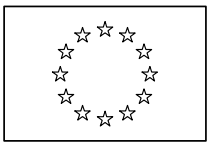

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DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES

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

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

COM(2010) 511 final

Important notice

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

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BELGIUM

Statistical data submitted

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

Comments of the Belgian authorities

1. LABORATORIES

Every year, all laboratories in Belgium that use animals for experimental purposes must provide statistical information on the number of animals used the previous year.

In 2008, 389 laboratories were approved as regards the use of animals for experimental purposes and they all provided their statistical data. A quarter of these laboratories had not used any animals for experimental purposes in 2008.

2. NUMBER OF ANIMALS USED IN EXPERIMENTS

In all 725370 animals were used. Rodents and rabbits accounted for 93%, fish, reptiles and amphibians for 4% and birds for 2% of the total number of animals used.

Dogs, cats and primates accounted respectively for 0,10%, 0,01% and 0,005% of the animals used in 2008 (*Figure 1: Breakdown of species used in experiments*)

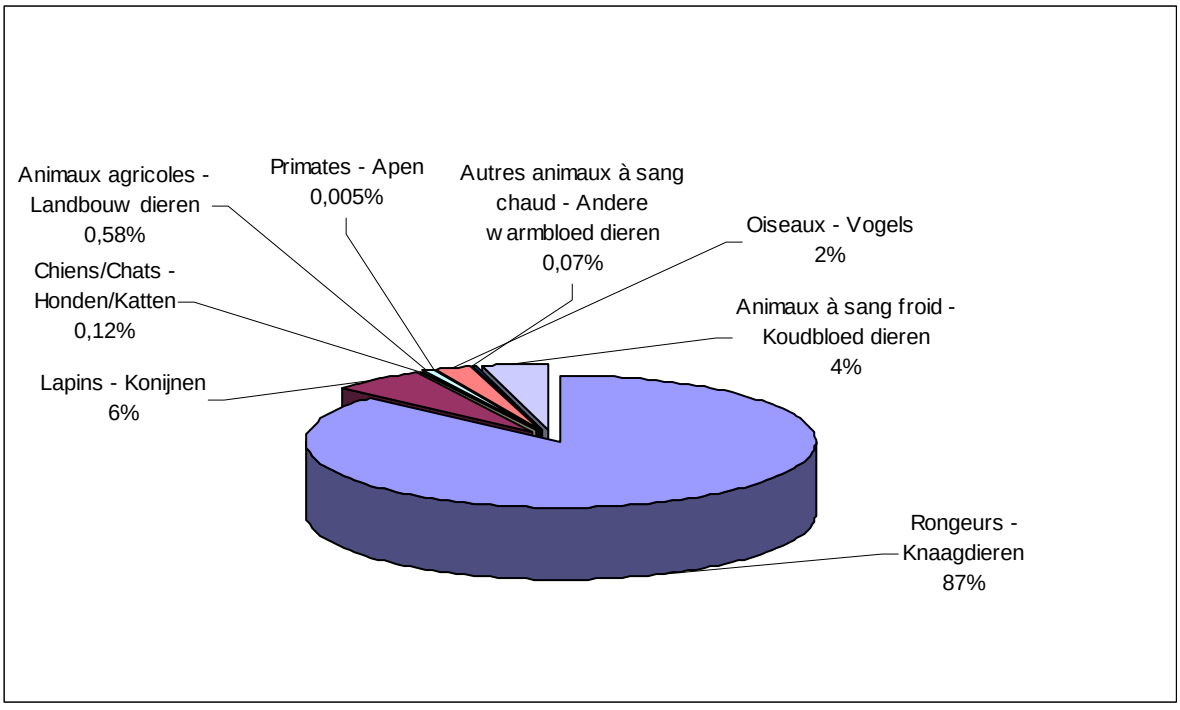


Figure 1: Breakdown of species used in experiments

A comparison of the absolute figures for 2008 with those for 2007 (*Table 1: Trend in the number of animals used in experiments*) shows an overall decrease of 54,490 animals (-7%).

This decrease concerns mainly rodents (-53,454; -8%) and fish (-12,489; -31%). However, for some species there has been a marked increase. These are rabbits (+7,301; +21%), mainly used in certain therapeutic polyclonal antibody development programmes, and birds (+4,622; +36%) which were used in 2008 for food tests on poultry. The number of monkeys remained stable and limited in 2008 (41 animals) and in 2007 (38 animals). These primates are used for vaccine quality control tests and for studies of human diseases (neurophysiology).

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

	2008	**2007**	**2006**	**2005**	**2004**
Mice	480.681	518.208	516.148	488.125	482.810
Rats	108.580	116.991	104.272	106.483	119.193
Guinea pigs	36.554	43.499	38.542	39.530	38.781
Hamsters	2.124	1.882	1.614	1.874	1.688
Other rodents	1.055	1.908	1.627	2.260	3.921
Rabbits	42.025	34.724	30.518	21.159	18.577
Total rodents and rabbits	671.019	717.212	692.721	659.431	664.970
Cats	78	46	107	81	184
Dogs	788	747	1.207	1.295	1.014
Ferrets	324	336	234	154	102
Other carnivores	0	0	0	0	0
Total carnivores	1.190	1.129	1.548	1.530	1.300
Horses, donkeys and cross-breeds	62	103	108	108	65
Pigs	2.969	2.657	2.022	1.876	2.272
Goats	195	122	116	157	125
Sheep	356	291	295	445	495
Cattle	657	616	758	944	982
Total ungulates	4.239	3.789	3.299	3.530	3.939
Prosimians	0	0	0	0	0
New world monkeys	0	0	0	0	7
Old world monkeys	41	38	196	449	579
Apes	0	0	0	0	0
Total primates	41	38	196	449	586
Other mammals	151	124	88	59	44
Total mammals	676.640	722.292	697.852	664.999	670.839
Quails	431	18	35	425	350
Other birds	17.151	12.942	16.127	13.266	10.492
Total birds	17.582	12.960	16.162	13.691	10.842
Reptiles	374	256	121	1.44	129
Amphibians	2.388	3477	3.516	6.177	6.362
Fish	28.386	40.875	39.064	33.965	20.574
Total cold-blooded animals	31.148	44.608	42.701	40.286	27.065
TOTAL ANIMALS	725.370	779.860	756.715	718.976	708.746

The headings in the statistical tables have remained unchanged since 1999. Taking 1999 as a reference year, figure 2 (*figure 2: Trend in the number of animals used since 1999*) shows that the number of animals used in Belgian laboratories has been relatively stable since then. In 2008 the figure was 8% lower than in 1999.

However, the number of animals has been increasing slightly each year since 2000. This trend must be seen in the context of the high level of research in Belgium, as the increase is essentially due to the rise in the number of animals used in basic research (+34,8% between 2000 and 2008).

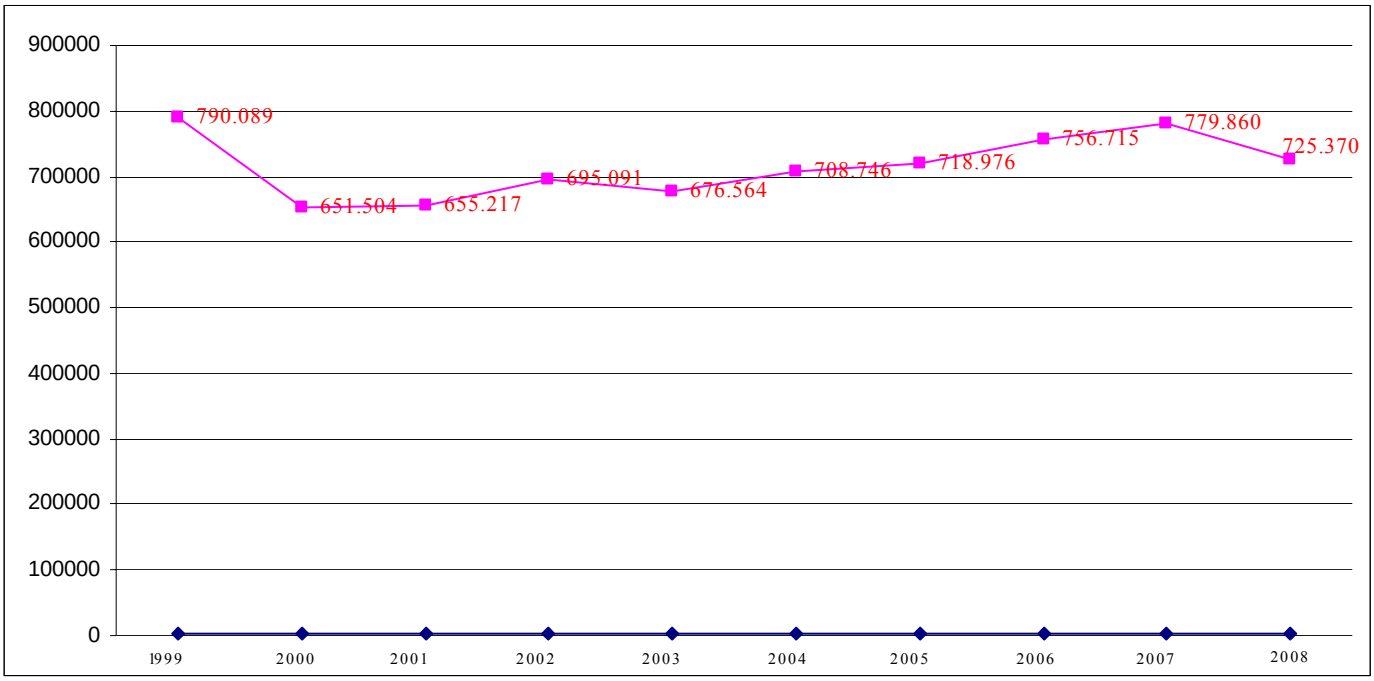


Figure 2: Trend in the number of animals used since 1999

3. EXPERIMENTS CARRIED OUT

In descending order, animals were used mainly to research and develop products and devices used in human and veterinary medicine (32% of the animals used), in basic research studies (30%) and in tests on the production and quality control of such products and devices (30%) (*Figure 3: Breakdown of the experimental fields*).

As regards production and quality control tests, 99% of the animals were used to comply with statutory requirements.

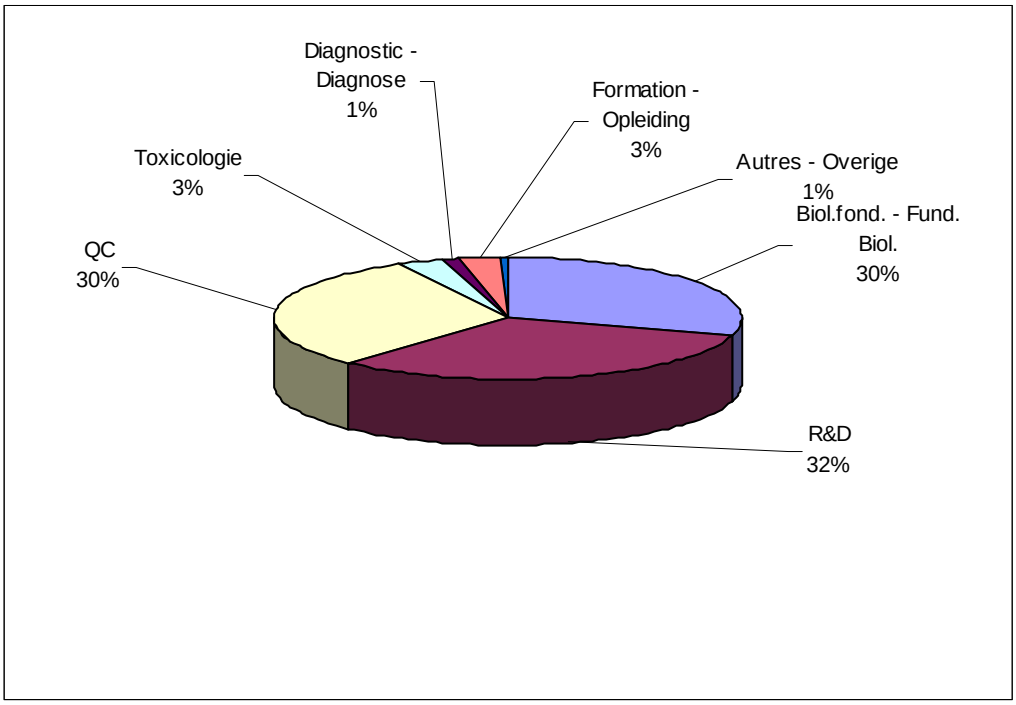


Figure 3: Breakdown of the experimental fields

The following diagram (*Figure 4: Breakdown of experimental fields by the animals most used*) shows that of all the species, rodents are the most used. Rodents account for 82% of animals used for basic research, 94% of animals used for research and development tests on products and devices used in human and veterinary medicine and 84% of animals used for tests on the production and quality control of medical products and devices. Fish account for 11% of the animals used in basic research.

Toxicology and safety tests account for 3% of the animals used in experiments in 2008; 85% of the animals used in toxicology tests were used in safety trials required by law (*Figure 5: Proportion of quality control and toxicology tests imposed by law*).

Rodents account for 91% of all the animals used in toxicology tests. The other species used are mainly rabbits (5%) and dogs (2,8%).

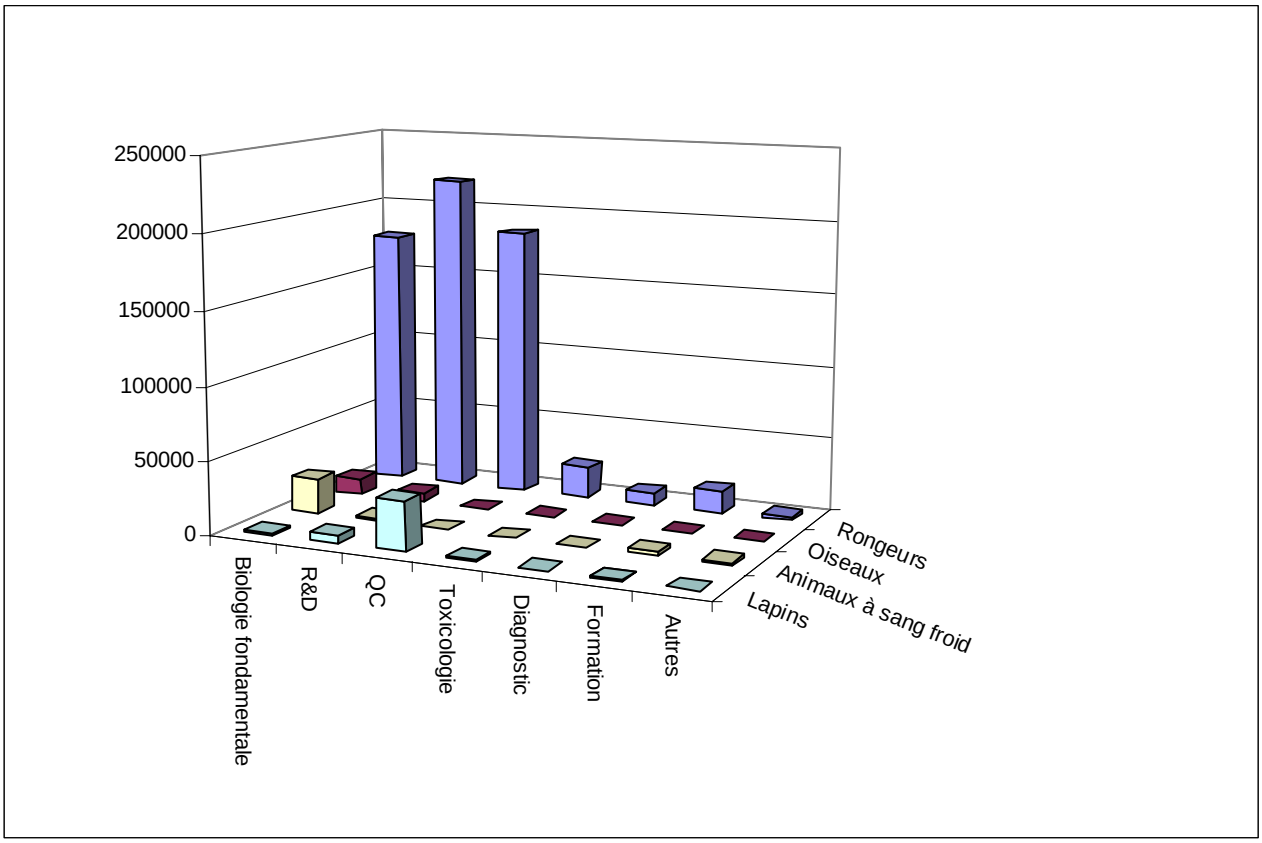


Figure 4: Breakdown of experimental fields by the animals most used

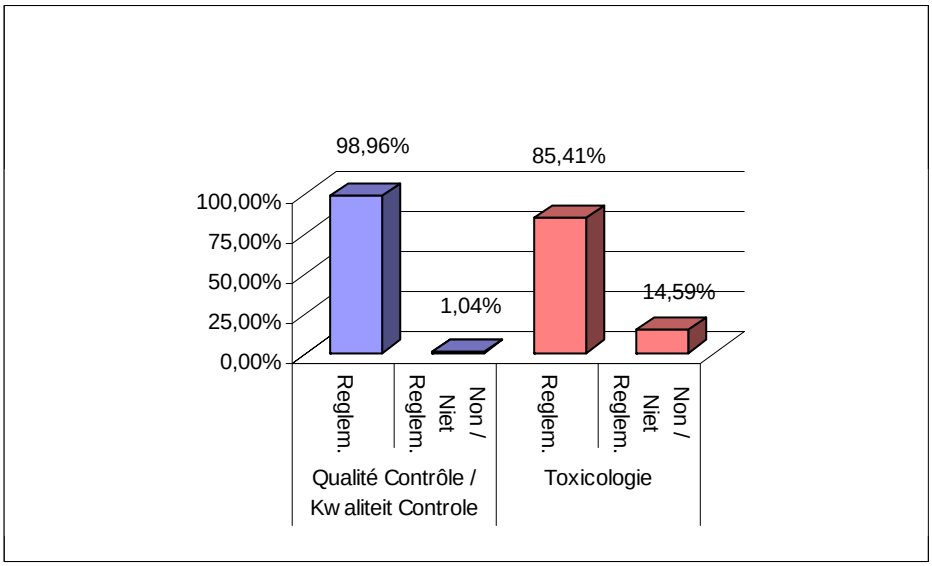


Figure 5: Proportion of quality control and toxicology tests imposed by law

Provenance of animals used in experiments

In 2008, 89,7% of the animals used for experimental purposes came from approved suppliers in Belgium, other countries of the European Union or members of the Council of Europe and 2,9% came from establishments outside these territories. The other species of animal that are not reared solely for the purposes of agricultural experiments come from establishments that meet the current legal requirements for commercial establishments. The number of animals reused in certain experiments was 0,16% of the total number of animals used in 2008.

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*)	480681	141865	317570	2367	18879	
1.b. Rats (*Rattus norvegicus*)	108580	19139	88029	116	1296	
1.c. Guinea-Pigs (*Cavia porcellus*)	36554	4648	29865	2041	0	
1.d. Hamsters (*Mesocricetus*)	2124	724	289	1074	37	
1.e. Other Rodents (other *Rodentia*)	1055					
1.f. Rabbits (*Oryctolagus cuniculus*)	42025	38836	3189	0	0	589
1.g. Cats (*Felis catus*)	78	31	47	0	0	48
1.h. Dogs (*Canis familiaris*)	788	47	289	0	452	483
1.i. Ferrets (*Mustela putorius furo*)	324	0	185	0	139	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	62					
1.l. Pigs (*Sus*)	2969					
1.m. Goats (*Capra*)	195					
1.n. Sheep (*Ovis)*	356					
1.o. Cattle (*Bos*)	657					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	5
1.r. Old World Monkeys (*Cercopithecoidea*)	41	0	12	0	29	28
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	151					
1.u. Quail (*Coturnix coturnix)*	431	431	0	0	0	
1.v. Other birds (other *Aves*)	17151					
1.w. Reptiles (*Reptilia*)	374					
1.x. Amphibians (*Amphibia*)	2388					
1.y. Fish (*Pisces*)	28386					
1.z. TOTAL	725370					

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	155149	155327	138227	2445	8950	8282	10086	2215	480681
2.b. Rats	20692	59947	11668	697	12705	246	2266	359	108580
2.c. Guinea-Pigs	388	3531	29243	647	153	0	2583	9	36554
2.d. Hamsters	377	0	2	1653	30	0	62	0	2124
2.e. Other Rodents	391	660	0	0	0	0	4	0	1055
2.f. Rabbits	1441	5293	3389	30388	1213	4	251	46	42025
2.g. Cats	27	33	0	18	0	0	0	0	78
2.h. Dogs	49	38	0	18	682	1	0	0	788
2.i. Ferrets	12	312	0	0	0	0	0	0	324
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	25	2	0	0	0	0	35	0	62
2.l. Pigs	1309	486	0	1097	0	2	11	64	2969
2.m. Goats	53	142	0	0	0	0	0	0	195
2.n. Sheep	183	161	0	4	0	0	8	0	356
2.o. Cattle	130	85	0	374	44	0	19	5	657
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	11	0	29	0	0	1	0	0	41
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	95	32	24	0	0	0	0	0	151
2.u. Quail	431	0	0	0	0	0	0	0	431
2.v. Other birds	10729	5855	0	87	0	0	0	480	17151
2.w. Reptiles	374	0	0	0	0	0	0	0	374
2.x. Amphibians	553	1500	0	0	108	0	227	0	2388
2.y. Fish	23406	265	0	0	66	0	3116	1533	28386
2.z. TOTAL	215825	233669	182582	37428	23951	8536	18668	4711	725370

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	6754	0	0	0	0	0	0	0	2196	8950
3.b. Rats	11310	0	45	0	0	0	0	0	1350	12705
3.c. Guinea-Pigs	153	0	0	0	0	0	0	0	0	153
3.d. Hamsters	30	0	0	0	0	0	0	0	0	30
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1213	0	0	0	0	0	0	0	0	1213
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	682	0	0	0	0	0	0	0	0	682
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	0	0	0	0	0	0	0	0	0
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	44	44
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	108	0	0	0	0	0	0	0	108
3.y. Fish	0	0	66	0	0	0	0	0	0	66
3.z. TOTAL	20142	108	111	0	0	0	0	0	3590	23951

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	6291	65749	42230	136336	3178	253784
4.b. Rats	1652	37145	1426	33261	106	73590
4.c. Guinea-Pigs	428	95	0	1805	67	2395
4.d. Hamsters	15	0	18	322	0	355
4.e. Other Rodents	0	640	0	320	76	1036
4.f. Rabbits	152	9	3	322	181	667
4.g. Cats	0	0	0	31	3	34
4.h. Dogs	202	0	0	56	0	258
4.i. Ferrets	0	0	0	312	12	324
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	36	36
4.l. Pigs	271	8	0	245	440	964
4.m. Goats	42	0	0	101	28	171
4.n. Sheep	145	0	0	0	3	148
4.o. Cattle	0	0	0	0	66	66
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	12	0	12
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	3	6	5	4	61	79
4.u. Quail	0	400	0	0	0	400
4.v. Other birds	0	0	0	0	7881	7881
4.w. Reptiles	0	0	0	0	43	43
4.x. Amphibians	20	0	0	0	0	20
4.y. Fish	0	0	0	0	2111	2111
4.z. TOTAL	9221	104052	43682	173127	14292	344374

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	13396	0	17081	109778	417	140672
5.b. Rats	0	752	0	2135	7635	1843	12365
5.c. Guinea-Pigs	0	1609	0	4708	23573	0	29890
5.d. Hamsters	0	579	0	0	1074	2	1655
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	1960	0	1049	30766	2	33777
5.g. Cats	0	18	0	0	0	0	18
5.h. Dogs	0	18	0	0	0	0	18
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0
5.l. Pigs	0	1097	0	0	0	0	1097
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	4	0	0	0	0	4
5.o. Cattle	13	361	0	0	0	0	374
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	29	0	29
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	24	24
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	87	0	0	0	0	87
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	13	19881	0	24973	172855	2288	220010

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	626	1113	0	0	5268	1943	8950
6.b. Rats	61	76	0	1350	9775	1443	12705
6.c. Guinea-Pigs	0	104	0	0	49	0	153
6.d. Hamsters	0	0	0	0	30	0	30
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	183	0	0	1030	0	1213
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	682	0	682
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	0	0
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	44	0	0	44
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	108	108
6.y. Fish	0	0	0	66	0	0	66
6.z. TOTAL	687	1476	0	1460	16834	3494	23951

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	471	9	2068	0	0	0	553	821	0	202	1611	0	3215	8950
7.b. Rats	0	301	4533	0	0	0	1611	1428	0	1236	2151	0	1445	12705
7.c. Guinea-Pigs	0	0	27	0	104	0	0	0	0	0	0	0	22	153
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	30	30
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	306	156	9	0	0	0	0	0	610	0	132	1213
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	409	0	0	0	82	0	0	0	0	0	191	682
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	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	0	0
7.o. Cattle	0	0	0	0	0	0	12	0	0	0	22	0	10	44
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	108	0	0	0	0	0	0	108
7.y. Fish	66	0	0	0	0	0	0	0	0	0	0	0	0	66
7.z. TOTAL	537	310	7343	156	113	0	2366	2249	0	1438	4394	0	5045	23951

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	471	283	7020	156	113	0	1786	2228	0	853	4372	0	2860	20142
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	108	0	0	0	0	0	0	108
8.c. Products/substances used or intended to be used mainly in industry	66	27	18	0	0	0	0	0	0	0	0	0	0	111
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i. Other toxicological or safety evaluations	0	0	305	0	0	0	472	21	0	585	22	0	2185	3590
8.j. TOTAL	537	310	7343	156	113	0	2366	2249	0	1438	4394	0	5045	23951

BULGARIA

Statistical data submitted

The statistical data have been submitted by the National Veterinary Service.

Comments of the Bulgaria authorities

The National Veterinary Service (NVS) is the competent authority on animal welfare matters (AW) in 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 veterinary services (RVS) within the NVS. 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 establishments, that are authorized as being in compliance with the requirements laid down in Article 153 (1) of the Law on Veterinary Activity and which have official permit signed by the NVS Director-General. The NVS Director-General would issue the above mentioned permit on the basis of an ethical assessment and a positive opinion from the Animal Ethics Commission with NVS. The Animal Ethics Commission has been established as a permanently operating consultative body with the NVS Director-General. This Commission includes the following staff:

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

The following experiments have been carried out in 2008 :

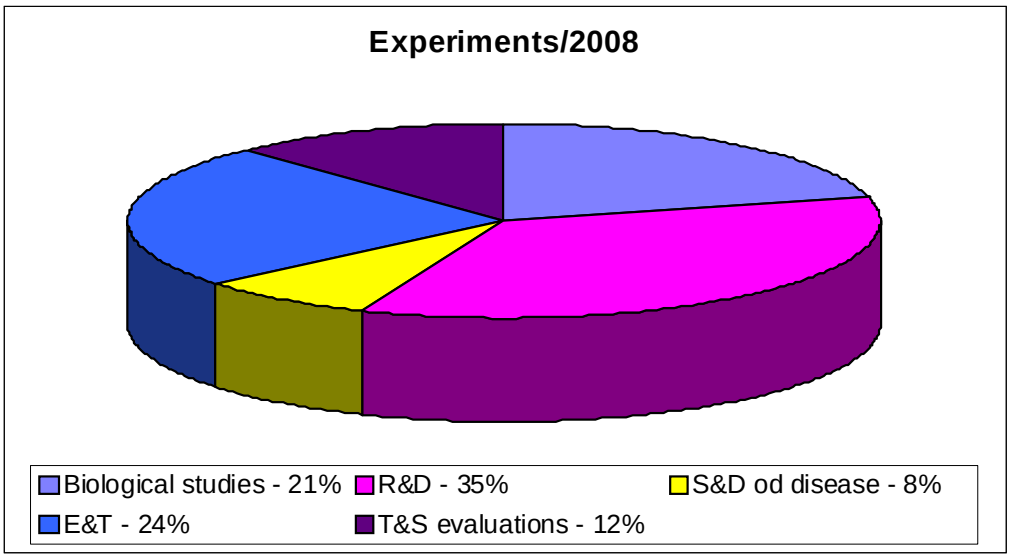
-Biological studies of a fundamental nature

-Research and development of products and devices for human medicine and dentistry and for veterinary medicine (R&D)

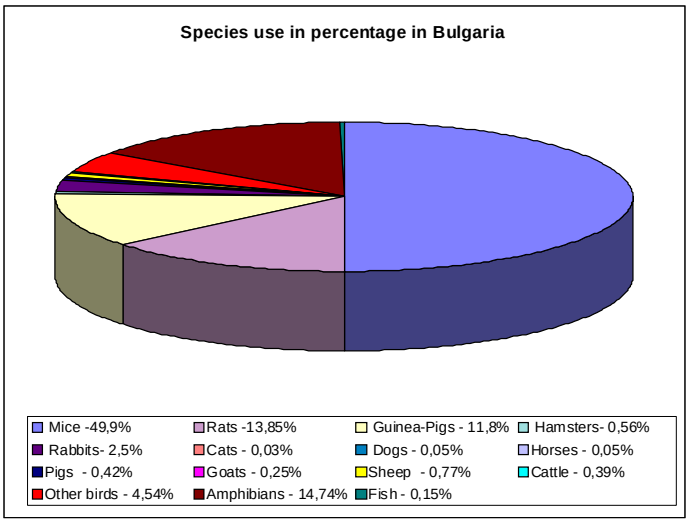
- Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine (T&S evaluations)

- Studies and Diagnosis of Human and Animal disease (S&D of disease)

- Education and training (E&T)



Species use in percentage in Bulgaria



The total number of animals used for experimental purposes was 32,581 in 2008 (mostly mice and hamsters). There have not been any non-human primates used for experimental purposes.

Experiments 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 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*)	16265	15820			445	
1.b. Rats (*Rattus norvegicus*)	4513	3124			1389	
1.c. Guinea-Pigs (*Cavia porcellus*)	3845	3807			38	
1.d. Hamsters (*Mesocricetus*)	182	112			70	
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	813	807			6	
1.g. Cats (*Felis catus*)	11	11				
1.h. Dogs (*Canis familiaris*)	15	13			2	
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	17					
1.l. Pigs (*Sus*)	137					
1.m. Goats (*Capra*)	80					
1.n. Sheep (*Ovis)*	250					
1.o. Cattle (*Bos*)	126					
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*)	1477					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	4800					
1.y. Fish (*Pisces*)	50					
1.z. TOTAL	32581					

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	6197	108	7050	264	1964		682		16265
2.b. Rats	237	684	529	30	1080		1953		4513
2.c. Guinea-Pigs	4	634	2057	54	1000		96		3845
2.d. Hamsters	178						4		182
2.e. Other Rodents									0
2.f. Rabbits	37	24	393	60	62	13	216	8	813
2.g. Cats			5	3	4		2		14
2.h. Dogs	2						10		12
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds							17		17
2.l. Pigs		24	10	10			93		137
2.m. Goats	20	60							80
2.n. Sheep	16	46				15	173		250
2.o. Cattle						16	110		126
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	239	16	30	920		224	48		1477
2.w. Reptiles									0
2.x. Amphibians	200						4600		4800
2.y. Fish							50		50
2.z. TOTAL	7130	1596	10074	1341	4110	268	8054	8	32581

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	1900					64				1964
3.b. Rats	1080									1080
3.c. Guinea-Pigs	1000									1000
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	62									62
3.g. Cats	4									4
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	4046	0	0	0	0	64	0	0	0	4110

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			480	1800		2280
4.b. Rats	40		50	85		175
4.c. Guinea-Pigs	4					4
4.d. Hamsters			100	8		108
4.e. Other Rodents						0
4.f. Rabbits	4			2	13	19
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					15	15
4.o. Cattle					16	16
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				9	254	263
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	48	0	630	1904	298	2880

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		7314					7314
5.b. Rats		30				529	559
5.c. Guinea-Pigs		2054				57	2111
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	10	443					453
5.g. Cats		5					5
5.h. Dogs	3						3
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs		10				10	20
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds	30	920					950
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	43	10776	0	0	0	596	11415

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	150	1700	64			50	1964
6.b. Rats		200				780	980
6.c. Guinea-Pigs	100	1000					1100
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		60	2				62
6.g. Cats			4				4
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	250	2960	70	0	0	830	4110

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	1864		100											1964
7.b. Rats	900	130	50											1080
7.c. Guinea-Pigs	1000													1000
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits	60			2										62
7.g. Cats													4	4
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	3824	130	150	2	0	0	0	0	0	0	0	0	4	4110

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	3760	130	150	2									4	4046
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	64													64
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	3824	130	150	2	0	0	0	0	0	0	0	0	4	4110

CZECH REPUBLIC

Statistical data submitted

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

Comments of the Czech authorities

Protection of animals and animal welfare in the Czech Republic (CR) is the responsibility of the Ministry of Agriculture *(Ministerstvo zemědělství)*. The Central Commission for Animal Welfare *(Ústřední komise pro ochranu zvířat)* has changed to the technical advisory board of the Minister 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 of these matters has been the responsibility of the Regional Veterinary Administrations' inspectors in 13 regions of the CR and the Municipal Veterinary Administration in Prague.

Altogether 132 inspections of experiments on animals were carried out in 2008, involving 77,694 animals. In 2 cases a penalty was imposed due to detected shortcomings.

Note: The Czech tables below, which were used for calculating the EU totals in the Sixth Report, do not include animals used by the Czech Academy of Sciences (CAS) due to the death of the responsible person at the time of data collection. However, these additional animals are included in the comments below.

In CAS 49,667 animals (32,995 mice, 10,106 rats, 733 guinea pigs, 56 other rodents, 299 pigs, 2,178 birds, 3,300 fish) were used and should be added to the tables provided below.

Therefore, in 2008 a total of 350,380 animals were used for experimental and other scientific purposes in the CR. It should be pointed out that 40,58% of it is represented by ringed birds (142,200 birds) since pursuant to the relevant Czech legislation even bird ringing is an experiment.

Of the remaining 208,180 animals used for experimental and scientific purposes only 0,02% were cats (45 cats), 0,26% dogs (552 dogs), 0,04% monkeys (80 monkeys), while no apes were used. Rodents and rabbits (62,39%, i.e. 129,887 animals) and fish (27,93%, i.e. 58,136 fish) represent the prevailing majority of animals used.

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

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

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

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*)	54776	51832	2888		56	
1.b. Rats (*Rattus norvegicus*)	21531	20600	931			
1.c. Guinea-Pigs (*Cavia porcellus*)	1902	1902				
1.d. Hamsters (*Mesocricetus*)	251	251				
1.e. Other Rodents (other *Rodentia*)	1233					
1.f. Rabbits (*Oryctolagus cuniculus*)	6304	6263	14		27	47
1.g. Cats (*Felis catus*)	45	15	30			
1.h. Dogs (*Canis familiaris*)	552	478	30		44	18
1.i. Ferrets (*Mustela putorius furo*)	122	122				
1.j. Other Carnivores (other *Carnivora*)	45					
1.k. Horses, donkeys and cross breds (*Equidae*)	378					
1.l. Pigs (*Sus*)	2013					
1.m. Goats (*Capra*)	174					
1.n. Sheep (*Ovis)*	1148					
1.o. Cattle (*Bos*)	799					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	80	80				59
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)	1774					
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)	148722					
1.w. Reptiles (*Reptilia*)	1012					
1.x. Amphibians (*Amphibia*)	3016					
1.y. Fish (*Pisces*)	54836					
1.z. TOTAL	300713					

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	14326	9138	2019	15795	703	6172	550	6073	54776
2.b. Rats	9878	4523	133	1260	3270	3	2359	105	21531
2.c. Guinea-Pigs	169	545	39	905	132	35	77		1902
2.d. Hamsters	14	180					57		251
2.e. Other Rodents	1125						83	25	1233
2.f. Rabbits	918	467	122	3533	202	217	780	65	6304
2.g. Cats		30		15					45
2.h. Dogs	44	335		18	151	2	2		552
2.i. Ferrets		118				4			122
2.j. Other Carnivores	9	36							45
2.k. Horses, donkeys and cross breds	19	30		306			13	10	378
2.l. Pigs	1146	208		468	100	8	83		2013
2.m. Goats	32	23					119		174
2.n. Sheep	108			100		250	65	625	1148
2.o. Cattle	54	29		332	4	162	184	34	799
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys		80							80
2.s. Apes									0
2.t. Other Mammals	1774								1774
2.u. Quail									0
2.v. Other birds	146422	594		506	746	54	371	29	148722
2.w. Reptiles	958						54		1012
2.x. Amphibians	2915						101		3016
2.y. Fish	16894			90	37402	300	150		54836
2.z. TOTAL	196805	16336	2313	23328	42710	7207	5048	6966	300713

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	553	8	155					45		761
3.b. Rats	947	405	1825					54		3231
3.c. Guinea-Pigs	71		100							171
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	142	24	60			2		12		240
3.g. Cats										0
3.h. Dogs	151									151
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs		8				100				108
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle		4								4
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals		210								210
3.u. Quail										0
3.v. Other birds	349	48								397
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish	305	677	1945	549	422	523		32066	950	37437
3.z. TOTAL	2518	1384	4085	549	422	625	0	32177	950	42710

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	185	181	6411	10073	2945	19795
4.b. Rats	2629	1865	1996	1901	2803	11194
4.c. Guinea-Pigs			12	135		147
4.d. Hamsters				52		52
4.e. Other Rodents					35	35
4.f. Rabbits	134		60	118	281	593
4.g. Cats						0
4.h. Dogs	39	2		2	42	85
4.i. Ferrets				122		122
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds					7	7
4.l. Pigs	102			3	537	642
4.m. Goats					147	147
4.n. Sheep	18			250	37	305
4.o. Cattle					114	114
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys	31			49		80
4.s. Apes						0
4.t. Other Mammals				10		10
4.u. Quail						0
4.v. Other birds				212	1641	1853
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					1925	1925
4.z. TOTAL	3138	2048	8479	12927	10514	37106

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	5884	11930					17814
5.b. Rats	67	1260		66			1393
5.c. Guinea-Pigs	180	741					921
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	88	3490					3578
5.g. Cats		15					15
5.h. Dogs		18					18
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds	292	14					306
5.l. Pigs	46	422					468
5.m. Goats							0
5.n. Sheep	3	97					100
5.o. Cattle		332					332
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	48	458				100	606
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish	90						90
5.z. TOTAL	6698	18777	0	66	0	100	25641

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	511					192	703
6.b. Rats	2755	41				474	3270
6.c. Guinea-Pigs	100	32					132
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	171	12				19	202
6.g. Cats							0
6.h. Dogs	151						151
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs						100	100
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						670	670
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	24468	9179				3835	37482
6.z. TOTAL	28156	9264	0	0	0	5290	42710

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		506			155								42	703
7.b. Rats	337		718		12		679		387	115	532		490	3270
7.c. Guinea-Pigs				10	116	6								132
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				97	19	26							60	202
7.g. Cats														0
7.h. Dogs	15						80						56	151
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs													100	100
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													670	670
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish	33782											3700		37482
7.z. TOTAL	34134	506	718	107	302	32	759	0	387	115	532	3700	1418	42710

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	255	506		68	35	11	477					138	1028	2518
8.b. Products/substances used or intended to be used mainly in agriculture	750		400		12		12						210	1384
8.c. Products/substances used or intended to be used mainly in industry	1067		318	39	255	21	270		387	95	532	975	126	4085
8.d. Products/substances used or intended to be used mainly in the household	549													549
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	422													422
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption								625						625
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	30421									20	45	1637	54	32177
8.i. Other toxicological or safety evaluations												950		950
8.j. TOTAL	33464	506	718	107	302	32	759	625	387	115	577	3700	1418	42710

DENMARK

Statistical data submitted

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

Comments of Danish authorities

None

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (*Mus musculus*)	168164	119674	44406	337	3747	
1.b. Rats (*Rattus norvegicus*)	75850	42343	30618	687	2202	
1.c. Guinea-Pigs (*Cavia porcellus*)	5343	703	4640	0	0	
1.d. Hamsters (*Mesocricetus*)	4	4	0	0	0	
1.e. Other Rodents (other *Rodentia*)	1760					
1.f. Rabbits (*Oryctolagus cuniculus*)	2931	758	1044	0	1129	140
1.g. Cats (*Felis catus*)	154	0	17	4	133	0
1.h. Dogs (*Canis familiaris*)	271	0	250	0	21	39
1.i. Ferrets (*Mustela putorius furo*)	117	97	20	0	0	0
1.j. Other Carnivores (other *Carnivora*)	101					
1.k. Horses, donkeys and cross breds (*Equidae*)	54					
1.l. Pigs (*Sus*)	6863					
1.m. Goats (*Capra*)	107					
1.n. Sheep (*Ovis)*	88					
1.o. Cattle (*Bos*)	939					
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*)	243					
1.u. Quail (*Coturnix coturnix)*	0	0	0	0	0	
1.v. Other birds (other *Aves*)	2820					
1.w. Reptiles (*Reptilia*)	221					
1.x. Amphibians (*Amphibia*)	293					
1.y. Fish (*Pisces*)	31245					
1.z. TOTAL	297568					

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	53293	82439	11900	155	4923	2932	1096	11426	168164
2.b. Rats	15346	45628	3244	0	7269	833	2628	902	75850
2.c. Guinea-Pigs	207	2017	1695	25	1311	76	12	0	5343
2.d. Hamsters	4	0	0	0	0	0	0	0	4
2.e. Other Rodents	62	1698	0	0	0	0	0	0	1760
2.f. Rabbits	357	1808	447	4	218	2	42	53	2931
2.g. Cats	123	0	0	0	0	10	0	21	154
2.h. Dogs	1	119	0	0	130	21	0	0	271
2.i. Ferrets	97	20	0	0	0	0	0	0	117
2.j. Other Carnivores	62	39	0	0	0	0	0	0	101
2.k. Horses, donkeys and cross breds	15	13	7	0	0	0	19	0	54
2.l. Pigs	2245	1862	0	43	648	102	1029	934	6863
2.m. Goats	0	93	0	0	0	0	0	14	107
2.n. Sheep	5	38	26	6	0	0	13	0	88
2.o. Cattle	616	124	0	18	0	131	50	0	939
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	233	0	0	0	0	0	10	0	243
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	2604	111	2	84	6	13	0	0	2820
2.w. Reptiles	198	23	0	0	0	0	0	0	221
2.x. Amphibians	92	65	0	0	0	136	0	0	293
2.y. Fish	5939	16602	0	0	8443	0	261	0	31245
2.z. TOTAL	81499	152699	17321	335	22948	4256	5160	13350	297568

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	2845	0	537	0	0	62	0	439	1040	4923
3.b. Rats	4515	74	0	1346	0	120	0	127	1087	7269
3.c. Guinea-Pigs	1260	0	0	0	0	24	0	0	27	1311
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	215	0	0	0	0	3	0	0	0	218
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	130	0	0	0	0	0	0	0	0	130
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	648	0	0	0	0	0	0	0	0	648
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	6	6
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	493	0	0	0	7950	0	0	8443
3.z. TOTAL	9613	74	1030	1346	0	209	7950	566	2160	22948

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	2802	59758	13426	35581	1150	112717
4.b. Rats	2075	34100	823	19699	40	56737
4.c. Guinea-Pigs	269	1700	0	194	0	2163
4.d. Hamsters	0	0	0	0	0	0
4.e. Other Rodents	0	1416	0	282	24	1722
4.f. Rabbits	199	0	1129	757	21	2106
4.g. Cats	0	0	0	0	85	85
4.h. Dogs	21	39	0	80	0	140
4.i. Ferrets	0	20	0	97	0	117
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	15	15
4.l. Pigs	471	179	0	1869	111	2630
4.m. Goats	0	0	87	6	0	93
4.n. Sheep	0	0	0	0	0	0
4.o. Cattle	0	0	0	79	36	115
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	130	130
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	64	0	0	0	240	304
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	151	0	0	0	151
4.y. Fish	0	8165	0	0	1180	9345
4.z. TOTAL	5901	105528	15465	58644	3032	188570

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	155	14	0	0	11870	16	12055
5.b. Rats	0	2408	0	0	836	0	3244
5.c. Guinea-Pigs	25	0	0	0	1310	385	1720
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	4	0	0	28	22	397	451
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	7	7
5.l. Pigs	43	0	0	0	0	0	43
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	6	0	0	0	0	26	32
5.o. Cattle	18	0	0	0	0	0	18
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	84	0	0	0	0	2	86
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	335	2422	0	28	14038	833	17656

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	667	0	0	0	2366	1890	4923
6.b. Rats	98	0	0	50	4502	2619	7269
6.c. Guinea-Pigs	0	0	0	72	1188	51	1311
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	216	2	218
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	130	0	130
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	648	0	648
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	6	0	0	0	0	0	6
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	493	0	0	0	0	7950	8443
6.z. TOTAL	1264	0	0	122	9050	12512	22948

Examples: **6.2 – France is testing due to a UK (or FR) specific requirement**
6.3 - UK is testing according to EC legislation
6.4 – Spain is testing due to a Norwegian requirement
6.5 – Poland is testing due to a US specific requirement
6.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

Note: **columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.**

Example: **a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.**

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	0	1955	0	931	0	382	0	0	658	45	0	952	4923
7.b. Rats	0	0	1146	0	0	0	3146	0	0	174	2372	0	431	7269
7.c. Guinea-Pigs	0	0	1223	0	0	0	0	0	0	0	0	0	88	1311
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	46	19	0	3	39	0	0	0	109	0	2	218
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	126	0	0	0	0	0	4	130
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	8	12	0	0	600	0	0	0	28	0	0	648
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	6	0	0	0	0	0	0	0	0	0	0	6
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	199	7950	0	0	0	0	0	0	0	0	0	294	0	8443
7.z. TOTAL	199	7950	4384	31	931	3	4293	0	0	832	2554	294	1477	22948

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	125	0	4027	31	407	0	4366	0	0	148	401	0	108	9613
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	18	0	0	0	56	0	0	74
8.c. Products/substances used or intended to be used mainly in industry	199	0	0	0	188	0	294	0	0	0	45	0	304	1030
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	1016	0	330	1346
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	3	120	0	0	0	0	0	86	209
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	7950	0	0	0	0	0	0	0	0	0	0	0	7950
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	566	0	0	0	566
8.i. Other toxicological or safety evaluations	0	0	21	0	336	0	0	0	0	118	1041	0	644	2160
8.j. TOTAL	324	7950	4048	31	931	3	4798	0	0	832	2559	0	1472	22948

GERMANY

Statistical data submitted

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

Comments of German authorities

The German Government's aim is to reduce to an unavoidable minimum the number of animals used for experimental and other scientific purposes. In the current state of the art, however, despite the increased use of alternative methods it is not yet possible to dispense with animal experiments entirely. This applies to medical research in particular.

Within the EU, Germany is making a major contribution towards the development of test methods which do not involve animal experiments. A leading part in this process is played both by the Federal Ministry of Education and Research, with its scheme to promote the development of methods to replace animal experiments and by the Central Office for the registration and assessment of methods replacing and supplementing animal experiments, which this year is celebrating its 20th anniversary.

Compared with the previous year, in 2008 in Germany the number of vertebrates used for experimental and other scientific purposes increased by 2,1% to 2,021,782. Whereas the number of mice used increased by 135,459 the number of fish used fell by 95,565.

At almost 87%, rodents constitute the largest group of animals used in experiments. In particular, mice account for 65% and rats for 19%.

The next largest groups comprise rabbits at 4,8%, fish at 3,3% and birds at 2,8%. All other species taken together account for 2,2% of the animals used.

Compared with the previous year, the number of Old World monkeys, New World monkeys and prosimians fell by 152 to 2,263. The largest proportion of these animals (1,858) was used for toxicological tests and other safety tests on products and appliances for human, dental and veterinary medicine. Apes were not used.

Compared with 2007, the number of dogs and cats used fell by 340; the total number corresponded roughly to the numbers for 2000 to 2006.

For basic biological research the number of fish used fell by 88,760 and the number of rats by 18,122. By contrast, the number of mice rose by 41,775 and the number of amphibians by 5,676. In total, 68,519 fewer animals were used in basic biological research (-7,3%).

For the research and development of products and for the manufacture and/or quality control of products for human, dental and veterinary medicine, 858,395 animals were used – an increase of 122,052 compared with the previous year. By contrast, in 2007, 97,770 fewer animals were used than in 2006. In the years 2001 to 2005 the number of animals used for these purposes was likewise within this range.

For toxicological tests and other safety tests on products and appliances for human, dental and veterinary medicine, 8,432 more animals were required than in 2007.

For products or substances used primarily in cosmetics or toiletries, no toxicological tests were carried out on animals in 2008 in Germany.

The proportion of animals used for research into human or animal diseases fell in 2008 compared with the previous year from 58,5% to 56,1%.

24,6% of the animals were used for legally required experiments in the manufacture or quality control of products for human, dental or veterinary medicine and/or for toxicological safety tests. Their proportion therefore increased by 5,0%.

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*)	1.314.493	1.167.335	129.636	10.760	6.762	
1.b. Rats (*Rattus norvegicus*)	390.853	305.309	79.003	5.395	1.146	
1.c. Guinea-Pigs (*Cavia porcellus*)	35.870	35.624	246	0	0	
1.d. Hamsters (*Mesocricetus*)	7.061	6.782	149	0	130	
1.e. Other Rodents (other *Rodentia*)	8.392					
1.f. Rabbits (*Oryctolagus cuniculus*)	97.938	97.313	621	4	0	9.076
1.g. Cats (*Felis catus*)	798	246	294	0	258	303
1.h. Dogs (*Canis familiaris*)	4.450	1.911	1.536	0	1.003	1.081
1.i. Ferrets (*Mustela putorius furo*)	55	11	44	0	0	0
1.j. Other Carnivores (other *Carnivora*)	410					
1.k. Horses, donkeys and cross breds (*Equidae*)	584					
1.l. Pigs (*Sus*)	12.361					
1.m. Goats (*Capra*)	531					
1.n. Sheep (*Ovis)*	4.638					
1.o. Cattle (*Bos*)	6.252					
1.p. Prosimians (*Prosimia*)	543	0	543	0	0	0
1.q. New World Monkeys (*Ceboidea*)	305	252	48	5	0	63
1.r. Old World Monkeys (*Cercopithecoidea*)	1.415	102	205	0	1.108	396
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	541					
1.u. Quail (*Coturnix coturnix)*	1.803	1.803	0	0	0	
1.v. Other birds (other *Aves*)	53.986					
1.w. Reptiles (*Reptilia*)	192					
1.x. Amphibians (*Amphibia*)	10.815					
1.y. Fish (*Pisces*)	67.496					
1.z. TOTAL	2.021.782					

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	723.037	273.935	148.754	41.668	75.985	7.855	26.200	17.059	1.314.493
2.b. Rats	74.880	180.418	51.412	10.468	53.312	1.609	16.248	2.506	390.853
2.c. Guinea-Pigs	936	6.002	16.870	3.700	6.623	18	616	1.105	35.870
2.d. Hamsters	2.036	2.822	16	1.331	40	52	295	469	7.061
2.e. Other Rodents	3.497	3.934	0	0	0	17	391	553	8.392
2.f. Rabbits	2.453	5.387	50.713	1.809	4.483	791	196	32.106	97.938
2.g. Cats	79	547	39	10	98	0	13	12	798
2.h. Dogs	193	1.003	0	939	1.935	189	161	30	4.450
2.i. Ferrets	42	0	0	2	0	0	1	10	55
2.j. Other Carnivores	15	0	0	311	0	80	0	4	410
2.k. Horses, donkeys and cross breds	346	121	0	2	0	75	39	1	584
2.l. Pigs	2.633	5.918	29	447	352	693	2.079	210	12.361
2.m. Goats	225	271	11	2	4	10	2	6	531
2.n. Sheep	692	1.150	2.151	116	3	167	216	143	4.638
2.o. Cattle	4.295	528	22	436	33	622	282	34	6.252
2.p. Prosimians	0	0	0	0	543	0	0	0	543
2.q. New World Monkeys	49	91	0	0	147	0	0	18	305
2.r. Old World Monkeys	43	91	0	0	1.168	2	10	101	1.415
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	495	6	4	0	0	0	7	29	541
2.u. Quail	0	0	0	0	1.786	0	17	0	1.803
2.v. Other birds	7.095	29.863	307	11.714	885	2.245	462	1.415	53.986
2.w. Reptiles	151	21	0	0	0	0	20	0	192
2.x. Amphibians	9.477	234	0	0	4	0	1.064	36	10.815
2.y. Fish	34.405	2.730	0	40	23.853	2.421	3.571	476	67.496
2.z. TOTAL	867.074	515.072	270.328	72.995	171.254	16.846	51.890	56.323	2.021.782

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	61.040	4.146	10.375	0	0	0	0	217	207	75.985
3.b. Rats	33.080	8.284	11.425	16	0	0	0	239	268	53.312
3.c. Guinea-Pigs	3.613	1.449	1.482	0	0	0	0	0	79	6.623
3.d. Hamsters	40	0	0	0	0	0	0	0	0	40
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	2.861	952	633	0	0	0	0	0	37	4.483
3.g. Cats	88	0	0	0	0	0	0	0	10	98
3.h. Dogs	1.902	20	8	0	0	0	0	0	5	1.935
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	352	0	0	0	0	0	0	0	0	352
3.m. Goats	0	4	0	0	0	0	0	0	0	4
3.n. Sheep	3	0	0	0	0	0	0	0	0	3
3.o. Cattle	33	0	0	0	0	0	0	0	0	33
3.p. Prosimians	543	0	0	0	0	0	0	0	0	543
3.q. New World Monkeys	147	0	0	0	0	0	0	0	0	147
3.r. Old World Monkeys	1.168	0	0	0	0	0	0	0	0	1.168
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	1.786	0	0	0	0	0	0	0	1.786
3.v. Other birds	182	577	0	0	0	0	44	0	82	885
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	4	4
3.y. Fish	3.855	14.681	2.367	0	0	0	80	2.870	0	23.853
3.z. TOTAL	108.907	31.899	26.290	16	0	0	124	3.326	692	171.254

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	60.950	105.707	107.646	388.614	5.404	668.321
4.b. Rats	16.279	26.241	4.369	87.061	1.014	134.964
4.c. Guinea-Pigs	130	47	0	4.271	239	4.687
4.d. Hamsters	387	825	98	2.531	45	3.886
4.e. Other Rodents	0	814	0	2.623	1.439	4.876
4.f. Rabbits	758	106	304	2.413	194	3.775
4.g. Cats	0	40	0	0	527	567
4.h. Dogs	3	0	75	84	765	927
4.i. Ferrets	0	0	0	35	0	35
4.j. Other Carnivores	0	0	0	2	80	82
4.k. Horses, donkeys and cross breds	0	0	0	43	294	337
4.l. Pigs	447	7	10	2.170	2.359	4.993
4.m. Goats	0	29	0	203	10	242
4.n. Sheep	59	48	0	528	919	1.554
4.o. Cattle	9	21	0	79	4.603	4.712
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	21	0	26	0	47
4.r. Old World Monkeys	4	16	0	80	0	100
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	44	0	42	0	86
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	118	48	0	2.239	7.706	10.111
4.w. Reptiles	0	10	0	0	47	57
4.x. Amphibians	224	56	0	468	0	748
4.y. Fish	1.768	958	131	3.913	5.368	12.138
4.z. TOTAL	81.136	135.038	112.633	497.425	31.013	857.245

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	174.107	0	850	11.320	4.145	190.422
5.b. Rats	0	61.747	0	0	0	133	61.880
5.c. Guinea-Pigs	0	19.743	0	512	0	315	20.570
5.d. Hamsters	0	1.347	0	0	0	0	1.347
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	42.765	0	0	8.697	1.060	52.522
5.g. Cats	0	39	0	0	0	10	49
5.h. Dogs	0	217	0	0	680	42	939
5.i. Ferrets	0	2	0	0	0	0	2
5.j. Other Carnivores	0	311	0	0	0	0	311
5.k. Horses, donkeys and cross breds	0	2	0	0	0	0	2
5.l. Pigs	0	436	0	0	0	40	476
5.m. Goats	0	0	0	0	2	11	13
5.n. Sheep	0	0	0	0	58	2.209	2.267
5.o. Cattle	0	412	0	0	0	46	458
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	1.005	0	0	10.158	858	12.021
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	40	0	0	0	0	40
5.z. TOTAL	0	302.173	0	1.362	30.915	8.873	343.323

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	153	55.706	0	537	16.213	3.376	75.985
6.b. Rats	110	27.852	10	16	21.608	3.716	53.312
6.c. Guinea-Pigs	0	4.117	0	0	2.503	3	6.623
6.d. Hamsters	0	40	0	0	0	0	40
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	3.515	0	0	891	77	4.483
6.g. Cats	14	74	0	0	0	10	98
6.h. Dogs	36	777	0	0	1.093	29	1.935
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	205	0	0	135	12	352
6.m. Goats	0	0	0	0	4	0	4
6.n. Sheep	0	0	0	0	0	3	3
6.o. Cattle	0	33	0	0	0	0	33
6.p. Prosimians	0	543	0	0	0	0	543
6.q. New World Monkeys	0	0	0	0	147	0	147
6.r. Old World Monkeys	0	0	0	0	1.168	0	1.168
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	320	0	0	1.466	0	1.786
6.v. Other birds	0	320	0	0	483	82	885
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	4	4
6.y. Fish	1.270	8.128	0	0	12.847	1.608	23.853
6.z. TOTAL	1.583	101.630	10	553	58.558	8.920	171.254

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	28.611	8.594	12.390	70	9.944	0	1.804	1.068	0	6.227	0	0	7.277	75.985
7.b. Rats	2.510	5.884	18.972	25	0	0	5.704	0	3.393	3.974	5.647	0	7.203	53.312
7.c. Guinea-Pigs	0	0	843	0	5.653	0	0	0	0	0	15	0	112	6.623
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	40	40
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	28	18	171	925	0	479	0	0	925	0	1.426	0	511	4.483
7.g. Cats	0	0	24	0	0	0	62	0	0	0	0	0	12	98
7.h. Dogs	0	339	747	0	0	0	639	0	0	0	0	0	210	1.935
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	11	88	0	0	0	34	0	0	0	0	0	219	352
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	4	4
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	3	3
7.o. Cattle	0	0	16	0	0	0	0	0	0	0	0	0	17	33
7.p. Prosimians	0	0	261	0	0	0	143	0	0	0	0	0	139	543
7.q. New World Monkeys	0	0	36	0	0	0	47	0	64	0	0	0	0	147
7.r. Old World Monkeys	0	0	184	0	0	0	750	0	176	0	58	0	0	1.168
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	459	217	0	0	0	0	0	0	0	0	176	0	934	1.786
7.v. Other birds	204	0	205	0	0	0	0	0	0	0	0	0	476	885
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	4	0	0	0	0	4
7.y. Fish	2.446	326	0	0	0	0	294	0	0	0	129	19.443	1.215	23.853
7.z. TOTAL	34.258	15.389	33.937	1.020	15.597	479	9.477	1.068	4.562	10.201	7.451	19.443	18.372	171.254

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	28.654	12.043	26.171	497	5.551	3	7.274	1.008	1.551	4.218	4.786	3.412	13.739	108.907
8.b. Products/substances used or intended to be used mainly in agriculture	3.244	2.572	2.680	367	2.793	372	974	0	1.072	1.271	725	11.884	3.945	31.899
8.c. Products/substances used or intended to be used mainly in industry	2.046	566	4.671	156	7.177	91	1.209	60	1.935	4.322	1.928	1.895	234	26.290
8.d. Products/substances used or intended to be used mainly in the household	16	0	0	0	0	0	0	0	0	0	0	0	0	16
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	80	44	124
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	289	208	239	0	0	0	20	0	0	0	12	2.172	386	3.326
8.i. Other toxicological or safety evaluations	9	0	176	0	76	13	0	0	4	390	0	0	24	692
8.j. TOTAL	34.258	15.389	33.937	1.020	15.597	479	9.477	1.068	4.562	10.201	7.451	19.443	18.372	171.254

ESTONIA

Statistical data submitted

The statistical data have been submitted by the Animal Welfare and Zootechnics bureau of the Ministry of Agriculture

Comments of Estonian authorities

Estonia has 7 approved experimental animal breeding and user establishments. Four of them are active by the University of Tartu.

Commission of the authorization of the animal testing permits first started in August 2004. During the period 2005-2008 there have been issued over a 100 licenses for conducting animal experiments in Estonia. Most of the experiments have been conducted at the University of Tartu.

The majority of laboratory animals used are from authorized breeding establishments in Estonia.

The most of experiments have been carried out in the fields of biological studies of a fundamental nature and research and development of products and devices for human medicine.

In the field of biological studies, the majority of experiments involved the investigation of human diseases (nervous and mental illnesses, various forms of cancer).

The authorization and licensing animal testing and conducting animal experiments is regulated by national and EU legislation.

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*)	28754	11779	13137		3838	
1.b. Rats (*Rattus norvegicus*)	5268	2058	3210	0	0	
1.c. Guinea-Pigs (*Cavia porcellus*)	22		22			
1.d. Hamsters (*Mesocricetus*)	120		120			
1.e. Other Rodents (other *Rodentia*)	0					
1.f. Rabbits (*Oryctolagus cuniculus*)	630	0	630	0	0	0
1.g. Cats (*Felis catus*)	0					
1.h. Dogs (*Canis familiaris*)	0					
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	0					
1.l. Pigs (*Sus*)						
1.m. Goats (*Capra*)	0					
1.n. Sheep (*Ovis)*						
1.o. Cattle (*Bos*)	0					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	0					
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)						
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)						
1.z. TOTAL	34794					

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	24323	4291	100		40				28754
2.b. Rats	2870	2398							5268
2.c. Guinea-Pigs						22			22
2.d. Hamsters	15	105							120
2.e. Other Rodents									0
2.f. Rabbits	510	120							630
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	27718	6914	100	0	40	22	0	0	34794

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						40				40
3.b. Rats										0
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits										0
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	0	0	0	0	0	40	0	0	0	40

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	621	11357	10124	6512		28614
4.b. Rats	510	3412		1346		5268
4.c. Guinea-Pigs					22	22
4.d. Hamsters				120		120
4.e. Other Rodents						0
4.f. Rabbits				630		630
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	1131	14769	10124	8608	22	34654

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					100		100
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	100	0	100

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					40		40
6.b. Rats							0
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits							0
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	0	0	0	0	40	0	40

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			40											40
7.b. Rats														0
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits														0
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	0	40	0	0	0	0	0	0	0	0	0	0	40

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
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		40												40
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	0	40	0	0	0	0	0	0	0	0	0	0	0	40

IRELAND

Statistical data submitted

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

Comments of Irish authorities

A total of 112,835 animals were used. This represents an increase of 197% compared to 2005.

259 new licences were issued in 2008. This is an increase of 51% compared to 2005.

Rodents accounted for 74% of all animals used which compares to 67% in 2005.

Fish accounted for 20% of all animals.

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

Of the animals used, 24% (26,609) were bred in registered breeding establishments in Ireland while 55% (62,003) came from other Member States in the EC.

Universities and Colleges accounted for 24% (27,198) of all animals used in scientific procedures.

Regulatory requirements (52,325) and studies related to human and animal diseases (40,233) accounted for 82% of all animals used in scientific procedures.

Animals Used for Selected Purposes

10% of animals (10,908) were involved in studies specific to animal diseases. Of the 224 pigs used in 2005, 88% (196) were involved in studies on human and animal diseases.

295 cats were used, 98 of which were used in toxicology and other safety evaluations.

557 dogs were used, 105 of which were used in toxicology and other safety evaluations.

59% (120) of rabbits used were for the study of human or animal diseases.

144 horses were used, a decrease of 45 since 2005. 69% of the horses used were for EC legislation including European Pharmacopoeia requirements.

Toxicological and other Safety Evaluations

No animals were used in the testing of cosmetic products. This was in accordance with Ireland's policy not to licence procedures involving the testing of cosmetics.

Toxicological and other safety evaluations accounted for 46% (52,065) of animals used which compares with 18% in 2005.

99% of the animals used in toxicological and other safety evaluations were mice.

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*)	71.224	12.271	57.264	1.009	680	
1.b. Rats (*Rattus norvegicus*)	11.741	4.396	4.423	2.880	42	
1.c. Guinea-Pigs (*Cavia porcellus*)	91	59	32	0	0	
1.d. Hamsters (*Mesocricetus*)	68	4	64	0	0	
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	204	6	198	0	0	0
1.g. Cats (*Felis catus*)	295	295	0	0	0	16
1.h. Dogs (*Canis familiaris*)	557	547	10	0	0	198
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	144					
1.l. Pigs (*Sus*)	224					
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*	456					
1.o. Cattle (*Bos*)	4.019					
1.p. Prosimians (*Prosimia*)						
1.q. New World Monkeys (*Ceboidea*)						
1.r. Old World Monkeys (*Cercopithecoidea*)						
1.s. Apes (*Hominoidea*)						
1.t. Other Mammals (other *Mammalia*)	32					
1.u. Quail (*Coturnix coturnix)*						
1.v. Other birds (other *Aves*)	582					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)	23.198					
1.z. TOTAL	112.835					

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	15.813	2.487	0	0	51.456	426	14	1.028	71.224
2.b. Rats	6.750	4.506	0	0	243	57	12	173	11.741
2.c. Guinea-Pigs	32	0	0	0	59	0	0	0	91
2.d. Hamsters	4	64	0	0	0	0	0	0	68
2.e. Other Rodents									0
2.f. Rabbits	6	114	0	0	84	0	0	0	204
2.g. Cats	0	197	0	0	98	0	0	0	295
2.h. Dogs	0	442	0	0	105	0	0	10	557
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds	21	0	0	99	0	3	13	8	144
2.l. Pigs	175	21	0	12	16	0	0	0	224
2.m. Goats									0
2.n. Sheep	282	2	0	10	0	120	42	0	456
2.o. Cattle	3.563	29	0	139	0	90	12	186	4.019
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	32	0	0	0	0	0	0	32
2.u. Quail									0
2.v. Other birds	201	287	0	0	4	90	0	0	582
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish	3.019	1.400	0	0	0	0	0	18.779	23.198
2.z. TOTAL	29.866	9.581	0	260	52.065	786	93	20.184	112.835

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	12	0		0		0		0	51.444	51.456
3.b. Rats									243	243
3.c. Guinea-Pigs	0	0		0		0		0	59	59
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits									84	84
3.g. Cats	98	0		0		0		0	0	98
3.h. Dogs	105	0		0		0		0	0	105
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs	16	0		0		0		0	0	16
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	4	0		0		0		0	0	4
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	235	0	0	0	0	0	0	0	51.830	52.065

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	770	5.534	2.374	9.030	1.018	18.726
4.b. Rats	1.525	7.778	42	1.840	128	11.313
4.c. Guinea-Pigs	0	0	0	32	0	32
4.d. Hamsters	0	0	0	64	4	68
4.e. Other Rodents						0
4.f. Rabbits	49	0	0	69	2	120
4.g. Cats	0	0	0	0	197	197
4.h. Dogs	0	0	0	4	438	442
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds					24	24
4.l. Pigs	94		43	0	59	196
4.m. Goats						0
4.n. Sheep	2	0	0	0	402	404
4.o. Cattle	0	0	0	0	3.682	3.682
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals					32	32
4.u. Quail						0
4.v. Other birds	12		2	1	563	578
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish	60	0	0	0	4.359	4.419
4.z. TOTAL	2.512	13.312	2.461	11.040	10.908	40.233

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State **1)**	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation **2)**	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds	0	99	0	0	0	0	99
5.l. Pigs	12	0	0	0	0	0	12
5.m. Goats							0
5.n. Sheep	0	10	0	0	0	0	10
5.o. Cattle	0	91	0	0	0	48	139
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	12	200	0	0	0	48	260

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.**

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State **1)**	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation **2)**	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	5.106	0	0	46.328	22	51.456
6.b. Rats	15	0	0	0	228	0	243
6.c. Guinea-Pigs	0	0	0	0	59	0	59
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	0	0	0	0	84	0	84
6.g. Cats	83	15	0	0	0	0	98
6.h. Dogs	57	48	0	0	0	0	105
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs	16	0	0	0	0	0	16
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	4	0	0	0	0	0	4
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	175	5.169	0	0	46.699	22	52.065

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	42.721	1.866	0	0	0	0	0	0	0	0	0	0	6.869	51.456
7.b. Rats	0	0	0	0	0	0	0	0	15	0	0	0	228	243
7.c. Guinea-Pigs	0	0	0	0	0	0	0	0	0	0	0	0	59	59
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits	0	0	0	0	0	0	0	0	0		0	0	84	84
7.g. Cats	0	0	0	0	0	0	0	0	0		0	0	98	98
7.h. Dogs	0	0	0	0	0	0	0	0	0		0	0	105	105
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	16	16
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	4	4
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	42.721	1.866	0	0	0	0	0	0	15	0	0	0	7.463	52.065

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	12	0	0	0	0	0	0	0	0	0	0	0	223	235
8.b. Products/substances used or intended to be used mainly in agriculture														
8.c. Products/substances used or intended to be used mainly in industry														
8.d. Products/substances used or intended to be used mainly in the household														
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														
8.i. Other toxicological or safety evaluations	1.866	0	0	0	0	0	0	0	15	0	0	0	49.949	51.830
8.j. TOTAL	1.878	0	0	0	0	0	0	0	15	0	0	0	50.172	52.065

GREECE

Statistical data submitted

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

Comments of Greek authorities

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

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

- Law No 2015/92 (Government Gazette I 30) approving the European Convention on the protection of animals used for experimental and other scientific purposes.

For the collection of statistics relating to 2008 use was made of the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 - 24-6-1997. The Ministry of Rural Development and Food, Directorate-General for Veterinary Affairs, Directorate for Veterinary Care, Drugs & Practice sent them directly to the educational establishments (universities and technological colleges), research centres, healthcare institutions and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. These documents were not sent to cosmetics manufacturers for the year in question, as our department was informed that no cosmetics company uses animals for experimental purposes in Greece.

The total number of animals used in experiments in Greece in 2008 was 28021.

Of these, 86,36% (24198 animals) were rodents (19,786 mice – accounting for 81,77%, 4,367 rats - accounting for 18,05%, 45 guinea pigs - accounting for 0,18%), 32,82% of which were used to study fundamental biological characteristics, 15,2% for research and development of medical, dental and veterinary products and appliances, 0,24% to control the production and quality of medical and dental products and appliances, 31,67% for toxicological and other safety studies, 16,02% for diagnosing illnesses, 2,5% for education and training purposes and, finally, 1,52% for other purposes.

Rabbits accounted for 5,34% of the animals used: (1,498 animals, of which 31 had already been used) of which 36,18% were used to study fundamental biological characteristics, 48,86% for research and development of medical, dental and veterinary products and appliances, 3,67% to control the production and quality of veterinary products and appliances, 2,67% for toxicological studies, 2,67% for diagnosing illnesses, 5,87% for education and training purposes and 0,06% for other purposes.

Fish accounted for 4,28% of the animals used (1200 animals), and were used to study fundamental biological characteristics.

Pigs accounted for 2,26% of the animals used (624 animals) of which 14,58% were used to study fundamental biological characteristics, 47,27% for research and development of medical, dental and veterinary products and appliances, 2,24% to control the production and quality of medical and dental products and appliances, and 35,89% for education and training purposes.

Amphibians accounted for 0,71% of the animals used (200 animals) of which 100% were used for education and training purposes.

Other birds accounted for 0,31% of the animals used (88 animals), of which 57,95% were used to study fundamental biological characteristics, 34% for diagnosing illnesses, 6,81% for education and training purposes, and 1,13% for other purposes.

Bovines accounted for 0,25% of the animals used (72 animals), and were used for education and training purposes.

Sheep accounted for 0,4% of the animals used (68 animals) of which 51,47% were used for diagnosing illnesses, 47,05% for education and training purposes, and 1,47% for other purposes.

Dogs accounted for 0,18% of the animals used (44 animals) of which 88,63% were used for research and development of medical, dental and veterinary products and appliances and 11,36% for education and training purposes.

Goats accounted for 0,09% of the animals used (24 animals), of which 75% were used for diagnosing illnesses and 25% for education and training purposes

Cats accounted for 0,01% of the animals used (4 animals), and were used for research and development of medical, dental and veterinary products and appliances.

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

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

It is apparent from the above data and from the tables that in 2008 the four categories of tests which used most animals were biological studies, followed by toxicological and other safety studies, research and development of medical, dental and veterinary products, and the diagnosis of illnesses. The main species used were rodents, fish, and rabbits.

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*)	19786	19493	206		87	
1.b. Rats (*Rattus norvegicus*)	4367	4332	20		15	
1.c. Guinea-Pigs (*Cavia porcellus*)	45	21			24	
1.d. Hamsters (*Mesocricetus*)	0					
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	1498	1467			31	
1.g. Cats (*Felis catus*)	4	4				
1.h. Dogs (*Canis familiaris*)	44	34	10			
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	1					
1.l. Pigs (*Sus*)	624					
1.m. Goats (*Capra*)	24					
1.n. Sheep (*Ovis)*	68					
1.o. Cattle (*Bos*)	72					
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*)	88					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	200					
1.y. Fish (*Pisces*)	1200					
1.z. TOTAL	28021					

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	6274	2271			7197	3574	172	298	19786
2.b. Rats	1670	1408	60		468	264	427	70	4367
2.c. Guinea-Pigs						40	5		45
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	542	732		55	40	40	88	1	1498
2.g. Cats		4							4
2.h. Dogs		39					5		44
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds							1		1
2.l. Pigs	91	295	14				224		624
2.m. Goats						18	6		24
2.n. Sheep						35	32	1	68
2.o. Cattle							72		72
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	51					30	6	1	88
2.w. Reptiles									0
2.x. Amphibians							200		200
2.y. Fish	1200								1200
2.z. TOTAL	9828	4749	74	55	7705	4001	1238	371	28021

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	120								7077	7197
3.b. Rats	430	12						26		468
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	40									40
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	590	12	0	0	0	0	0	26	7077	7705

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	1838	1756	1196	2512	207	7509
4.b. Rats	570	447	40	1138	11	2206
4.c. Guinea-Pigs					40	40
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	489	18		625	31	1163
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	237			122		359
4.m. Goats					18	18
4.n. Sheep					35	35
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					30	30
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish	1000	200				1200
4.z. TOTAL	4134	2421	1236	4397	372	12560

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State **1)**	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation **2)**	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats		60					60
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		55					55
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs		14					14
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	129	0	0	0	0	129

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		120			7077		7197
6.b. Rats	38	430					468
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		40					40
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	38	590	0	0	7077	0	7705

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		7077											120	7197
7.b. Rats			12							26			430	468
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													40	40
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	7077	12	0	0	0	0	0	0	26	0	0	590	7705

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													590	590
8.b. Products/substances used or intended to be used mainly in agriculture			12											12
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										26				26
8.i. Other toxicological or safety evaluations		7077												7077
8.j. TOTAL	0	7077	12	0	0	0	0	0	0	26	0	0	590	7705

SPAIN

Statistical data submitted

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

Comments of Spanish authorities

The statistical information was put together by the Ministry of the Environment and the Rural and Marine Environment (MARM) on the basis of data it had collected itself or received from the individual Autonomous Communities.

220 establishments are registered for 2009. The number of establishments has remained at around the same level for the past few years.

The MARM is currently changing its system for registering holdings, suppliers and users of animals for scientific purposes so that they will be included in the REGA database (register of livestock holdings).

As regards the trend in the past few years in the number of animals used within the scope of Directive 86/609/EEC, while the total has gone down, there has been an increase in the use for research purposes of 'non-traditional' species, such as farm animals.

The tables on the use of animals and the possible regulatory requirements show an increase in the number of animals used in the production and quality control of medical, dental or veterinary products, greater pressure from EU regulation and a fall in the use of animals to meet the requirements of 'other rules'.

Finally, there has been a fall in the number of animals used for training 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*)	543680	467820	67595	41	8224	
1.b. Rats (*Rattus norvegicus*)	175325	147505	27397	0	423	275
1.c. Guinea-Pigs (*Cavia porcellus*)	12620	9601	3019	0	0	
1.d. Hamsters (*Mesocricetus*)	1262	1138	113	0	11	
1.e. Other Rodents (other *Rodentia*)	251					
1.f. Rabbits (*Oryctolagus cuniculus*)	19626	18651	873	0	102	396
1.g. Cats (*Felis catus*)	100	73	0	0	27	0
1.h. Dogs (*Canis familiaris*)	1046	990	43	0	13	1
1.i. Ferrets (*Mustela putorius furo*)	287	14	0	0	273	0
1.j. Other Carnivores (other *Carnivora*)	5					
1.k. Horses, donkeys and cross breds (*Equidae*)	90					
1.l. Pigs (*Sus*)	15121					902
1.m. Goats (*Capra*)	372					20
1.n. Sheep (*Ovis)*	2386					3
1.o. Cattle (*Bos*)	1091					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	
1.q. New World Monkeys (*Ceboidea*)	8	0	8	0	0	
1.r. Old World Monkeys (*Cercopithecoidea*)	517	362	152	3	0	
1.s. Apes (*Hominoidea*)	0	0	0	0	0	
1.t. Other Mammals (other *Mammalia*)	28					
1.u. Quail (*Coturnix coturnix)*	138	81	0	0	57	
1.v. Other birds (other *Aves*)	52104					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	704					
1.y. Fish (*Pisces*)	71098					
1.z. TOTAL	897859					

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	268703	136072	16012	19904	63052	20338	6665	12934	543680
2.b. Rats	63513	65305	2311	9750	8810	11256	8305	6075	175325
2.c. Guinea-Pigs	149	4537	868	3370	3566	102	28	0	12620
2.d. Hamsters	564	409	0	0	156	119	14	0	1262
2.e. Other Rodents	206	10	0	0	0	0	0	35	251
2.f. Rabbits	1247	3658	879	5318	6765	488	232	1039	19626
2.g. Cats	48	17	0	4	0	0	0	31	100
2.h. Dogs	65	389	0	176	349	6	44	17	1046
2.i. Ferrets	14	241	0	0	32	0	0	0	287
2.j. Other Carnivores	5	0	0	0	0	0	0	0	5
2.k. Horses, donkeys and cross breds	0	0	0	90	0	0	0	0	90
2.l. Pigs	841	2428	0	903	4925	329	2013	3682	15121
2.m. Goats	52	37	27	0	0	0	125	131	372
2.n. Sheep	186	1070	50	812	78	44	124	22	2386
2.o. Cattle	154	472	0	304	58	0	103	0	1091
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	8	0	0	0	0	0	0	0	8
2.r. Old World Monkeys	16	74	0	0	427	0	0	0	517
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	16	0	12	0	0	28
2.u. Quail	57	57	0	0	24	0	0	0	138
2.v. Other birds	664	4113	344	4991	35297	30	42	6623	52104
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	661	0	0	0	0	0	13	30	704
2.y. Fish	52521	5780	0	0	940	400	152	11305	71098
2.z. TOTAL	389674	224669	20491	45638	124479	33124	17860	41924	897859

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	19644	0	0	0	126	0	1023	557	41702	63052
3.b. Rats	6570	170	296	120	124	0	0	0	1530	8810
3.c. Guinea-Pigs	3530	0	32	0	0	0	0	0	4	3566
3.d. Hamsters	156	0	0	0	0	0	0	0	0	156
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	6298	43	272	42	110	0	0	0	0	6765
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	254	52	0	0	0	0	0	0	43	349
3.i. Ferrets	32	0	0	0	0	0	0	0	0	32
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	791	0	0	0	0	0	4134	0	0	4925
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	78	0	0	0	0	0	0	0	0	78
3.o. Cattle	58	0	0	0	0	0	0	0	0	58
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	427	0	0	0	0	0	0	0	0	427
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	24	0	0	0	0	0	0	0	24
3.v. Other birds	1268	0	0	0	0	0	34029	0	0	35297
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	504	0	0	0	0	286	150	940
3.z. TOTAL	39106	289	1104	162	360	0	39186	843	43429	124479

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	15692	36425	85628	48186	7331	193262
4.b. Rats	11159	33110	2520	58447	586	105822
4.c. Guinea-Pigs	0	234	60	4687	298	5279
4.d. Hamsters	51	103	349	68	175	746
4.e. Other Rodents	0	231	0	10	0	241
4.f. Rabbits	6	6	0	1989	2541	4542
4.g. Cats	4	9	0	3	0	16
4.h. Dogs	47	0	45	88	94	274
4.i. Ferrets	0	0	0	241	0	241
4.j. Other Carnivores	27	0	0	4	5	36
4.k. Horses, donkeys and cross breds	0	0	0	0	86	86
4.l. Pigs	352	5	3	906	2592	3858
4.m. Goats	20	0	0	8	0	28
4.n. Sheep	26	36	24	170	873	1129
4.o. Cattle	0	0	0	0	606	606
4.p. Prosimians	0	0	0	3	0	3
4.q. New World Monkeys	0	3	0	0	0	3
4.r. Old World Monkeys	0	59	0	15	8	82
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	12	12
4.u. Quail	0	0	0	57	0	57
4.v. Other birds	0	0	0	20	7325	7345
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	5	130	382	0	517
4.y. Fish	200	500	485	23378	4866	29429
4.z. TOTAL	27584	70726	89244	138662	27398	353614

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	33234	0	403	0	2279	35916
5.b. Rats	0	11278	0	655	128	0	12061
5.c. Guinea-Pigs	0	3344	0	731	0	163	4238
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	5337	0	0	16	844	6197
5.g. Cats	4	0	0	0	0	0	4
5.h. Dogs	176	0	0	0	0	0	176
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	90	0	0	0	0	90
5.l. Pigs	0	507	0	0	130	266	903
5.m. Goats	0	27	0	0	0	0	27
5.n. Sheep	0	749	54	0	0	59	862
5.o. Cattle	26	278	0	0	0	0	304
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	16	0	0	0	0	16
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	3496	0	1321	0	518	5335
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	206	58356	54	3110	274	4129	66129

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	1147	18053	30	0	40120	3702	63052
6.b. Rats	290	2934	0	244	4286	1056	8810
6.c. Guinea-Pigs	0	434	84	288	2752	8	3566
6.d. Hamsters	80	76	0	0	0	0	156
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	100	764	0	218	5547	136	6765
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	30	0	0	284	35	349
6.i. Ferrets	0	32	0	0	0	0	32
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	329	0	0	4585	11	4925
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	28	0	0	44	6	78
6.o. Cattle	0	0	0	0	58	0	58
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	75	0	0	352	0	427
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	24	0	0	0	0	0	24
6.v. Other birds	0	1	0	0	34029	1267	35297
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	504	150	0	0	286	0	940
6.z. TOTAL	2145	22906	114	750	92343	6221	124479

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	6991	39161	908	56	298	0	840	0	0	0	0	0	14798	63052
7.b. Rats	246	398	949	290	76	0	2593	0	0	0	437	0	3821	8810
7.c. Guinea-Pigs	0	303	24	0	326	0	0	0	0	0	0	0	2913	3566
7.d. Hamsters	16	0	0	0	0	0	80	0	0	0	0	0	60	156
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	22	0	143	397	0	248	0	0	94	0	69	0	5792	6765
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	276	0	0	0	0	0	73	349
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	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	40	0	0	119	0	0	0	0	0	4766	4925
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	78	78
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	58	58
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	18	0	0	0	0	0	405	0	0	0	0	0	4	427
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	24	0	0	0	0	0	0	0	0	0	0	0	24
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	35297	35297
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	213	504	0	0	0	223	940
7.z. TOTAL	7293	39886	2024	783	700	248	4313	213	598	0	506	0	67915	124479

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub-chronic and chronic toxicity	8.7 Carcinogenicity	8.8 Developmental toxicity	8.9 Mutagenicity	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebrates not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	2082	2797	1788	416	602	62	3942		94		506		26817	39106
8.b. Products/substances used or intended to be used mainly in agriculture		39		105			141						4	289
8.c. Products/substances used or intended to be used mainly in industry		28	236	75	98	113	50		504					1104
8.d. Products/substances used or intended to be used mainly in the household				139		23								162
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	60	202		48		50								360
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		1023											38163	39186
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	557							213					73	843
8.i. Other toxicological or safety evaluations	4594	35797					180						2858	43429
8.j. TOTAL	7293	39886	2024	783	700	248	4313	213	598	0	506	0	67915	124479