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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

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

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BELGIUM

Statistical data submitted

The statistical data were submitted by the "*SPF Santé Publique, Sécurité de la Chaine Alimentaire et Environnement*" (Federal Public Service Health, Food Chain Safety and Environment).

Comments of the Belgian authorities

1. LABORATORIES

In 2011, 367 laboratories were approved for the use of animals for experimental purposes. They all provided their statistical data on the number of animals used in the course of 2011. Of these laboratories, 21% did not carry out any animal experiments in 2011.

2. NUMBER OF ANIMALS USED IN EXPERIMENTS

A total of 665,079 animals were used (*Table 1*), which is 5% less than the figure for 2010.

Table 1: 2011 - Number of animals used in experiments

Species	Number
Mice	408 883
Rats	89 547
Guinea pigs	24 300
Hamsters	2 435
Other rodents	421
Rabbits	54 001
Cats	630
Dogs	490
Ferrets	192
Other carnivores	0
Horses, donkeys and cross-breeds	54
Pigs	2 622
Goats	86
Sheep	542
Cattle	810

Prosimians	0
New world monkeys	0
Old world monkeys	20
Apes	0
Other mammals	64
Quails	651
Other birds	16 493
Reptiles	459
Amphibians	2 113
Fish	60 266
TOTAL	**665 079**

As regards the breakdown of the different animal species (*Table 2*), rodents and rabbits together made up 87.15% of the total number of animals used. Next come, in descending order, reptiles, amphibians and fish (9%) and birds (2.58%). Other species (farm animals, dogs and cats, monkeys) were much less used.

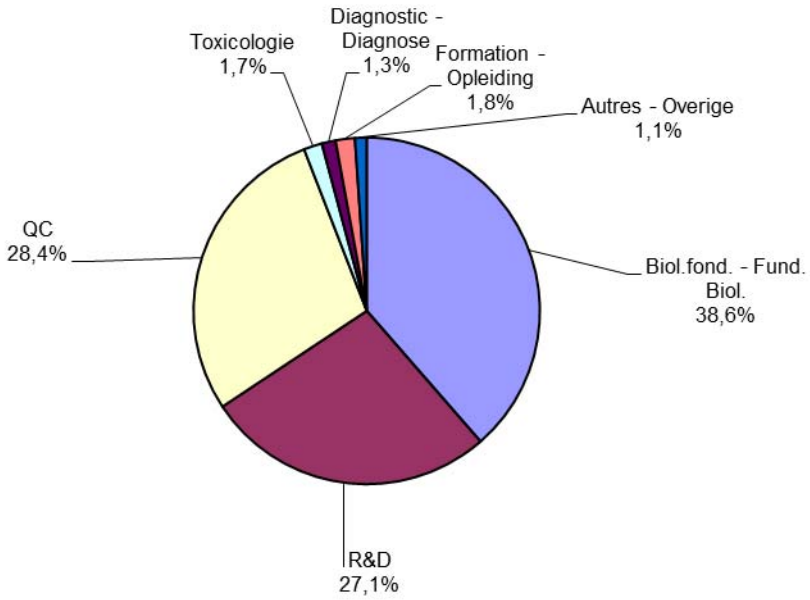
Table 2: 2011 - Breakdown of species used in experiments

Species	**Percentage**	**Number**
Rodents	79.03%	525 586
Rabbits	8.12%	54 001
Dogs/Cats	0.17%	1 120
Farm animals	0.62%	4 114
Primates	0.0030%	20
Birds	2.58%	17 144
Other warm-blooded animals	0.04%	256
Cold-blooded animals	9.45%	62 838

3. EXPERIMENTS CARRIED OUT

Animals are most used in the following fields (*Figures 1 and 2*):

- Basic research (38%), where the most commonly used animals were rodents (73%) and fish (20%).
- Research and development of products and devices used in human and veterinary medicine (27%), where 96% of the animals used were rodents.
- Tests on the production and quality control of products and devices used in human and veterinary medicine (28%); 72% of the animals used were rodents and 26% rabbits. As regards these tests, 98% of the animals were used to comply with statutory requirements.



Key to table:

Toxicologie - Toxicology

Diagnostic - Diagnosis

Formation - Training

Autres - Other

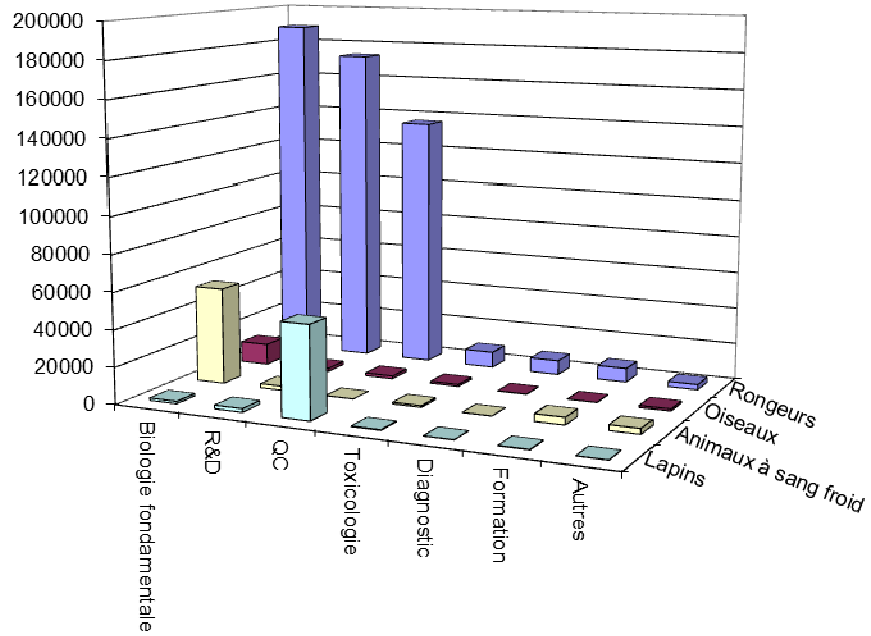
Biol. Fond - Basic biology

R&D - Research and Development

QC - Quality Control

Figure 1: 2011 - Breakdown of the experimental fields

In 2011, toxicological safety tests accounted for only 1.7% of the animals used in experiments; 85% of these animals were used in safety tests required by law. Rodents accounted for 76% of all the animals used in toxicological tests. The other species used were mainly fish (5%), birds (9%), dogs (3%) and rabbits (2%).



Key to table:

Rongeurs - Rodents

Oiseaux - Birds

Animaux à sang froid - Cold-blooded animals

Lapins - Rabbits

Autres - Other

Formation - Training

Diagnostic - Diagnosis

Toxicologie - Toxicology

QC - Quality Control

R&D - Research and Development

Biologie fondamentale - Basic biology

Figure 2: 2011 - Breakdown of experimental fields by the animals most used

The increase in the number of cats used as test animals (from 349 in 2010 to 630 in 2011) is mainly due to the research project on the sterilisation / early castration of cats. The project is part of the multiannual plan of the Animal Welfare Service of the Federal Public Service (SPF) for Public Health.

4. THE PROVENANCE OF THE ANIMALS USED IN EXPERIMENTS

In 2011, 87% of the animals provided by approved establishments came from Council of Europe Member States. The other species of animal that must not be reared solely for the purposes of animal experiments (farm animals) came from establishments that meet the current legal requirements for commercial establishments. The number of animals reused in certain experiments was 0.01% of the total number of animals used in 2011.

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*)	408883	135811	250514	40	22518	
1.b. Rats (*Rattus norvegicus*)	89547	17337	71081	0	1129	
1.c. Guinea-Pigs (*Cavia porcellus*)	24300	1942	22358	0	0	
1.d. Hamsters (*Mesocricetus*)	2435	412	1683	0	340	
1.e. Other Rodents (other *Rodentia*)	421					
1.f. Rabbits (*Oryctolagus cuniculus*)	54001	53146	851	0	4	379
1.g. Cats (*Felis catus*)	630	24	20	0	586	53
1.h. Dogs (*Canis familiaris*)	490	13	427	0	50	408
1.i. Ferrets (*Mustela putorius furo*)	192	0	192	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	54					
1.l. Pigs (*Sus*)	2622					
1.m. Goats (*Capra*)	86					
1.n. Sheep (*Ovis)*	542					
1.o. Cattle (*Bos*)	810					
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*)	20	10	6	3	1	54
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	64					
1.u. Quail (*Coturnix coturnix)*	651	11	0	0	640	
1.v. Other birds (other *Aves*)	16493					
1.w. Reptiles (*Reptilia*)	459					
1.x. Amphibians (*Amphibia*)	2113					
1.y. Fish (*Pisces*)	60266					
1.z. TOTAL	665079					

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	169926	118167	100056	3341	1939	7424	5308	2722	408883
2.b. Rats	18109	52400	9850	594	6524	387	1585	98	89547
2.c. Guinea-Pigs	252	2200	19469	1600	190	0	586	3	24300
2.d. Hamsters	350	532	0	1426	0	0	127	0	2435
2.e. Other Rodents	368	0	0	0	0	0	15	38	421
2.f. Rabbits	1280	1941	49354	1036	257	0	123	10	54001
2.g. Cats	22	4	0	18	0	586	0	0	630
2.h. Dogs	37	8	0	34	349	50	12	0	490
2.i. Ferrets	0	177	0	0	0	0	15	0	192
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	19	6	0	2	0	0	27	0	54
2.l. Pigs	1285	334	0	533	92	15	107	256	2622
2.m. Goats	20	66	0	0	0	0	0	0	86
2.n. Sheep	351	105	0	48	0	14	24	0	542
2.o. Cattle	379	104	0	237	63	0	17	10	810
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	9	11	0	0	0	0	0	0	20
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	15	49	0	0	0	0	0	0	64
2.u. Quail	651	0	0	0	0	0	0	0	651
2.v. Other birds	10884	1801	0	1536	1080	102	2	1088	16493
2.w. Reptiles	375	84	0	0	0	0	0	0	459
2.x. Amphibians	730	900	0	0	336	0	147	0	2113
2.y. Fish	51605	1250	0	0	551	0	3860	3000	60266
2.z. TOTAL	256667	180139	178729	10405	11381	8578	11955	7225	665079

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	1322	20	60	0	0	321	0	0	216	1939
3.b. Rats	6251	9	209	0	0	0	0	0	55	6524
3.c. Guinea-Pigs	190	0	0	0	0	0	0	0	0	190
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	251	6	0	0	0	0	0	0	0	257
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	349	0	0	0	0	0	0	0	0	349
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	55	0	0	0	0	0	0	0	37	92
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	14	0	0	0	0	0	0	0	49	63
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	552	0	0	0	0	0	0	0	528	1080
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	336	0	0	0	0	0	0	0	336
3.y. Fish	0	137	414	0	0	0	0	0	0	551
3.z. TOTAL	8984	508	683	0	0	321	0	0	885	11381

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	14294	44652	46555	125337	4758	232925
4.b. Rats	4332	29474	1749	28049	384	63926
4.c. Guinea-Pigs	800	0	0	1284	82	2166
4.d. Hamsters	0	0	14	490	0	504
4.e. Other Rodents	0	0	0	603	108	711
4.f. Rabbits	160	0	21	1147	104	1425
4.g. Cats	0	0	0	31	590	621
4.h. Dogs	115	0	0	5	54	174
4.i. Ferrets	0	0	0	177	0	177
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	8	8
4.l. Pigs	239	0	0	157	324	720
4.m. Goats	20	0	0	0	0	20
4.n. Sheep	286	0	0	126	17	429
4.o. Cattle	0	0	0	0	266	266
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	15	0	15
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	16	15	0	31
4.u. Quail	0	640	0	0	0	640
4.v. Other birds	0	45	0	292	8612	8949
4.w. Reptiles	0	0	0	0	84	84
4.x. Amphibians	0	0	0	404	38	442
4.y. Fish	0	80	0	2096	6053	8229
4.z. TOTAL	20246	74891	48355	160228	21482	322462

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	9859	0	12626	79132	1780	103397
5.b. Rats	90	0	0	3060	5254	2040	10444
5.c. Guinea-Pigs	0	1121	0	2848	17100	0	21069
5.d. Hamsters	0	84	0	0	1342	0	1426
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	369	0	758	49263	0	50390
5.g. Cats	0	18	0	0	0	0	18
5.h. Dogs	0	30	0	0	4	0	34
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	2	0	0	0	0	2
5.l. Pigs	0	533	0	0	0	0	533
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	48	0	0	0	0	48
5.o. Cattle	0	237	0	0	0	0	237
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	1536	0	0	0	0	1536
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	90	13837	0	19292	152095	3820	189134

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	25	537	0	0	797	580	1939
6.b. Rats	114	55	0	0	5965	390	6524
6.c. Guinea-Pigs	0	0	0	0	0	190	190
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	0	0	0	255	2	257
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	349	0	349
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	92	0	92
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	39	24	63
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	552	0	0	528	0	1080
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	336	336
6.y. Fish	0	0	0	414	0	137	551
6.z. TOTAL	139	1144	0	414	8025	1659	11381

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	180	128	415	0	80	0	427	0	0	0	208	0	501	1939
7.b. Rats	0	52	2213	0	0	0	815	490	0	454	2062	0	438	6524
7.c. Guinea-Pigs	0	0	0	0	0	0	0	0	0	0	0	0	190	190
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	49	3	0	3	0	0	0	0	197	0	5	257
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	229	0	0	0	0	0	0	0	0	0	120	349
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	55	0	0	0	0	0	0	0	0	0	37	92
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	24	0	0	0	0	0	39	63
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	1080	1080
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	336	0	336
7.y. Fish	414	0	0	0	0	0	0	0	0	0	0	137	0	551
7.z. TOTAL	594	180	2961	3	80	3	1266	490	0	454	2467	473	2410	11381

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	180	180	2743	0	0	0	1042	490	0	454	2467	0	1428	8984
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	9	3	20	3	0	0	0	0	0	473	0	508
8.c. Products/substances used or intended to be used mainly in industry	414	0	209	0	60	0	0	0	0	0	0	0	0	683
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	321	321
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i. Other toxicological or safety evaluations	0	0	0	0	0	0	224	0	0	0	0	0	661	885
8.j. TOTAL	594	180	2961	3	80	3	1266	490	0	454	2467	473	2410	11381

BULGARIA

Statistical data submitted

The statistical data were submitted by the Ministry of Agriculture and Food.

Comments of the Bulgarian authorities

The objective of this report is to present the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, the statistical data on the number of animals used for experimental and other scientific purposes in Republic of Bulgaria.

This report contains statistical data on the animals used for experimental and other scientific purposes. The data for this report covers the year 2011.

The Bulgarian Food Safety Agency (BFSA) is the competent authority on Animal welfare issues in Republic of Bulgaria. An organizational and implementation principle is that the AW requirements on the matters concerning animals used for experimental purposes must be performed by the 28 Regional Food Safety Directorates (RFSD) within the BFSA. The requirements of Directive 86/609/EEC have been transposed into the national legislation, namely in Ordinance № 15 on the minimum requirements for protection and welfare of laboratory animals and the requirements to the establishments using, breeding and/or supplying such animals (in force since 01.05.2006; published in SG No. 17 of 24 February 2006) and in the Law for Veterinary Activities.

In Bulgaria, experiments involving usage of live animals are carried out only where it is not possible to apply any alternative method(s) of the same purpose and result.

The use of experimental animals is permitted only in premises, that are authorized as being in compliance with the requirements laid down in Article 153 (1) of the Law on Veterinary Activities and which have official permit signed by the BFSA Executive Director. The BFSA Executive Director would issue the above mentioned permit on the basis of an ethical assessment and a positive opinion from the Animal Ethics Commission within BFSA. The Animal Ethics Commission has been established as a permanently operating consultative body with the BFSA Executive Director.

The members of the Animal Ethics Commission are as follows:

An official veterinary officer representing BFSA;

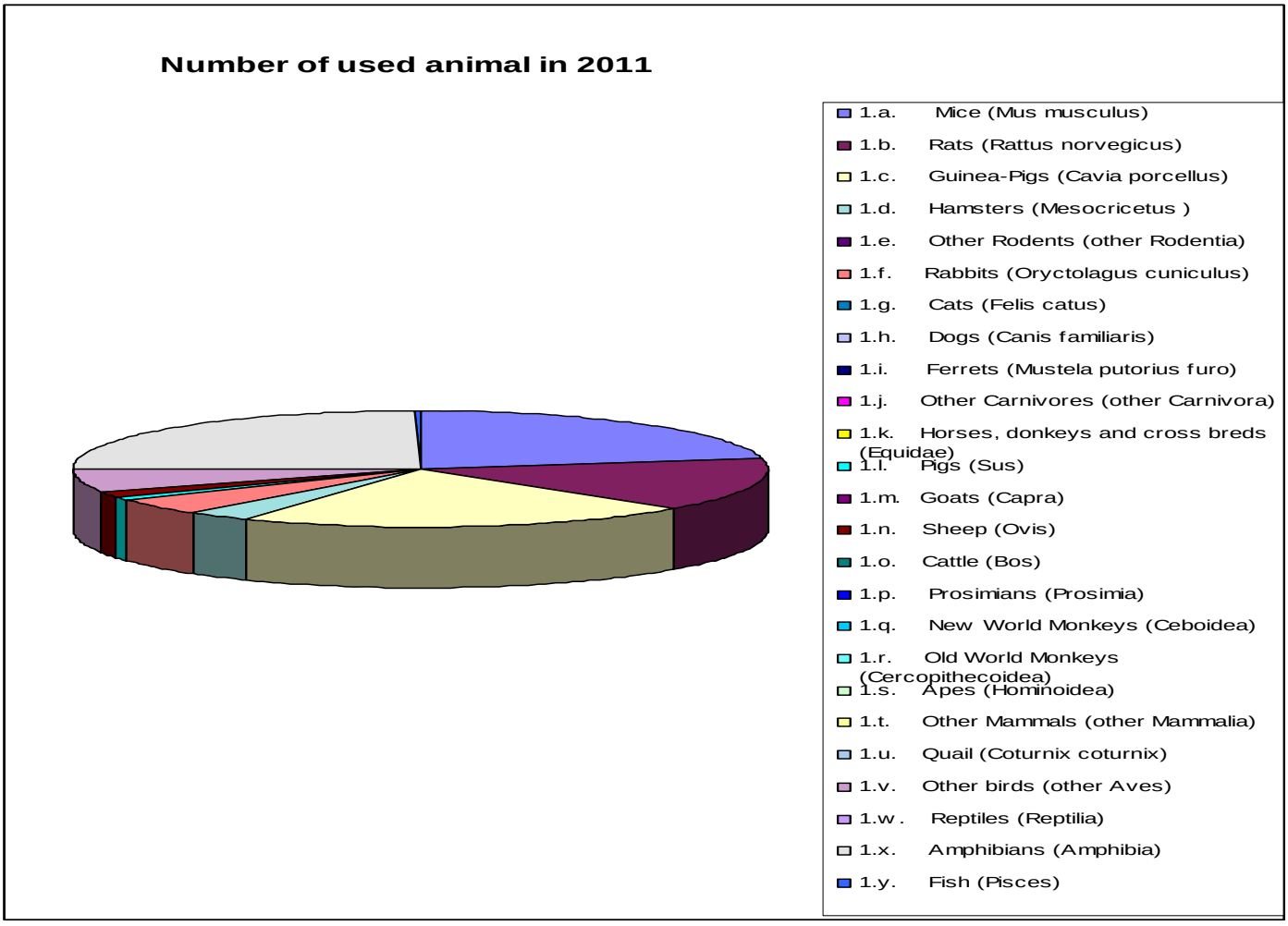
1. A veterinarian representing the Faculties of Veterinary Medicine;
2. A physician of toxicological specialization representing Ministry of Health;
3. A scientist or researcher of biological specialization representing Bulgarian Academy of Sciences;
4. An environmental expert representing Ministry of Environment and Water;
5. A zoologist representing the Biology Faculty at Sofia University;
6. A physician representing the Medical University in Sofia;
7. Two representatives of NGOs operating in the field of AW and protection of animals;
8. A lawyer representing the Ministry of Agriculture and Food;
9. A veterinarian representing the Ministry of Agriculture and Food.

The BFSA have a register of licenses for animals used for scientific purposes, published on the web-site:

http://babh.government.bg/uploads/File/ENG/Registers/ZHOJ/Register_engl_opitni_jivotni.pdf

The register is updated regularly.

In order to present an overall evaluation and subsequently a graphical analysis, animal species were grouped. The Figure 1 gives an overview of the species used in 2011 in Republic of Bulgaria.



Amphibians represent the highest percentage of the animals used in 2011 (24.83%) followed by the mice (22.13%) and guinea pigs (21.44%) are by far the most commonly used species.

Comparison between proportions of classes of animals used in 2008 and 2011

Class of species	2008 (%)	2011(%)
Mice	49,90	22,13
Rats	13,85	14,88
Guinea-Pigs	11,80	21,44
Hamsters	0,56	2,99
Rabbits-	2,50	

Cats	0,03	4,76
Dogs	0,05	0,05
Horses	0,05	
Pigs	0,42	
Goats	0,25	
Sheep	0,77	
Cattle	0,39	
Other birds	4,54	0,64
Amphibians	14,74	24.83
Fish -	0,15	0.17

Comparison with the data of the previous report

The comparison aims to detect changes in trends rather than draw formal conclusions.

The most significant change that has taken place since 2008 is that the number of animals used for research and development for human medicine, dentistry and veterinary medicine has dropped sharply from 32,581 to 17,259.

The number of mice used in 2011 has drastically decreased with more than 25% - from 49.90 % in 2008 to 22.13% in 2011. In 2011 the use of cold-blooded animals has increased with about 10% - from 14, 75% in 2008 to 24,83%.

Birds seem to be decrease over the years from 4.54 to 0.64%. The group of horses, donkeys and cross-bred animals (artiodactyla) and pigs, goats, sheep and cattle (perissodactyla) fluctuates at around 1%.

In Bulgaria the animals used for scientific purposes in 2011 are originated from EU countries.

The following experiments were carried out in 2011:

- Education and training (E&T)
- Biological studies of a fundamental nature
- Research and development of products and devices for human medicine and dentistry and for veterinary medicine (R&D)
- Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary
- Medicine (T&S evaluations)
- Studies and Diagnosis of Human and Animal disease (S&D of disease)

Experiments which are not permitted in Bulgaria:

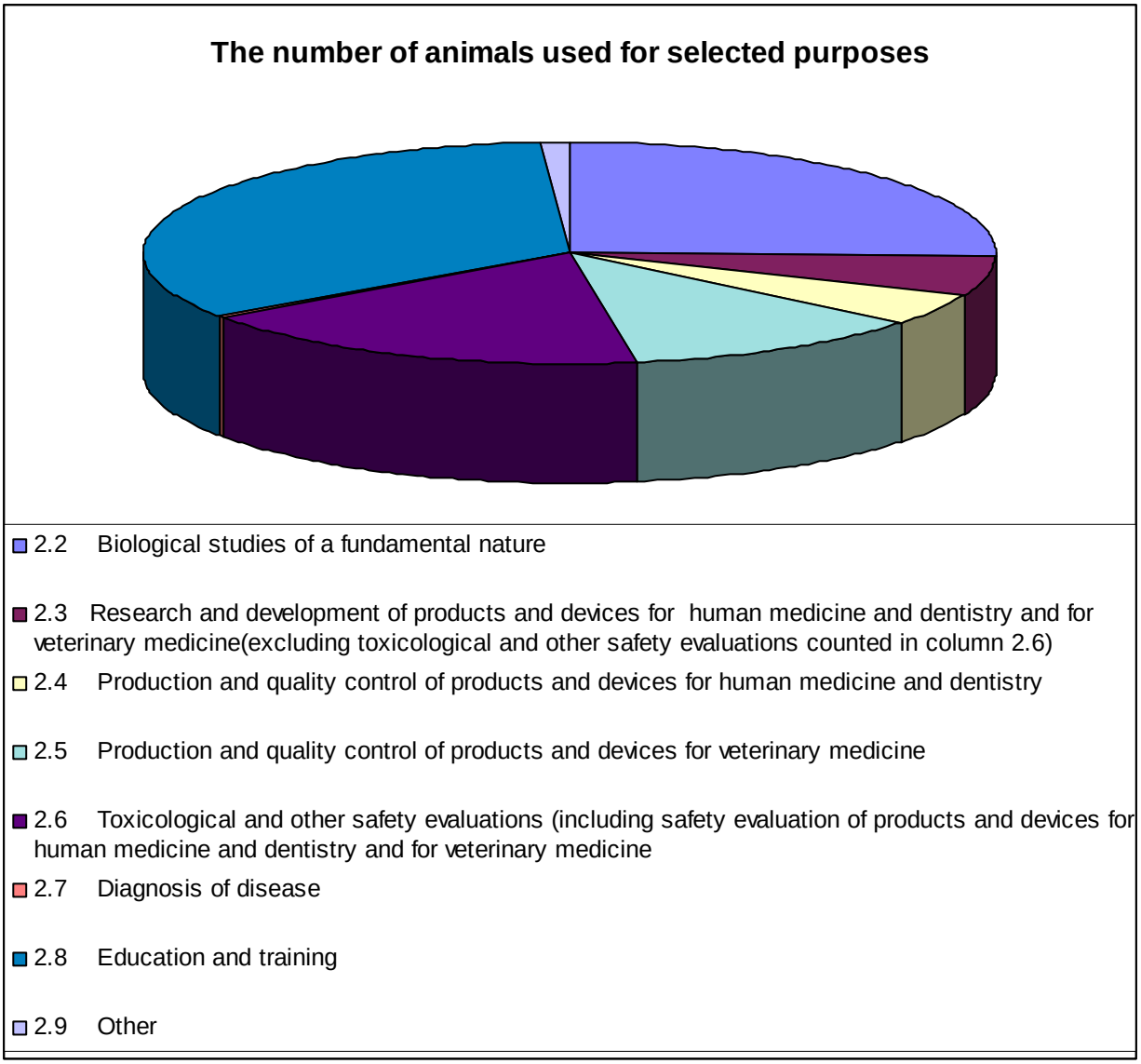
(1) for educational purposes, which cause death of animals; in educational establishments animal experiments shall be replaced by other methods for visualizing the subject taught in all cases where the use of animals might be replaced by other methods and if the aim is not to provide the students with specific practical skills;

(2) if the result can be achieved with any method not involving the use of live animal(s);

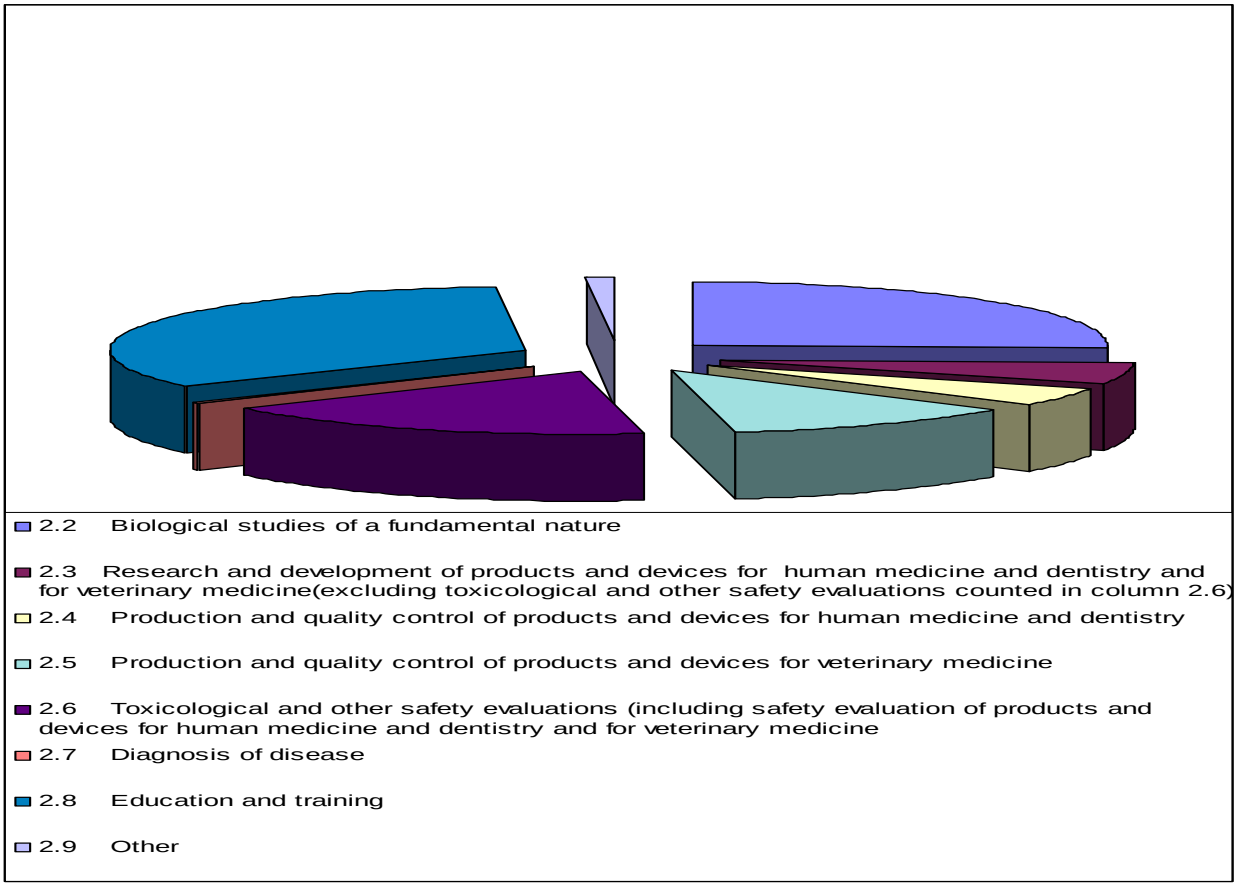
(3) if they use stray and/or domestic dogs or cats as experimental animals.

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in Republic of Bulgaria in 2011.

The number of animals used for selected purposes is presented in Figure 2:



The percentage of animals used for selected purposes is presented in Figure 3:



The main percentage of used animals is for education and training – 33.79%. The 25, 59% of animals were used in fundamental biological studies.

Toxicological and other safety evaluation represents 17.41% of the total number of animals used for experimental purposes.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 4.64% of the total number of animals.

Conclusion:

In 2011 in Republic of Bulgaria there **is a huge decrease with about 53%** in the total number of animals used. The main percentage of used animals is for education and training.

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*)	3819	2206	13	1600		
1.b. Rats (*Rattus norvegicus*)	2569	2569				
1.c. Guinea-Pigs (*Cavia porcellus*)	3700	700		3000		
1.d. Hamsters (*Mesocricetus*)	516	516				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	822	579	3	240		110
1.g. Cats (*Felis catus*)	8	8				
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*)	110					
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*	320					
1.o. Cattle (*Bos*)						
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)*	0					
1.v. Other birds (other *Aves*)	1080					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	4285					
1.y. Fish (*Pisces*)	30					
1.z. TOTAL	17259					

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	1034	265	200	400	1195	40	685		3819
2.b. Rats	1082	682			10		627	168	2569
2.c. Guinea-Pigs	390		532	1200	1510		68		3700
2.d. Hamsters	512						4		516
2.e. Other Rodents									0
2.f. Rabbits	9		60	310	240		193	10	822
2.g. Cats			8						8
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs				110					110
2.m. Goats									0
2.n. Sheep	300			20					320
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	1030				50				1080
2.w. Reptiles									0
2.x. Amphibians	60						4225		4285
2.y. Fish							30		30
2.z. TOTAL	4417	947	800	2040	3005	40	5832	178	17259

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	945								250	1195
3.b. Rats									10	10
3.c. Guinea-Pigs	1100								410	1510
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	120								120	240
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									50	50
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	2165	0	0	0	0	0	0	0	840	3005

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	40	211		204	170	625
4.b. Rats		5		233	84	322
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits				16		16
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					80	80
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	40	216	0	453	334	1043

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		600					600
5.b. Rats							0
5.c. Guinea-Pigs		1600					1732
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		150					370
5.g. Cats		8					8
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs							110
5.m. Goats							0
5.n. Sheep							20
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	2358	0	0	0	0	2840

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		1195					1195
6.b. Rats		10					10
6.c. Guinea-Pigs		1510					1510
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		240					240
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		50					50
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	0	3005	0	0	0	0	3005

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		945						50					200	1195
7.b. Rats								10						10
7.c. Guinea-Pigs		1100						110					300	1510
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits		120											120	240
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								50						50
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	2165	0	0	0	0	0	220	0	0	0	0	620	3005

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		1325						220					620	2165
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		840												840
8.j. TOTAL	0	2165	0	0	0	0	0	220	0	0	0	0	620	3005

CZECH REPUBLIC

Statistical data submitted

The statistical data were submitted by the Ministry of Agriculture (*Ministerstvo zemědělství*).

Comments of the Czech authorities

Protection of animals and animal welfare in the Czech Republic (CR) is the responsibility of the Ministry of Agriculture. The animal welfare activities are implemented pursuant to Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended. The supervision over these matters has been the responsibility of the State Veterinary Administrations' inspectors in 13 regions of the CR and in Prague since 1992.

Altogether 131 inspections of experiments on animals were carried out in 2011, involving 118,558 animals. The administrative procedure was carried out with the user establishment taking blood samples of horses for pharmacological purposes.

In 2011 a total of 354,196 animals were used for experimental and other scientific purposes in the CR. It shall be pointed out that 45.95% of it is represented by ringed birds (162,768 birds) since pursuant to the relevant Czech legislation even bird ringing is an experiment.

Only 0.09 % were cats (181 cats), 0.72 % dogs (1,386 dogs), 0.02% monkeys (30 monkeys) of the remaining 191,428 animals used for experimental and scientific purposes while no apes were used. Rodents and rabbits (60.60%, i.e. 116,010 animals) and fish (27.61%, i.e. 52,861 fish) represent the prevailing majority of animals used.

In the last couple of years the number of experimental animals used in the CR was approximately the same (approximately 210,000 animals excluding ringed birds). Fluctuations in numbers, if any, are caused by experiments using fish and poultry because these experiments are usually conducted on a large group of animals (a flock in houses or stock in water reservoirs).

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

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

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*)	72855	72599	256	0	0	
1.b. Rats (*Rattus norvegicus*)	30829	30641	188	0	0	
1.c. Guinea-Pigs (*Cavia porcellus*)	3304	3304	0	0	0	
1.d. Hamsters (*Mesocricetus*)	119	49	70	0	0	
1.e. Other Rodents (other *Rodentia*)	1316					
1.f. Rabbits (*Oryctolagus cuniculus*)	7677	4540	3137	0	0	20
1.g. Cats (*Felis catus*)	181	181	0	0	0	260
1.h. Dogs (*Canis familiaris*)	1386	1346	40	0	0	52
1.i. Ferrets (*Mustela putorius furo*)	193	185	8	0	0	0
1.j. Other Carnivores (other *Carnivora*)	45					
1.k. Horses, donkeys and cross breds (*Equidae*)	595					
1.l. Pigs (*Sus*)	2283					
1.m. Goats (*Capra*)	106					
1.n. Sheep (*Ovis)*	1147					
1.o. Cattle (*Bos*)	783					
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*)	30	30	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	2838					
1.u. Quail (*Coturnix coturnix)*	230	230	0	0	0	
1.v. Other birds (other *Aves*)	170261					
1.w. Reptiles (*Reptilia*)	1258					
1.x. Amphibians (*Amphibia*)	3989					
1.y. Fish (*Pisces*)	52771					
1.z. TOTAL	354196					

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	41191	4154	286	12623	5310	4594	2924	1773	72855
2.b. Rats	21280	5046	78	550	2228	122	1525	0	30829
2.c. Guinea-Pigs	1263	316	0	1071	600	2	52	0	3304
2.d. Hamsters	12	100	0	0	0	0	4	3	119
2.e. Other Rodents	1163	0	0	0	70	0	48	35	1316
2.f. Rabbits	1123	111	69	5665	418	83	163	45	7677
2.g. Cats	0	56	0	8	112	0	5	0	181
2.h. Dogs	0	1021	0	118	232	0	15	0	1386
2.i. Ferrets	0	185	0	0	8	0	0	0	193
2.j. Other Carnivores	13	0	0	0	32	0	0	0	45
2.k. Horses, donkeys and cross breds	6	170	0	387	11	0	13	8	595
2.l. Pigs	1042	487	0	556	127	0	71	0	2283
2.m. Goats	62	0	0	0	0	20	18	6	106
2.n. Sheep	646	58	0	92	0	315	36	0	1147
2.o. Cattle	259	167	0	253	21	20	63	0	783
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	28	0	0	0	0	0	2	30
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	2477	0	0	182	179	0	0	0	2838
2.u. Quail	161	0	0	0	0	0	69	0	230
2.v. Other birds	162768	5608	0	689	0	55	349	792	170261
2.w. Reptiles	1166	0	0	0	0	0	92	0	1258
2.x. Amphibians	3891	0	0	0	0	0	64	34	3989
2.y. Fish	13772	0	0	0	32490	284	644	5581	52771
2.z. TOTAL	252295	17507	433	22194	41838	5495	6155	8279	354196

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	4739	0	62	0	0	0	0	237	272	5310
3.b. Rats	1366	0	862	0	0	0	0	0	0	2228
3.c. Guinea-Pigs	469	0	131	0	0	0	0	0	0	600
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	70	0	0	0	0	0	0	0	0	70
3.f. Rabbits	358	0	60	0	0	0	0	0	0	418
3.g. Cats	112	0	0	0	0	0	0	0	0	112
3.h. Dogs	232	0	0	0	0	0	0	0	0	232
3.i. Ferrets	8	0	0	0	0	0	0	0	0	8
3.j. Other Carnivores	32	0	0	0	0	0	0	0	0	32
3.k. Horses, donkeys and cross breds	11	0	0	0	0	0	0	0	0	11
3.l. Pigs	127	0	0	0	0	0	0	0	0	127
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	21	0	0	0	0	0	0	0	0	21
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	179	0	0	0	0	0	0	0	0	179
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	560	0	0	0	0	29102	2828	32490
3.z. TOTAL	7724	0	1675	0	0	0	0	29339	3100	41838

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	1196	1873	10234	13084	1008	27395
4.b. Rats	2107	1700	2516	8609	367	15299
4.c. Guinea-Pigs	0	0	0	141	94	235
4.d. Hamsters	0	0	0	30	70	100
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	116	0	0	390	185	691
4.g. Cats	0	0	0	4	52	56
4.h. Dogs	9	0	0	68	944	1021
4.i. Ferrets	0	0	0	185	0	185
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	6	170	176
4.l. Pigs	150	76	24	279	558	1087
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	2	0	0	919	58	979
4.o. Cattle	0	0	0	6	182	188
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	28	0	28
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	2709	4157	6866
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	697	697
4.z. TOTAL	3580	3649	12774	26458	8542	55003

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	3327	8742	0	125	0	715	12909
5.b. Rats	61	550	0	17	0	0	628
5.c. Guinea-Pigs	326	745	0	0	0	0	1071
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	168	5069	0	0	0	497	5734
5.g. Cats	0	8	0	0	0	0	8
5.h. Dogs	0	118	0	0	0	0	118
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	338	20	0	0	17	12	387
5.l. Pigs	60	0	0	0	198	0	258
5.m. Goats	0	298	0	0	0	0	298
5.n. Sheep	3	0	0	0	76	13	92
5.o. Cattle	0	0	0	0	232	0	232
5.p. Prosimians	0	21	0	0	0	0	21
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	68	182	0	15	606	0	871
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	4351	15753	0	157	1129	1237	22627

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	1030	4043	0	0	0	237	5310
6.b. Rats	853	1375	0	0	0	0	2228
6.c. Guinea-Pigs	88	512	0	0	0	0	600
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	70	0	0	0	0	70
6.f. Rabbits	89	99	0	0	0	0	188
6.g. Cats	0	230	0	0	0	0	230
6.h. Dogs	114	112	0	0	0	0	226
6.i. Ferrets	0	118	0	0	0	0	118
6.j. Other Carnivores	0	8	0	0	0	0	8
6.k. Horses, donkeys and cross breds	0	32	0	0	0	0	32
6.l. Pigs	0	11	0	0	0	0	11
6.m. Goats	0	127	0	0	0	0	127
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	21	0	0	0	0	21
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	179	0	0	0	0	179
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	30580	1910	0	0	0	0	32490
6.z. TOTAL	32754	8847	0	0	0	237	41838

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	295	543	429	0	99	0	0	0	0	0	0	0	3944	5310
7.b. Rats	196	853	108	0	0	0	314	0	127	269	280	0	81	2228
7.c. Guinea-Pigs	0	0	0	88	166	0	0	0	0	0	0	0	346	600
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	70	70
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	230	230
7.f. Rabbits	10	0	29	131	0	18	0	0	0	0	0	0	112	300
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	118	118
7.h. Dogs	0	0	0	0	0	0	0	0	0	0	0	0	122	122
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	32	32
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	11	11
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	127	127
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	21	21
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	179	179
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	20793	8909	0	0	0	0	0	0	0	0	0	2788	0	32490
7.z. TOTAL	21294	10305	566	219	265	18	314	0	127	269	280	2788	5393	41838

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	245	1396	29	177	78	0	206	0	127	160	0	0	5306	7724
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	736	0	108	42	187	18	108	0	0	109	280	0	87	1675
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	20181	7563	157	0	0	0	0	0	0	0	0	1438	0	29339
8.i. Other toxicological or safety evaluations	132	1346	272	0	0	0	0	0	0	0	0	1350	0	3100
8.j. TOTAL	21294	10305	566	219	265	18	314	0	127	269	280	2788	5393	41838

DENMARK

Statistical data submitted

The statistical data were submitted by the '*Dyreforsøgstilsynet*' (Animal Experiments Inspectorate).

Comments of Danish authorities

In 2011, 282,840 animals were used for experimental purposes in Denmark, 11,372 more than in 2010. This is a modest increase of 4.2%.

However the number of traditional laboratory animals such as mice and rats decreased from 2010 to 2011 from 154,963 to 141,991 mice and from 69,186 to 67,159 rats. This is probably due to random changes and a general decrease in activity due to financial difficulties in Denmark.

However attention should be drawn to one particular figure: the increase in the use of fish for experimental purposes. From 2010 to 2011 the number of fish increased from 27,780 animals in 2010 to 51,159 animals in 2011. This increase alone almost explains the total increase of animals used for experimental purposes in 2011.

A large portion of the fish – 24,968 - were used for modeling human neurological disorders. But many fish were also used for development of vaccines for fish in aquaculture, potentially reducing the need for antibiotics.

When collecting the statistical information for 2011, the Animal Experiments Inspectorate also asked for data on which and how many of the animals were genetically modified.

A total of 21,961 mice, 60 rats, 50 pigs and 7,278 fish included in the statistics were used for *in vivo* experimental purposes. Furthermore 13 new genetic modified mice strains and 83 cloned pigs were produced. 12 of the cloned pigs were used in experiments. 4,746 mice not included in the statistics, were used for *in vitro* 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*)	141991	105803	32302	14	3872	
1.b. Rats (*Rattus norvegicus*)	67159	41624	23412	0	2123	
1.c. Guinea-Pigs (*Cavia porcellus*)	4672	290	4378	0	4	
1.d. Hamsters (*Mesocricetus*)	178	0	90	0	88	
1.e. Other Rodents (other *Rodentia*)	115					
1.f. Rabbits (*Oryctolagus cuniculus*)	3602	509	688	0	2405	82
1.g. Cats (*Felis catus*)	0	0	0	0	0	0
1.h. Dogs (*Canis familiaris*)	470	13	426	0	31	51
1.i. Ferrets (*Mustela putorius furo*)	129	129	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	197					
1.k. Horses, donkeys and cross breds (*Equidae*)	67					
1.l. Pigs (*Sus*)	8694					
1.m. Goats (*Capra*)	74					
1.n. Sheep (*Ovis)*	191					
1.o. Cattle (*Bos*)	513					
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*)	32					
1.u. Quail (*Coturnix coturnix)*	0	0	0	0	0	
1.v. Other birds (other *Aves*)	3245					
1.w. Reptiles (*Reptilia*)	237					
1.x. Amphibians (*Amphibia*)	115					
1.y. Fish (*Pisces*)	51159					
1.z. TOTAL	282840					

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	50102	65748	11983	200	3490	1223	1540	7705	141991
2.b. Rats	13806	38037	7700	0	5190	53	1724	649	67159
2.c. Guinea-Pigs	187	312	4015	15	88	0	19	36	4672
2.d. Hamsters	88	0	0	0	90	0	0	0	178
2.e. Other Rodents	0	115	0	0	0	0	0	0	115
2.f. Rabbits	114	572	300	56	150	2405	5	0	3602
2.g. Cats	0	0	0	0	0	0	0	0	0
2.h. Dogs	31	115	0	0	311	0	13	0	470
2.i. Ferrets	111	18	0	0	0	0	0	0	129
2.j. Other Carnivores	197	0	0	0	0	0	0	0	197
2.k. Horses, donkeys and cross breds	16	31	4	0	0	0	16	0	67
2.l. Pigs	4265	1695	450	40	629	81	950	584	8694
2.m. Goats	0	13	0	0	0	54	0	7	74
2.n. Sheep	80	0	0	0	0	0	44	67	191
2.o. Cattle	392	28	5	5	0	0	83	0	513
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	32	0	0	0	0	0	0	0	32
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	2950	215	2	72	0	4	2	0	3245
2.w. Reptiles	237	0	0	0	0	0	0	0	237
2.x. Amphibians	115	0	0	0	0	0	0	0	115
2.y. Fish	41565	2855	0	0	600	0	139	6000	51159
2.z. TOTAL	114288	109754	24459	388	10548	3820	4535	15048	282840

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	490	706	2132	0	0	0	0	0	162	3490
3.b. Rats	2512	238	156	386	0	216	10	1656	16	5190
3.c. Guinea-Pigs	58	0	0	0	0	0	0	0	30	88
3.d. Hamsters	90	0	0	0	0	0	0	0	0	90
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	122	0	0	0	0	0	0	0	28	150
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	308	0	0	0	0	0	0	0	3	311
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	599	0	0	0	0	0	0	0	30	629
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	600	0	0	0	0	0	0	0	0	600
3.z. TOTAL	4779	944	2288	386	0	216	10	1656	269	10548

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	2765	25452	9063	45769	340	83389
4.b. Rats	2500	24728	407	17345	14	44994
4.c. Guinea-Pigs	60	126	0	93	28	307
4.d. Hamsters	0	0	0	0	0	0
4.e. Other Rodents	0	0	0	115	0	115
4.f. Rabbits	0	0	2405	470	0	2875
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	0	8	27	80	30	145
4.i. Ferrets	0	0	0	111	0	111
4.j. Other Carnivores	0	0	0	0	42	42
4.k. Horses, donkeys and cross breds	0	0	0	0	13	13
4.l. Pigs	469	95	62	2122	51	2799
4.m. Goats	0	0	54	8	0	62
4.n. Sheep	0	0	0	72	0	72
4.o. Cattle	0	0	0	0	0	0
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	20	20
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	117	1050	1167
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	105	0	0	0	105
4.y. Fish	0	24968	0	0	0	24968
4.z. TOTAL	5794	75482	12018	66302	1588	161184

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	9950	0	1165	1043	25	12183
5.b. Rats	0	206	0	0	7494	0	7700
5.c. Guinea-Pigs	15	3593	0	0	60	362	4030
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	12	34	0	0	0	310	356
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	4	4
5.l. Pigs	40	22	0	0	428	0	490
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	0	0	0
5.o. Cattle	5	0	0	0	0	5	10
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	72	0	0	0	2	0	74
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	144	13805	0	1165	9027	706	24847

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	216	0	0	0	248	3026	3490
6.b. Rats	303	0	0	0	2428	2459	5190
6.c. Guinea-Pigs	22	0	0	0	36	30	88
6.d. Hamsters	0	0	0	0	90	0	90
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	150	0	150
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	311	0	311
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	629	0	629
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	0	600	600
6.z. TOTAL	541	0	0	0	3892	6115	10548

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	706	275	6	102	0	78	107	0	101	0	0	2115	3490
7.b. Rats	0	0	1340	196	32	0	1184	48	0	96	1952	0	342	5190
7.c. Guinea-Pigs	0	0	22	0	0	0	36	0	0	0	0	0	30	88
7.d. Hamsters	0	0	90	0	0	0	0	0	0	0	0	0	0	90
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	39	66	0	0	45	0	0	0	0	0	0	150
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	2	0	0	0	309	0	0	0	0	0	0	311
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	4	0	0	0	531	0	0	0	86	0	8	629
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	0	0	0	0	0	0	0	0	0	0	0	0	600	600
7.z. TOTAL	0	706	1772	268	134	0	2183	155	0	197	2038	0	3095	10548

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub-chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop-mental toxicity	8.9 Muta-genicity	8.10 Repro-ductive toxicity	8.11 Toxicity to aquatic vertebra-tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	0	1758	240	134	0	1924	0	0	29	86	0	608	4779
8.b. Products/substances used or intended to be used mainly in agriculture	0	706	0	0	0	0	0	0	0	0	238	0	0	944
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	4	0	168	56	0	2060	2288
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	46	0	340	386
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	216	0	0	0	0	0	0	216
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	10	0	0	0	0	0	0	10
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	44	0	0	1612	0	0	1656
8.i. Other toxicological or safety evaluations	0	0	14	28	0	0	33	107	0	0	0	0	87	269
8.j. TOTAL	0	706	1772	268	134	0	2183	155	0	197	2038	0	3095	10548

GERMANY

Statistical data submitted

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

Comments of German authorities

In 2011, a total of 2,073,702 vertebrates were used in Germany for experimental and other scientific purposes. This is a decrease of 4,338 animals compared to the previous year. This means that for the second time in a row, the number of animals used for the first time has decreased from the previous year. Almost 87% of the test animals used were rodents, primarily mice and rats. Fish accounted for 6%, and rabbits for 4%. While there was an increase particularly in the numbers of mice, fish and sheep used, there were also some decreases, including for rats, birds, dogs, cats and monkeys.

60% of the animals were used to research diseases in humans or animals.

With regard to the purposes of the experiments, there was an increase of 2.7% in basic biological research, 4.4% in the production and quality control of medical products and 0.5% in toxicological testing or other safety testing. On the other hand, there was a decrease of 10.1% in their use in the research and development of products and equipment for medicine, dentistry and veterinary medicine, and a decrease of 21.7% in the diagnosis of diseases.

The current state of scientific knowledge means that experiments on animals cannot be dispensed with altogether, despite the increased use of alternative methods. The German Government nevertheless aims to limit these to the extent they cannot be avoided and, in cases where animal testing is currently indispensable, to ensure that the conditions in which the animals are kept and used are in line with animal protection laws. Despite this, all efforts must continue to be made to replace animal testing with alternative methods whenever possible.

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*)	1 451 046	1 242 489	193 228	6 894	8 435	
1.b. Rats (*Rattus norvegicus*)	312 740	216 556	95 205	72	907	
1.c. Guinea-Pigs (*Cavia porcellus*)	24 258	23 177	990	17	74	
1.d. Hamsters (*Mesocricetus*)	4 187	3 391	592	0	204	
1.e. Other Rodents (other *Rodentia*)	4 111					
1.f. Rabbits (*Oryctolagus cuniculus*)	87 303	85 679	1 616	0	8	1 857
1.g. Cats (*Felis catus*)	585	214	182	0	189	328
1.h. Dogs (*Canis familiaris*)	2 474	832	750	0	892	1 015
1.i. Ferrets (*Mustela putorius furo*)	96	6	15	40	35	0
1.j. Other Carnivores (other *Carnivora*)	262					
1.k. Horses, donkeys and cross breds (*Equidae*)	1 140					
1.l. Pigs (*Sus*)	15 090					
1.m. Goats (*Capra*)	394					
1.n. Sheep (*Ovis)*	3 287					
1.o. Cattle (*Bos*)	4 300					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	80
1.q. New World Monkeys (*Ceboidea*)	191	157	5	0	29	219
1.r. Old World Monkeys (*Cercopithecoidea*)	1 579	244	1 331	0	4	848
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	1 154					
1.u. Quail (*Coturnix coturnix)*	2 821	2 821	0	0	0	
1.v. Other birds (other *Aves*)	31 271					
1.w. Reptiles (*Reptilia*)	1 011					
1.x. Amphibians (*Amphibia*)	4 453					
1.y. Fish (*Pisces*)	119 949					
1.z. TOTAL	2 073 702					

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	860 843	322 810	101 215	9 430	63 820	9 816	42 134	40 978	1 451 046
2.b. Rats	65 804	128 824	46 788	3 637	48 180	415	16 370	2 722	312 740
2.c. Guinea-Pigs	815	4 102	13 642	655	3 875	10	393	766	24 258
2.d. Hamsters	1 082	2 375	49	0	66	0	159	456	4 187
2.e. Other Rodents	1 775	1 451	0	0	0	461	189	235	4 111
2.f. Rabbits	1 193	3 574	78 308	854	2 115	56	239	964	87 303
2.g. Cats	35	369	71	1	66	5	14	24	585
2.h. Dogs	25	954	0	0	1 260	197	26	12	2 474
2.i. Ferrets	87	9	0	0	0	0	0	0	96
2.j. Other Carnivores	49	0	0	213	0	0	0	0	262
2.k. Horses, donkeys and cross breds	305	302	0	23	0	424	57	29	1 140
2.l. Pigs	2 878	6 616	92	556	339	2 096	2 287	226	15 090
2.m. Goats	97	185	6	0	2	9	90	5	394
2.n. Sheep	772	974	1 166	6	19	64	179	107	3 287
2.o. Cattle	1 063	839	6	730	32	730	802	98	4 300
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	82	11	0	0	0	0	0	98	191
2.r. Old World Monkeys	36	56	0	0	1 072	0	199	216	1 579
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	1 117	0	4	0	0	0	26	7	1 154
2.u. Quail	10	0	0	0	2 804	0	7	0	2 821
2.v. Other birds	11 559	5 602	8 334	791	424	1 507	608	2 446	31 271
2.w. Reptiles	569	14	0	0	0	412	16	0	1 011
2.x. Amphibians	3 303	34	0	0	140	5	734	237	4 453
2.y. Fish	64 436	364	0	60	50 442	117	3 201	1 329	119 949
2.z. TOTAL	1 017 935	479 465	249 681	16 956	174 656	16 324	67 730	50 955	2 073 702

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	50 679	4 858	7 922	0	0	0	0	40	321	63 820
3.b. Rats	24 817	8 943	13 234	135	0	0	0	787	264	48 180
3.c. Guinea-Pigs	2 594	676	509	76	0	0	0	0	20	3 875
3.d. Hamsters	16	0	50	0	0	0	0	0	0	66
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1 593	342	178	2	0	0	0	0	0	2 115
3.g. Cats	66	0	0	0	0	0	0	0	0	66
3.h. Dogs	1 166	94	0	0	0	0	0	0	0	1 260
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	339	0	0	0	0	0	0	0	0	339
3.m. Goats	0	2	0	0	0	0	0	0	0	2
3.n. Sheep	19	0	0	0	0	0	0	0	0	19
3.o. Cattle	32	0	0	0	0	0	0	0	0	32
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	1 072	0	0	0	0	0	0	0	0	1 072
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	2 804	0	0	0	0	0	0	0	2 804
3.v. Other birds	40	342	0	0	0	0	0	0	42	424
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	140	0	140
3.y. Fish	3 994	14 444	2 890	0	0	0	0	28 994	120	50 442
3.z. TOTAL	86 427	32 505	24 783	213	0	0	0	29 961	767	174 656

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	104 726	175 441	267 231	464 178	5 571	1 017 147
4.b. Rats	31 810	57 964	9 645	82 775	1 198	183 392
4.c. Guinea-Pigs	519	197	18	3 031	53	3 818
4.d. Hamsters	1 549	5	56	1 343	0	2 953
4.e. Other Rodents	0	193	0	1 587	951	2 731
4.f. Rabbits	1 257	137	131	2 359	273	4 157
4.g. Cats	0	7	0	9	378	394
4.h. Dogs	239	6	7	115	654	1 021
4.i. Ferrets	0	6	0	90	0	96
4.j. Other Carnivores	0	0	0	0	29	29
4.k. Horses, donkeys and cross breds	0	0	0	17	976	993
4.l. Pigs	2 219	113	55	1 403	5 358	9 148
4.m. Goats	9	15	0	138	79	241
4.n. Sheep	245	63	0	828	508	1 644
4.o. Cattle	5	0	0	289	1 421	1 715
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	7	33	0	44	0	84
4.r. Old World Monkeys	8	4	17	32	0	61
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	141	0	50	1	192
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	108	0	0	1 460	7 032	8 600
4.w. Reptiles	0	39	0	0	462	501
4.x. Amphibians	438	91	0	629	5	1 163
4.y. Fish	1 248	2 823	371	5 330	553	10 325
4.z. TOTAL	144 387	237 278	277 531	565 707	25 502	1 250 405

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	90 686	0	16 092	80	3 787	110 645
5.b. Rats	0	49 838	0	0	196	391	50 425
5.c. Guinea-Pigs	0	13 842	0	185	11	259	14 297
5.d. Hamsters	0	49	0	0	0	0	49
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	42 872	0	0	1 352	34 938	79 162
5.g. Cats	0	71	0	0	0	1	72
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	213	0	0	0	0	213
5.k. Horses, donkeys and cross breds	0	17	0	0	0	6	23
5.l. Pigs	75	470	0	0	0	103	648
5.m. Goats	0	0	0	0	0	6	6
5.n. Sheep	24	0	0	0	0	1 148	1 172
5.o. Cattle	0	730	0	0	0	6	736
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	4	4
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	869	0	0	8 057	199	9 125
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	60	60
5.z. TOTAL	99	199 657	0	16 277	9 696	40 908	266 637

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	89	54 028	0	0	8 673	1 030	63 820
6.b. Rats	361	24 238	0	299	20 199	3 083	48 180
6.c. Guinea-Pigs	0	3 279	0	0	596	0	3 875
6.d. Hamsters	0	66	0	0	0	0	66
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	1 453	0	0	662	0	2 115
6.g. Cats	28	38	0	0	0	0	66
6.h. Dogs	2	573	0	94	577	14	1 260
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	236	0	0	99	4	339
6.m. Goats	0	0	0	0	2	0	2
6.n. Sheep	0	0	0	0	19	0	19
6.o. Cattle	0	32	0	0	0	0	32
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	234	0	0	838	0	1 072
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	370	0	0	2 434	0	2 804
6.v. Other birds	0	50	0	0	292	82	424
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	140	140
6.y. Fish	556	7 143	0	120	20 435	22 188	50 442
6.z. TOTAL	1 036	91 740	0	513	54 826	26 541	174 656

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	27 634	1 829	6 599	0	7 771	0	1 222	1 054	130	5 644	342	0	11 595	63 820
7.b. Rats	1 818	2 545	15 606	560	0	0	5 848	1 880	2 546	2 930	6 778	0	7 669	48 180
7.c. Guinea-Pigs	20	0	0	0	3 417	0	0	0	0	0	254	0	184	3 875
7.d. Hamsters	0	0	0	0	0	0	0	0	0	50	0	0	16	66
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	73	281	15	180	19	0	138	0	1 043	0	366	2 115
7.g. Cats	0	0	32	0	0	0	12	0	0	0	0	0	22	66
7.h. Dogs	0	123	318	0	0	0	386	0	0	0	0	0	433	1 260
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	39	114	0	0	0	12	0	0	0	0	0	174	339
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	2	2
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	19	19
7.o. Cattle	0	0	16	0	0	0	0	0	0	0	0	0	16	32
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	208	0	0	0	465	0	266	0	15	0	118	1 072
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	164	370	0	0	0	0	0	0	0	0	0	0	2 270	2 804
7.v. Other birds	55	0	20	0	0	0	0	0	0	0	0	0	349	424
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	140	0	0	0	0	0	0	0	0	0	0	140
7.y. Fish	2 451	0	0	0	0	0	5 396	0	8 170	0	2 502	29 895	2 028	50 442
7.z. TOTAL	32 142	4 906	23 126	841	11 203	180	13 360	2 934	11 250	8 624	10 934	29 895	25 261	174 656

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	28 254	2 446	14 560	71	4 465	46	5 635	1 174	2 114	2 644	4 250	1 671	19 097	86 427
8.b. Products/substances used or intended to be used mainly in agriculture	2 097	2 312	2 313	96	1 408	87	852	1 140	7 078	2 185	3 735	4 567	4 635	32 505
8.c. Products/substances used or intended to be used mainly in industry	1 569	110	5 891	674	5 059	45	1 397	0	748	3 634	2 949	1 866	841	24 783
8.d. Products/substances used or intended to be used mainly in the household	0	0	55	0	76	2	80	0	0	0	0	0	0	213
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	172	38	307	0	0	0	5 396	620	1 310	0	0	21 791	327	29 961
8.i. Other toxicological or safety evaluations	50	0	0	0	195	0	0	0	0	161	0	0	361	767
8.j. TOTAL	32 142	4 906	23 126	841	11 203	180	13 360	2 934	11 250	8 624	10 934	29 895	25 261	174 656