectively used in further experiments for a toxicological evaluation of substances.

To the Table 4 Explanation to the column 4.5. The animals were used for the purpose of investigation of immune systems, infectious diseases and metabolism disorders in humans and in the column 4.6 in animals.

To the Table No 5 In the Slovak Republic the experiments upon animals are performed in compliance with the valid national legislation, in which the legal acts of the European Communities and the European Union are incorporated. In the column 5.3 the experiments are performed in compliance with the valid legislation of the European Pharmacopoeia. In the column 5.7 the methods for the control of human products/substances were used that were created by the experimental establishment as a modified method based on the approved pharmacopoeial methods or as a new individual method.

To the Table 6 The Slovak Republic has adopted the legislation in the field of medicines and medical devices e.g. Act No 362/2011 Coll. on Medicines and Medical Devices and on change and supplement of some acts, in the field of chemical substances and preparations the Act No 163/2001 Coll. on Chemical Substances and Preparations, we have adopted the Decree of the Ministry of Economy No 2/2005 Annex 5 Part B Methods B for testing of substances according to OECD methods that

are conformable to OECD methods. The acts are elaborated and prepared in compliance with the EU legislation according to which the individual preparations, products are tested. In the column 6.3 the numbers of animals used in compliance with the European Pharmacopoeia are indicated.

To the Table 7 In the column 7.2.1. the tests were performed mainly by methods OECD TG 402, 423, 425. In the column 7.2.3 mainly the tests of the control of the product quality, tests of wholesomeness and efficiency according to the Slovak Pharmacopoeia 1 and the European Pharmacopoeia 6 were carried out.

In compliance with the Ordinance of the Government of the Slovak Republic No 23/2009 Coll. each approved establishment shall be obliged, in order to maintain its approval, to submit yearly to the SVFA SR a notification on the number of used animals for the respective year. The notification shall be submitted according to the specimen presented in the Ordinance of the Government. The approved establishments shall be obliged to keep records on the number of used GMO animals in the experiment. Based on the collected data, the SVFA SR shall yearly work out a notification about the activity of the SVFA SR in which the numbers of approved establishments, the numbers of approved and refused experiments as well as the numbers and species of used animals in the experiment for the respective year are published.

The competent authority performs consulting services for public in the field of animal welfare, organizes trainings for employees of approved establishments the purpose of which is interpretation of the valid legislation of the Slovak Republic in the field of animal welfare, it organizes seminars and lectures in respect of the protection of experimental animals used for experimental purposes.

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*)	8747	6560	2187	0	0	0
1.b. Rats (*Rattus norvegicus*)	5327	3943	1384	0	0	0
1.c. Guinea-Pigs (*Cavia porcellus*)	645	329	316			
1.d. Hamsters (*Mesocricetus*)	0					
1.e. Other Rodents (other *Rodentia*)	17					
1.f. Rabbits (*Oryctolagus cuniculus*)	299	237	62			82
1.g. Cats (*Felis catus*)	10	10				
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*)						
1.l. Pigs (*Sus*)	84					
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*	14					5
1.o. Cattle (*Bos*)	0					1
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)*	88	88				
1.v. Other birds (other *Aves*)	486					150
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)						
1.z. TOTAL	15717					

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	4333	1561	0	403	188	2215	47	0	8747
2.b. Rats	3311	695	0	0	633	0	300	388	5327
2.c. Guinea-Pigs		507				100		38	645
2.d. Hamsters									0
2.e. Other Rodents	17								17
2.f. Rabbits	78	114	15	65	15	12			299
2.g. Cats	10								10
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs	2	82							84
2.m. Goats									0
2.n. Sheep	5	9							14
2.o. Cattle		0							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	88								88
2.v. Other birds	108		45	216	90			27	486
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	7952	2968	60	684	926	2327	347	453	15717

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	188	0	0	0	0	0	0	0	0	188
3.b. Rats	275	0	118	0	0	0	90	0	150	633
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	15									15
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	90									90
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	568	0	118	0	0	0	90	0	150	926

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	403	141	2019	3531	2015	8109
4.b. Rats	1586	914	297	1209		4006
4.c. Guinea-Pigs				607		607
4.d. Hamsters						0
4.e. Other Rodents	17					17
4.f. Rabbits		60		144		204
4.g. Cats				10		10
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs		2		47	35	84
4.m. Goats						0
4.n. Sheep				9	5	14
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				88		88
4.v. Other birds				108		108
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	2006	1117	2316	5753	2055	13247

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	403	0	0	0	0	403
5.b. Rats	0	0	0	0	0	0	0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		65				15	80
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							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		216				45	261
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	684	0	0	0	60	744

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	0	188	0	0	0	0	188
6.b. Rats	220	413	0	0	0	0	633
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		15					15
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		90					90
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	220	706	0	0	0	0	926

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			20				120			48				188
7.b. Rats	55						90		220		268			633
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits					3	12								15
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			90											90
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	55	0	110	0	3	12	210	0	220	48	268	0	0	926

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	55		110		3	12	120		70	48	150			568
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											118			118
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							90							90
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									150					
8.j. TOTAL	55		110	0	3	12	210	0	220	48	268	0	0	926

FINLAND

Statistical data submitted

The statistical data were collected by the Regional State Administrative Agency of Southern Finland and submitted by the Ministry of Agriculture and Forestry.

Comments of Finnish authorities

In 2011, a total of 136,043 experimental animals were used in Finland. From the year 2008 with 138,600 animals, no significant changes have been seen in the numbers of animals used or reasons for their use.

Of all experimental animals used 68% were mice (73,503 animals) and rats (18,586 animals). Fish accounted for about 23% (30,766 animals) of the total use. There has been a continuous slight decrease in the use of rats and rabbits from year to year since 2008. The increased numbers of cats (454 animals) and dogs (2,805 animals) resulted from the research projects studying the genetic diseases of these species with blood samplings from pet animals. Besides these projects, 51 dogs and 0 cats and were used in experiments.

As in previous years, a major part of the animals (75%) were used for biological studies of a fundamental nature or for research and development of human and veterinary medicine (20%).

The most important human diseases studied in Finland with animals were the nervous and mental disorders, indicating the major role of research groups in universities and private sector focusing on this research area.

The use for toxicological and other safety evaluations was 1% of the total use, rats and fish being the species used. The use of animals for education and training was also minimal, 1% of the total number of animals used.

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*)	73503	50985	21512	32	974	
1.b. Rats (*Rattus norvegicus*)	18586	5208	12680		698	
1.c. Guinea-Pigs (*Cavia porcellus*)	11		11			
1.d. Hamsters (*Mesocricetus*)	201	30	28		143	
1.e. Other Rodents (other *Rodentia*)	2682					
1.f. Rabbits (*Oryctolagus cuniculus*)	357	96	261			28
1.g. Cats (*Felis catus*)	454	454				
1.h. Dogs (*Canis familiaris*)	2805	2755	50			16
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)	656					
1.k. Horses, donkeys and cross breds (*Equidae*)	23					
1.l. Pigs (*Sus*)	681					
1.m. Goats (*Capra*)	40					
1.n. Sheep (*Ovis)*	684					
1.o. Cattle (*Bos*)	63					
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*)	17					
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)	4426					
1.w. Reptiles (*Reptilia*)	15					
1.x. Amphibians (*Amphibia*)	73					
1.y. Fish (*Pisces*)	30766					
1.z. TOTAL	136043	59528	34542	32	1815	44

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	55762	16869			81	40	711	40	73503
2.b. Rats	8172	9438			479		497		18586
2.c. Guinea-Pigs	11								11
2.d. Hamsters	60	141							201
2.e. Other Rodents	2680						2		2682
2.f. Rabbits	205	109			31	12			357
2.g. Cats	454								454
2.h. Dogs	2753	24			28				2805
2.i. Ferrets									0
2.j. Other Carnivores	656								656
2.k. Horses, donkeys and cross breds	22						1		23
2.l. Pigs	214	83	210			15	79	80	681
2.m. Goats	40								40
2.n. Sheep	13		650			20	1		684
2.o. Cattle	25	12		24		1	1		63
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	17								17
2.u. Quail									0
2.v. Other birds	912	9		3095		8	18	384	4426
2.w. Reptiles	15								15
2.x. Amphibians	73								73
2.y. Fish	29894				720		152		30766
2.z. TOTAL	101978	26685	860	3119	1339	96	1462	504	136043

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-nents 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	81									81
3.b. Rats	261		140						78	479
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	31									31
3.g. Cats										0
3.h. Dogs	28									28
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								720		720
3.z. TOTAL	401	0	140	0	0	0	0	720	78	1339

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	7268	20901	5422	7391		40982
4.b.	Rats	1555	10484	1409	1353		14801
4.c.	Guinea-Pigs						0
4.d.	Hamsters			143			143
4.e.	Other Rodents						0
4.f.	Rabbits	121			145		266
4.g.	Cats					454	454
4.h.	Dogs	22		2		2753	2777
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.l.	Pigs	284			20		304
4.m.	Goats						0
4.n.	Sheep	1			29		30
4.o.	Cattle					67	67
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				2	17	19
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish				8960		8960
4.z.	TOTAL	9251	31385	6976	17900	3291	68803

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							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs						210	210
5.m. Goats							0
5.n. Sheep						650	650
5.o. Cattle	24						24
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						3095	3095
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	24	0	0	0	0	3955	3979

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		6				75	81
6.b. Rats	261	140				78	479
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		3				28	31
6.g. Cats							0
6.h. Dogs	28						28
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						720	720
6.z. TOTAL	289	149	0	0	0	901	1339

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		6	75											81
7.b. Rats			293						100				86	479
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits			3			28								31
7.g. Cats														0
7.h. Dogs			28											28
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							90				630			720
7.z. TOTAL	0	6	399	0	0	28	90	0	100	0	630	0	86	1339

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		6	347			28							20	401
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			40						100					140
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							90				630			720
8.i. Other toxicological or safety evaluations			12										66	78
8.j. TOTAL	0	6	399	0	0	28	90	0	100	0	630	0	86	1339

SWEDEN

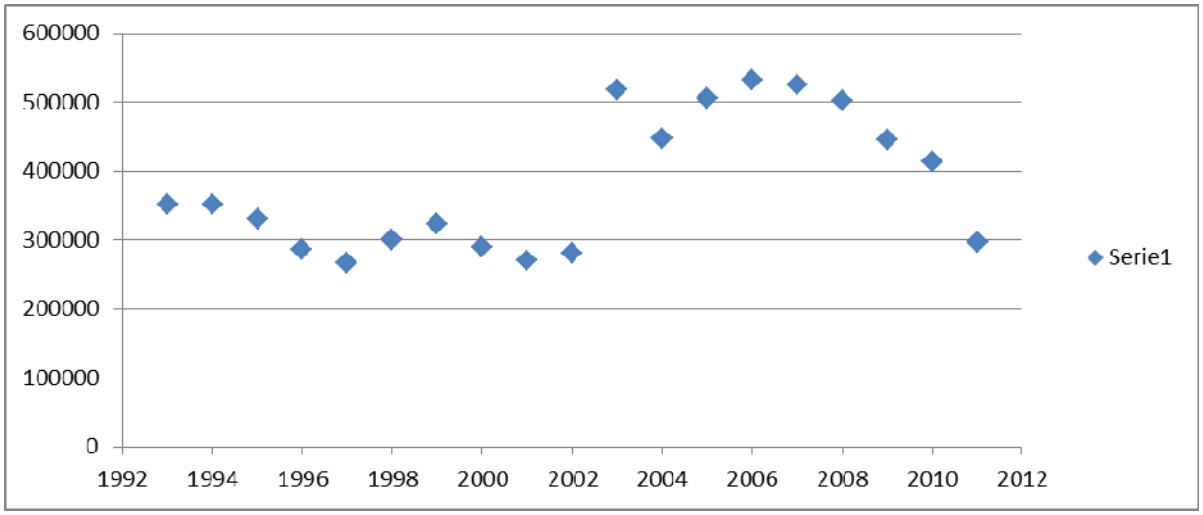
Statistical data submitted

The statistical data were submitted by the Board of Agriculture.

Comments of Swedish authorities

According to the EU definition (Directive 86/609/EEC), the number of laboratory animals used during 2011 in Sweden was 296,684 including reused animals and 271,041 excluding reused animals. This is a decrease compared to the 501,499 animals (including reused animals) reported for 2008 mostly explained by the fact that tagged fish are no longer, starting 2009, included in these statistics. During 2011, the number of fish used for this purpose was 120,500. Apart from that, the figures for 2011 also reflect well the minor fluctuation that has been seen during the last 5 years in the number of laboratory animals used in Sweden.

From 1990 until 2002, the mean number of laboratory animals used in Sweden was about 315,000 with the highest number 1994 (approximately 351,000) and the lowest 1997 (approximately 267,000). From 2003-2008, however, there has been an increase in the number of animals used due to the fact that tagging of fish for assessment studies have been included. Apart from fish, mice and rats are the animals predominately used in animal experimentation in Sweden. During the last 10 years the trend has been an increase in the use of mice whereas the use of rats, rabbits and guinea pigs has decreased. The increased use of mice as laboratory animals is most probably due to the increased use of transgenic technique(s).



Specific use of animals

As in previous years, most laboratory animals used during 2011 were used for fundamental biological research.

Only 3.5% of the animals were used in toxicological research, and the most common animals used in toxicological research were rats, mice and fish.

Swedish definition

According to Swedish legislation, all use of animals with a scientific purpose is defined as animal experimentation. Sweden therefore also collects statistical data on for example animals used in behaviour studies, feeding trials and animals being killed for the use of their tissues and organs. During 2011, 412,629 animals were reported being used for these purposes. In addition, Sweden also keeps statistical records of fish used in assessment studies. In this category, during 2011 approximately 7,734,200 fish were caught by trawling or netting, whereas 120,500 fish were tagged.

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*)	185913	136491	46206		3216	
1.b. Rats (*Rattus norvegicus*)	35202	7559	27545		98	
1.c. Guinea-Pigs (*Cavia porcellus*)	1151	747	404			
1.d. Hamsters (*Mesocricetus*)	881	0	881			
1.e. Other Rodents (other *Rodentia*)	1483					
1.f. Rabbits (*Oryctolagus cuniculus*)	710	675	35	0		6
1.g. Cats (*Felis catus*)	34	0	0	34		0
1.h. Dogs (*Canis familiaris*)	530	447	33	2	48	133
1.i. Ferrets (*Mustela putorius furo*)	76	76	0	0		0
1.j. Other Carnivores (other *Carnivora*)	256					
1.k. Horses, donkeys and cross breds (*Equidae*)	107					
1.l. Pigs (*Sus*)	2277					
1.m. Goats (*Capra*)	13					
1.n. Sheep (*Ovis)*	285					
1.o. Cattle (*Bos*)	370					
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	7	7
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	1625					
1.u. Quail (*Coturnix coturnix)*	0	0	0	0	0	
1.v. Other birds (other *Aves*)	2804					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	1216					
1.y. Fish (*Pisces*)	36108					
1.z. TOTAL	271041					

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	129685	50027	2		531	1008	567	4093	185913
2.b. Rats	16700	14564	6		2888	340	471	233	35202
2.c. Guinea-Pigs	158	824					50	119	1151
2.d. Hamsters	14	758			90		19		881
2.e. Other Rodents	1483								1483
2.f. Rabbits	330	365	4		2		3	6	710
2.g. Cats	20							14	34
2.h. Dogs	81	59			284	104	2		530
2.i. Ferrets	76						33		109
2.j. Other Carnivores	256								256
2.k. Horses, donkeys and cross breds	51					10		13	74
2.l. Pigs	1124	271				208	582	92	2277
2.m. Goats	0							13	13
2.n. Sheep	64							221	285
2.o. Cattle	9	74				6	280	1	370
2.p. Prosimians	0								0
2.q. New World Monkeys	0								0
2.r. Old World Monkeys	0								0
2.s. Apes	0								0
2.t. Other Mammals	1617							8	1625
2.u. Quail	0								0
2.v. Other birds	2358	216	60			130		40	2804
2.w. Reptiles	0								0
2.x. Amphibians	536				680				1216
2.y. Fish	10790				9369	31	5020	10898	36108
2.z. TOTAL	165352	67158	72	0	13844	1837	7027	15751	271041

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	530							1		531
3.b. Rats	2837							51		2888
3.c. Guinea-Pigs										0
3.d. Hamsters	90									90
3.e. Other Rodents										0
3.f. Rabbits	2									2
3.g. Cats										0
3.h. Dogs	284									284
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								680		680
3.y. Fish	2533							5356	1480	9369
3.z. TOTAL	6276	0	0	0	0	0	0	6088	1480	13844

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	16401	48508	29123	79082	1689	174803
4.b. Rats	2991	17328	788	9837		30944
4.c. Guinea-Pigs	40	463		479		982
4.d. Hamsters	745			27		772
4.e. Other Rodents				99	824	923
4.f. Rabbits	254	54	2	389		699
4.g. Cats		20				20
4.h. Dogs	54			5	185	244
4.i. Ferrets		76				76
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds					61	61
4.l. Pigs	416	8	1	559	271	1255
4.m. Goats						0
4.n. Sheep	37			27	80	144
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				20		20
4.u. Quail						0
4.v. Other birds				1015	1318	2333
4.w. Reptiles						0
4.x. Amphibians	75	31		430		536
4.y. Fish	0		274	60	1378	1712
4.z. TOTAL	21013	66488	30188	92029	5806	215524

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						2	2
5.b. Rats						6	6
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	4						4
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							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						60	60
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	4	0	0	0	0	68	72

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					530	1	531
6.b. Rats					2837	51	2888
6.c. Guinea-Pigs							0
6.d. Hamsters					90		90
6.e. Other Rodents							0
6.f. Rabbits					2		2
6.g. Cats							0
6.h. Dogs					284		284
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						680	680
6.y. Fish	651				1508	7210	9369
6.z. TOTAL	651	0	0	0	5251	7942	13844

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.			196				200		1				134	531
7.b. Rats			1099				463		184	448	75		619	2888
7.c. Guinea-Pigs														0
7.d. Hamsters			80										10	90
7.e. Other Rodents														0
7.f. Rabbits													2	2
7.g. Cats														0
7.h. Dogs			74				207							281
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds													3	3
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									500			180		680
7.y. Fish		28							4798		1969	2574		9369
7.z. TOTAL	0	28	1449	0	0	0	870	0	5483	448	2044	2754	768	13844

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		28	1449				819		1529	448	1235		768	6276
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							51		3954		809	1274		6088
8.i. Other toxicological or safety evaluations												1480		1480
8.j. TOTAL	0	28	1449	0	0	0	870	0	5483	448	2044	2754	768	13844

UNITED KINGDOM

Statistical data submitted

The United Kingdom statistical data for 2011 were prepared, quality assured and submitted by the Home Office.

Within the United Kingdom (UK), Great Britain (GB) and Northern Ireland (NI) publish separate, annual statistical reports based largely on the number of procedures started rather than numbers of animals used. The 2011 data collection process was 100% complete.

In accord with our established practice the UK figures presented here have been recompiled from the original data in terms of animal numbers for the classes of animal use recorded in the EU statistical tables. It should be noted that the UK also regulates, and the UK domestic statistical reports enumerate, animals bred for the maintenance of colonies of genetically modified or harmful mutant animals, and that category of animal use largely accounts for the differences in the figures in the original GB & NI publications and those in this EU report.

Comments of United Kingdom authorities

In the UK, just over 2.05 million animals were used for the first time in procedures started in 2011, a fall of 216,426 (-10%) on the number reported for 2008. The decrease was largely accounted for by decreases in numbers of rats (-90,852), fish (-63,730), mice (-56,323) and guinea pigs (-17,736) along with an increase in the use of other birds (+37,775).

1,828,672 (89%) of the animals used (2,050,458) were mice (56%), fish (20%) or rats (12%).

Cold-blooded animals (fish, amphibia, and reptiles) accounted for 425,240 (21%) of the animals used.

Cats, dogs, equidae and non-human primates are accorded special protection in the UK and collectively amounted to 4,877 animals, 0.2% of the animals used, a reduction of 3228 (-40%) compared with 2008.

Non-human primates accounted for 1,459 animals, 0.07% of animals used, a decrease of 1895 animals (-56%) compared with 2008 (there was a fall in the numbers of new world monkeys and old world monkeys used).

1,425,640 animals (70%) were used for fundamental biological studies, research and development and production and quality control relating to human medicine, dentistry and veterinary medicine.

Toxicological or other safety evaluation used 229,674 animals (11%), a decrease of 55,214 since 2008.

There was a decrease in the number of toxicology and other safety evaluation experiments carried out in 2011 not to satisfy any regulatory requirements (45,546), down 48,639 compared with 2008, largely due to decreases in such use of fish (-47,084).

146,505 animals (7%) were used for the production and quality control of products and devices for human medicine, dentistry or veterinary medicine, 29,857 less than in

2008. This decrease was accounted for by a decrease in the number of mice (-16,669) and fish (-15,393).

Approximately 43% of animals used received some form of anaesthesia, compared to approximately 40% in 2008 (for the other animals the use of anaesthesia would have been deemed to increase the severity of the procedure.

As in 2008 no animals were used in 2011 to evaluate the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2011 for monoclonal antibody production using the ascites method.

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*)	1155920	1143119	5171	33	7597	
1.b. Rats (*Rattus norvegicus*)	252437	251420	593	1	423	
1.c. Guinea-Pigs (*Cavia porcellus*)	11514	7788	3726	0	0	
1.d. Hamsters (*Mesocricetus*)	2003	1546	457	0	0	
1.e. Other Rodents (other *Rodentia*)	3243					
1.f. Rabbits (*Oryctolagus cuniculus*)	11920	11049	799	0	72	2042
1.g. Cats (*Felis catus*)	172	62	97	0	13	75
1.h. Dogs (*Canis familiaris*)	2872	2205	375	0	292	731
1.i. Ferrets (*Mustela putorius furo*)	552	552	0	0	0	139
1.j. Other Carnivores (other *Carnivora*)	742					
1.k. Horses, donkeys and cross breds (*Equidae*)	374					
1.l. Pigs (*Sus*)	4370					
1.m. Goats (*Capra*)	117					
1.n. Sheep (*Ovis)*	9556					
1.o. Cattle (*Bos*)	4310					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	244	244	0	0	0	103
1.r. Old World Monkeys (*Cercopithecoidea*)	1215	340	48	0	827	375
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals(other *Mammalia*)	771					
1.u. Quail (*Coturnix coturnix)*	34	34	0	0	0	
1.v. Other birds (other *Aves*)	162852					
1.w. Reptiles (*Reptilia*)	383					
1.x. Amphibians (*Amphibia*)	4542					
1.y. Fish (*Pisces*)	420315					
1.z. TOTAL	2050458					

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	684033	86787	99881	12961	54212	4493	903	212650	1155920
2.b. Rats	79959	55152	3005	0	99255	6	1165	13895	252437
2.c. Guinea-Pigs	2283	1567	4354	1112	1274	94	100	730	11514
2.d. Hamsters	883	222	0	118	470	0	0	310	2003
2.e. Other Rodents	2316	214	0	0	230	0	0	483	3243
2.f. Rabbits	1174	427	1744	1520	5287	1402	14	352	11920
2.g. Cats	125	13	0	0	23	0	0	11	172
2.h. Dogs	125	158	65	25	2421	0	0	78	2872
2.i. Ferrets	285	0	24	4	0	9	13	217	552
2.j. Other Carnivores	557	0	0	19	0	0	0	166	742
2.k. Horses, donkeys and cross breds	67	23	0	46	50	36	0	152	374
2.l. Pigs	1404	170	24	910	852	0	0	1010	4370
2.m. Goats	33	0	3	3	6	69	0	3	117
2.n. Sheep	6059	48	412	398	161	1204	0	1274	9556
2.o. Cattle	2497	220	0	967	102	120	0	404	4310
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	125	0	79	0	27	0	0	13	244
2.r. Old World Monkeys	77	85	17	0	994	0	0	42	1215
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	751	0	0	0	0	0	0	20	771
2.u. Quail	34	0	0	0	0	0	0	0	34
2.v. Other birds	14559	30	59	10778	4945	1873	0	130608	162852
2.w. Reptiles	383	0	0	0	0	0	0	0	383
2.x. Amphibians	4086	0	0	0	419	0	0	37	4542
2.y. Fish	330979	1225	0	7977	58946	0	0	21188	420315
2.z. TOTAL	1132794	146341	109667	36838	229674	9306	2195	383643	2050458

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	32882	5789	5364	0	0	0	0	0	10177	54212
3.b. Rats	64995	12431	12433	0	0	0	0	704	8692	99255
3.c. Guinea-Pigs	1260	0	0	0	0	0	0	0	14	1274
3.d. Hamsters	390	0	80	0	0	0	0	0	0	470
3.e. Other Rodents	0	48	0	0	0	0	0	0	182	230
3.f. Rabbits	3511	1008	646	0	0	0	0	0	122	5287
3.g. Cats	23	0	0	0	0	0	0	0	0	23
3.h. Dogs	2224	65	0	0	0	0	0	0	132	2421
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	50	0	0	0	0	0	0	0	0	50
3.l. Pigs	451	5	0	0	0	0	0	0	396	852
3.m. Goats	0	6	0	0	0	0	0	0	0	6
3.n. Sheep	145	0	0	0	0	0	0	0	16	161
3.o. Cattle	83	19	0	0	0	0	0	0	0	102
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	27	0	0	0	0	0	0	0	0	27
3.r. Old World Monkeys	775	0	0	0	0	0	0	0	219	994
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	3184	1433	0	0	0	0	0	64	264	4945
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	400	19	419
3.y. Fish	44796	1965	668	0	0	0	0	11205	312	58946
3.z. TOTAL	154796	22769	19191	0	0	0	0	12373	20545	229674

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	49326	133047	165534	652881	15108	1015896
4.b. Rats	12368	63367	3205	137521	121	216582
4.c. Guinea-Pigs	666	280	0	9234	1112	11292
4.d. Hamsters	0	32	32	1606	127	1797
4.e. Other Rodents	1696	124	0	710	60	2590
4.f. Rabbits	820	226	0	7494	1599	10139
4.g. Cats	0	6	0	119	47	172
4.h. Dogs	93	0	0	2364	262	2719
4.i. Ferrets	0	38	0	497	4	539
4.j. Other Carnivores	19	0	0	538	23	580
4.k. Horses, donkeys and cross breds	1	0	0	102	271	374
4.l. Pigs	222	104	6	1946	2060	4338
4.m. Goats	10	0	0	95	5	110
4.n. Sheep	92	30	0	8081	1056	9259
4.o. Cattle	14	0	0	2603	1677	4294
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	8	79	0	157	0	244
4.r. Old World Monkeys	10	22	0	977	0	1009
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	13	0	738	20	771
4.u. Quail	0	0	0	34	0	34
4.v. Other birds	929	1617	0	13945	143157	159648
4.w. Reptiles	0	0	0	383	0	383
4.x. Amphibians	0	29	80	3977	0	4086
4.y. Fish	108	12363	5692	314547	19975	352685
4.z. TOTAL	66382	211377	174549	1160549	186684	1799541

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	190	3843	0	359	107628	822	112842
5.b.	Rats	77	680	0	0	2147	101	3005
5.c.	Guinea-Pigs	120	541	0	199	4606	0	5466
5.d.	Hamsters	0	118	0	0	0	0	118
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	0	0	0	0	3254	10	3264
5.g.	Cats	0	0	0	0	0	0	0
5.h.	Dogs	0	0	0	0	90	0	90
5.i.	Ferrets	0	0	0	0	28	0	28
5.j.	Other Carnivores	19	0	0	0	0	0	19
5.k.	Horses, donkeys and cross breds	0	40	0	0	6	0	46
5.l.	Pigs	26	393	0	0	515	0	934
5.m.	Goats	0	0	0	0	6	0	6
5.n.	Sheep	52	141	0	4	613	0	810
5.o.	Cattle	0	562	0	0	405	0	967
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	79	0	79
5.r.	Old World Monkeys	0	0	0	0	17	0	17
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	944	437	0	0	9456	0	10837
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	3296	0	0	0	4681	7977
5.z.	TOTAL	1428	10051	0	562	128850	5614	146505

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	39	4181	46	221	47335	2390	54212
6.b. Rats	170	220	0	272	95038	3555	99255
6.c. Guinea-Pigs	4	58	0	22	1054	136	1274
6.d. Hamsters	0	0	0	0	470	0	470
6.e. Other Rodents	4	0	0	0	191	35	230
6.f. Rabbits	0	1051	0	36	3977	223	5287
6.g. Cats	0	15	0	0	8	0	23
6.h. Dogs	0	35	0	0	2293	93	2421
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	32	0	0	18	0	50
6.l. Pigs	2	389	0	38	423	0	852
6.m. Goats	0	0	0	0	6	0	6
6.n. Sheep	0	20	0	69	72	0	161
6.o. Cattle	0	8	0	0	94	0	102
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	14	13	27
6.r. Old World Monkeys	0	0	0	0	987	7	994
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	591	1844	0	0	2246	264	4945
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	419	0	419
6.y. Fish	858	7994	0	1137	10127	38830	58946
6.z. TOTAL	1668	15847	46	1795	164772	45546	229674

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	1180	4443	7857	0	1306	0	1945	1806	355	2166	156	0	32998	54212
7.b. Rats	1948	3203	27072	0	0	0	10847	2032	2987	4766	34214	0	12186	99255
7.c. Guinea-Pigs	122	0	0	0	0	0	0	0	0	0	0	0	1152	1274
7.d. Hamsters	0	0	40	0	0	0	96	0	0	0	0	0	334	470
7.e. Other Rodents	182	4	0	0	0	0	0	0	0	0	0	0	44	230
7.f. Rabbits	0	0	178	987	0	692	45	0	1795	0	162	0	1428	5287
7.g. Cats	0	0	2	0	0	0	0	0	0	0	0	0	21	23
7.h. Dogs	0	0	1244	0	0	0	840	0	0	0	95	0	242	2421
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	32	0	0	0	0	0	0	0	0	0	18	50
7.l. Pigs	0	0	124	8	0	0	104	0	0	0	0	0	616	852
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	6	6
7.n. Sheep	0	0	0	0	0	0	30	0	0	0	0	0	131	161
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	102	102
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	13	0	0	0	0	0	0	0	0	0	14	27
7.r. Old World Monkeys	0	0	539	0	0	0	228	0	0	0	0	0	227	994
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	368	182	594	0	0	0	0	0	0	0	556	0	3245	4945
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	400	0	0	0	0	0	0	0	0	0	19	419
7.y. Fish	5488	2228	8870	0	0	0	4032	0	0	0	1280	0	37048	58946
7.z. TOTAL	9288	10060	46965	995	1306	692	18167	3838	5137	6932	36463	0	89831	229674

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	122	1616	35252	181	308	8	14003	2502	4520	5285	22153	0	68846	154796
8.b. Products/substances used or intended to be used mainly in agriculture	1865	3105	3980	518	40	414	1629	1336	433	0	2785	0	6664	22769
8.c. Products/substances used or intended to be used mainly in industry	511	802	3183	292	898	266	771	0	88	1299	7515	0	3566	19191
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	4224	1147	4294	0	0	0	540	0	0	0	1384	0	784	12373
8.i. Other toxicological or safety evaluations	2566	3390	256	4	60	4	1224	0	96	348	2626	0	9971	20545
8.j. TOTAL	9288	10060	46965	995	1306	692	18167	3838	5137	6932	36463	0	89831	229674