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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**

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**Important notice**

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

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

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# FRANCE

## Statistical data submitted

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

## Comments of the French authorities

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

The number of animals used in France shows a steady state since 1999 with about 2.5 million. It represents a decrease of 30% in comparison with the figures of the first statistical study in 1990. In 2007, a slight increasing tendency could be observed which led to values similar to the 1997 figures. Since 1999, the amount of rodents used is stable (2.1 million). Even if some animal groups are more often used (the number of birds and rabbits has doubled and the number of fish has increased by 37%), there is a reverse tendency for other species (the amount of dogs has decreased by 15%). The use of non human primates is steady from 1999, probably because of their incompressible scientific interests.

Concerning the results of the survey, when significant differences were revealed between 2007 and previous years, some verification was done in order to identify the origin of these sudden evolutions. These differences could always be explained by: either new activity, for example the production of therapeutic antibodies giving an explanation to rabbits increase observed since 2004, or the opening or the closure of laboratories. The other variations were not significant and supported the figures provided by experimental centres and laboratories.

This study showed that the public sector used half (47%) of the total amount of animals, of which 80% is for basic research and education. On the other hand, the private sector used the remaining 53%, of which 40% are dedicated to research and development, 37% to production and control, and 6% to toxicological evaluations.

Similar to the numbers observed in 2004, the present study shows that there are about 450 centres for animal experimentation (this number can vary depending on juridical conventions that link laboratories to these centres).

It represents a third of the figure established in 1990. This decrease in the number of experimental centres shows that laboratories are merged or clustered in order to share centralized installations and competent staff. The « disappearance » of 900 experimental animal houses shows the pressure brought by the animal protection associations and the concerned authorities for fifteen years. It was supported by very significant investments to come up to the current sanitary, ethic and scientific expectations. Of course, this diminution did not obviously result in a proportional decrease of the number of animals, but it sets practices that warrant respect and well-being to animals.

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	1.561.809	1.423.488	47.564	2.534	88.223	
1.b. Rats ( <i>Rattus norvegicus</i> )	392.773	367.102	16.411	10	9.250	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	46.030	41.952	3.895	0	183	
1.d. Hamsters ( <i>Mesocricetus</i> )	12.063	10.271	959	0	833	
1.e. Other Rodents (other <i>Rodentia</i> )	3.594					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	96.427	96.169	5	0	253	430
1.g. Cats ( <i>Felis catus</i> )	1.848	1.391	245	3	209	644
1.h. Dogs ( <i>Canis familiaris</i> )	4.131	2.928	262	0	941	805
1.i. Ferrets ( <i>Mustela putorius furo</i> )	800	591	0	0	209	0
1.j. Other Carnivores (other <i>Carnivora</i> )	0					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	652					
1.l. Pigs ( <i>Sus</i> )	8.768					
1.m. Goats ( <i>Capra</i> )	1.159					
1.n. Sheep ( <i>Ovis</i> )	3.573					
1.o. Cattle ( <i>Bos</i> )	3.206					
1.p. Prosimians ( <i>Prosimia</i> )	718	718	0	0	0	33
1.q. New World Monkeys ( <i>Ceboidea</i> )	233	213	20	0	0	135
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	1.797	610	262	0	925	244
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	0					
1.u. Quail ( <i>Coturnix coturnix</i> )	1.548	48	1.500	0	0	
1.v. Other birds (other <i>Aves</i> )	156.814					
1.w. Reptiles ( <i>Reptilia</i> )	758					
1.x. Amphibians ( <i>Amphibia</i> )	9.451					
1.y. Fish ( <i>Pisces</i> )	20.228					
1.z. TOTAL	2.328.380					

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

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

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

**Purpose versus species**

2.1 Species	2.2 Biological studies of a fundamenta l nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	585.129	429.558	279.987	45.522	50.866	12.308	18.947	139.492	1.561.809
2.b. Rats	80.421	182.333	5.161	13.121	47.447	697	14.196	49.397	392.773
2.c. Guinea-Pigs	739	3.705	30.748	2.230	7.317	2	274	1.015	46.030
2.d. Hamsters	1.590	2.618	0	6.414	21	10	4	1.406	12.063
2.e. Other Rodents	941	1.690	0	0	0	0	918	45	3.594
2.f. Rabbits	3.348	6.202	50.152	7.147	7.737	125	799	20.917	96.427
2.g. Cats	138	790	0	544	24	0	3	349	1.848
2.h. Dogs	354	1.072	0	732	1.834	0	8	131	4.131
2.i. Ferrets	0	162	8	0	237	0	13	380	800
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	196	139	83	20	0	0	75	139	652
2.l. Pigs	470	2.860	0	2.545	434	23	241	2.195	8.768
2.m. Goats	330	41	3	19	29	0	18	719	1.159
2.n. Sheep	1.331	638	27	655	205	0	56	661	3.573
2.o. Cattle	310	541	0	298	84	140	30	1.803	3.206
2.p. Prosimians	568	0	0	0	0	150	0	0	718
2.q. New World Monkeys	63	77	0	0	0	0	0	93	233
2.r. Old World Monkeys	184	198	139	0	1.128	0	0	148	1.797
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	0	0
2.u. Quail	0	0	0	0	0	0	1.548	0	1.548
2.v. Other birds	2.821	7.491	9.280	86.122	5.251	1.400	6.593	37.856	156.814
2.w. Reptiles	758	0	0	0	0	0	0	0	758
2.x. Amphibians	5.013	52	0	0	179	0	4.207	0	9.451
2.y. Fish	5.836	200	0	0	2.954	0	7.643	3.595	20.228
2.z. TOTAL	690.540	640.367	375.588	165.369	125.747	14.855	55.573	260.341	2.328.380

**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	23.187	3.441	2.074	0	704	0	0	3.776	17.684	50.866
3.b. Rats	26.440	6.006	3.375	159	0	0	0	1.499	9.968	47.447
3.c. Guinea-Pigs	4.468	608	1.755	0	38	0	0	0	448	7.317
3.d. Hamsters	0	0	21	0	0	0	0	0	0	21
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	5.247	563	481	0	43	0	0	0	1.403	7.737
3.g. Cats	24	0	0	0	0	0	0	0	0	24
3.h. Dogs	1.160	104	0	0	0	0	0	0	570	1.834
3.i. Ferrets	237	0	0	0	0	0	0	0	0	237
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	404	0	0	0	0	0	0	30	0	434
3.m. Goats	21	0	0	0	0	0	0	8	0	29
3.n. Sheep	205	0	0	0	0	0	0	0	0	205
3.o. Cattle	84	0	0	0	0	0	0	0	0	84
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	930	0	0	0	0	0	0	0	198	1.128
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	25	0	0	0	0	0	5.000	0	226	5.251
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	179	0	0	0	0	0	0	0	0	179
3.y. Fish	0	1.457	0	0	300	0	0	1.047	150	2.954
3.z. TOTAL	62.611	12.179	7.706	159	1.085	0	5.000	6.360	30.647	125.747



**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	60.574	232.877	180.979	333.623	218.942	1.026.995
4.b. Rats	45.947	84.717	15.812	106.175	10.800	263.451
4.c. Guinea-Pigs	479	312	190	2.639	826	4.446
4.d. Hamsters	434	708	0	1.042	2.034	4.218
4.e. Other Rodents	300	1.774	60	191	306	2.631
4.f. Rabbits	1.197	2	123	6.710	1.643	9.675
4.g. Cats	0	31	0	60	837	928
4.h. Dogs	114	133	13	499	667	1.426
4.i. Ferrets	0	0	0	162	0	162
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	335	335
4.l. Pigs	736	0	0	547	2.070	3.353
4.m. Goats	0	10	0	6	355	371
4.n. Sheep	140	62	0	97	1.670	1.969
4.o. Cattle	0	0	0	0	991	991
4.p. Prosimians	0	40	0	308	370	718
4.q. New World Monkeys	0	4	0	115	21	140
4.r. Old World Monkeys	0	20	0	362	0	382
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	120	0	0	11.592	11.712
4.w. Reptiles	0	0	0	0	758	758
4.x. Amphibians	0	52	2.399	658	1.956	5.065
4.y. Fish	900	250	0	930	3.956	6.036
4.z. TOTAL	110.821	321.112	199.576	454.124	260.129	1.345.762

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

**Regulatory requirements versus species**

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	2.709	71.121	371	407	244.482	6.419	325.509
5.b. Rats	4.053	194	405	12.732	383	515	18.282
5.c. Guinea-Pigs	0	5.042	0	32	27.904	0	32.978
5.d. Hamsters	0	6.414	0	0	0	0	6.414
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	10	37.019	0	0	3.859	16.411	57.299
5.g. Cats	0	536	0	8	0	0	544
5.h. Dogs	0	732	0	0	0	0	732
5.i. Ferrets	0	0	0	0	8	0	8
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	20	0	0	83	0	103
5.l. Pigs	0	2.454	0	91	0	0	2.545
5.m. Goats	19	0	0	0	3	0	22
5.n. Sheep	189	466	0	0	27	0	682
5.o. Cattle	0	298	0	0	0	0	298
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	139	0	139
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	86.034	0	80	9.280	8	95.402
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	6.980	210.330	776	13.350	286.168	23.353	540.957

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement  
5.3 - UK is testing according to EC legislation  
5.4 - Spain is testing due to a Norwegian requirement  
5.5 – Poland is testing due to a US specific requirement  
5.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	6.960	13.193	658	2.783	20.930	6.342	50.866
6.b. Rats	8.250	5.748	79	9.219	20.712	3.439	47.447
6.c. Guinea-Pigs	286	2.516	0	0	4.515	0	7.317
6.d. Hamsters	21	0	0	0	0	0	21
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	260	1.314	0	1.405	4.734	24	7.737
6.g. Cats	0	24	0	0	0	0	24
6.h. Dogs	53	191	0	723	867	0	1.834
6.i. Ferrets	211	0	0	26	0	0	237
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross bred	0	0	0	0	0	0	0
6.l. Pigs	55	18	0	149	212	0	434
6.m. Goats	29	0	0	0	0	0	29
6.n. Sheep	0	0	0	0	205	0	205
6.o. Cattle	0	84	0	0	0	0	84
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	190	0	732	198	8	1.128
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	25	0	5.000	0	226	5.251
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	179	0	179
6.y. Fish	82	0	0	0	1.457	1.415	2.954
6.z. TOTAL	16.207	23.303	737	20.037	54.009	11.454	125.747

**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	1.455	7.107	9.877	648	1.733	0	12.298	2.524	730	139	0	0	14.355	50.866
7.b. Rats	36	1.169	5.128	12	1.290	78	16.839	5.287	2.075	1.547	4.489	0	9.497	47.447
7.c. Guinea-Pigs	0	0	36	0	6.584	0	0	0	0	0	86	0	611	7.317
7.d. Hamsters	0	0	0	0	0	0	0	0	0	21	0	0	0	21
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	349	1.059	0	377	568	0	669	0	965	0	3.750	7.737
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.h. Dogs	0	0	461	0	0	0	1.106	0	0	0	18	0	249	1.834
7.i. Ferrets	0	0	211	0	0	0	0	0	0	0	0	0	26	237
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	56	0	0	0	84	0	294	434
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	29	29
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	205	205
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	84	84
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	80	0	0	0	864	0	0	0	0	0	184	1.128
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	5.251	5.251
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	179	179
7.y. Fish	1.907	0	0	0	0	0	890	0	0	0	0	82	75	2.954
7.z. TOTAL	3.398	8.276	16.142	1.719	9.607	455	32.621	7.811	3.474	1.707	5.642	82	34.813	125.747

**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	1.965	5.233	9.654	638	4.460	170	14.646	3.293	1.141	1.480	5.211	0	14.720	62.611
8.b. Products/substances used or intended to be used mainly in agriculture	1.430	310	0	100	608	88	5.944	2.682	867	0	150	0	0	12.179
8.c. Products/substances used or intended to be used mainly in industry	0	1.378	665	942	1.673	182	230	246	626	101	60	0	1.603	7.706
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	159	0	0	0	0	0	0	159
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	300	0	43	39	699	4	0	0	0	0	0	0	0	1.085
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	5.000	5.000
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	2.600	0	0	0	0	2.014	0	0	890	327	82	447	6.360
8.i. Other toxicological or safety evaluations	221	3.397	589	0	0	6	3.792	2.604	300	0	1.902	0	17.836	30.647
8.j. TOTAL	3.916	12.918	10.951	1.719	7.440	450	26.785	8.825	2.934	2.471	7.650	82	39.606	125.747

## **ITALY**

### **Statistical data submitted**

The statistical data have been submitted by the Ministry of Health – Department for public veterinary health food and animal safety, Directorate-General for animal health and veterinary medicines, Office X

### **Comments of the Italian authorities**

None

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	553000	528861	12593	223	11323	
1.b. Rats ( <i>Rattus norvegicus</i> )	230347	224605	5077	0	665	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	13875	9924	3951	0	0	
1.d. Hamsters ( <i>Mesocricetus</i> )	717	604	36	0	77	
1.e. Other Rodents (other <i>Rodentia</i> )	1235					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	9706	9061	645	0	0	603
1.g. Cats ( <i>Felis catus</i> )	26	0	0	0	26	0
1.h. Dogs ( <i>Canis familiaris</i> )	943	720	70	0	153	52
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i> )	0					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	46					
1.l. Pigs ( <i>Sus</i> )	3607					
1.m. Goats ( <i>Capra</i> )	41					
1.n. Sheep ( <i>Ovis</i> )	469					
1.o. Cattle ( <i>Bos</i> )	462					
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	18	11	7	0	0	53
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	344	182	107	2	53	72
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	151					
1.u. Quail ( <i>Coturnix coturnix</i> )	249	4	0	0	245	
1.v. Other birds (other <i>Aves</i> )	32241					
1.w. Reptiles ( <i>Reptilia</i> )	454					
1.x. Amphibians ( <i>Amphibia</i> )	2432					
1.y. Fish ( <i>Pisces</i> )	13955					
1.z. TOTAL	864318					

**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	311807	143156	26423	2300	34150	21911	10	13243	553000
2.b. Rats	86363	55681	67788	205	17730	1340	159	1081	230347
2.c. Guinea-Pigs	2710	2170	3521	397	4751	30	0	296	13875
2.d. Hamsters	227	258	0	0	145	87	0	0	717
2.e. Other Rodents	160	215	0	0	0	860	0	0	1235
2.f. Rabbits	1628	1140	4538	305	2009	6	0	80	9706
2.g. Cats	26	0	0	0	0	0	0	0	26
2.h. Dogs	20	46	0	0	877	0	0	0	943
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	31	0	15	0	0	0	0	0	46
2.l. Pigs	1350	1174	15	84	435	0	344	205	3607
2.m. Goats	37	3	0	1	0	0	0	0	41
2.n. Sheep	171	190	62	12	23	0	0	11	469
2.o. Cattle	270	134	0	6	9	2	0	41	462
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	18	0	0	0	0	0	0	18
2.r. Old World Monkeys	12	41	51	0	238	0	0	2	344
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	104	0	0	47	0	0	0	0	151
2.u. Quail	4	0	0	0	0	0	0	245	249
2.v. Other birds	7393	3565	12	12736	6621	1081	0	833	32241
2.w. Reptiles	454	0	0	0	0	0	0	0	454
2.x. Amphibians	2346	20	0	0	0	66	0	0	2432
2.y. Fish	6049	400	0	2518	2018	0	0	2970	13955
2.z. TOTAL	421162	208211	102425	18611	69006	25383	513	19007	864318



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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contaminants in the general environment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	8016	80	208	0	0	54	169	4082	21541	34150
3.b. Rats	14149	254	1142	0	0	205	0	0	1980	17730
3.c. Guinea-Pigs	4408	87	215	0	0	0	0	0	41	4751
3.d. Hamsters	145	0	0	0	0	0	0	0	0	145
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1896	9	41	0	0	0	0	0	63	2009
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	877	0	0	0	0	0	0	0	0	877
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	147	0	0	0	0	0	288	0	0	435
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	23	0	0	0	0	0	0	0	0	23
3.o. Cattle	9	0	0	0	0	0	0	0	0	9
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	238	0	0	0	0	0	0	0	0	238
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	5691	450					480	0	0	6621
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	210	0	158	0	0	0	0	1650	0	2018
3.z. TOTAL	35809	880	1764	0	0	259	937	5732	23625	69006

**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	17719	72970	123899	130189	7073	351850
4.b. Rats	6348	42732	4325	33482	545	87432
4.c. Guinea-Pigs	380	326	0	2366	182	3254
4.d. Hamsters	20	21	50	357	0	448
4.e. Other Rodents	0	244	0	297	654	1195
4.f. Rabbits	82	262	54	1410	13	1821
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	12	0	0	17	0	29
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	31	31
4.l. Pigs	163	0	8	170	110	451
4.m. Goats	0	0	0	0	3	3
4.n. Sheep	31	0	0	42	16	89
4.o. Cattle	7	0	0	2	2	11
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	18	0	0	0	18
4.r. Old World Monkeys	0	2	0	41	0	43
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	6	6
4.u. Quail	0	0	0	0	249	249
4.v. Other birds	0	0	0	0	1358	1358
4.w. Reptiles	0	0	0	0	86	86
4.x. Amphibians	0	101	0	241	66	408
4.y. Fish	0	0	1629	66	3268	4963
4.z. TOTAL	24762	116676	129965	168680	13662	453745

**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	6375	7376	0	100	13027	1845	28723
5.b. Rats	241	1730	0	0	64208	1814	67993
5.c. Guinea-Pigs	657	627	0	0	2634	0	3918
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	344	3773	0	0	714	12	4843
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	15	0	0	0	0	0	15
5.l. Pigs	99	0	0	0	0	0	99
5.m. Goats	1	0	0	0	0	0	1
5.n. Sheep	65	0	0	0	0	9	74
5.o. Cattle	6	0	0	0	0	0	6
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	51	0	51
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	13	34	0	0	0	0	47
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	853	11895	0	0	0	0	12748
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	2170	0	0	0	348	0	2518
5.z. TOTAL	10839	25435	0	100	80982	3680	121036

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement  
5.3 - UK is testing according to EC legislation  
5.4 – Spain is testing due to a Norwegian requirement  
5.5 – Poland is testing due to a US specific requirement  
5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	19994	4665	0	0	9102	389	34150
6.b. Rats	2093	5724	0	0	9557	356	17730
6.c. Guinea-Pigs	104	3731	0	0	916	0	4751
6.d. Hamsters	0	122	0	0	23	0	145
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	6	1389	0	0	566	48	2009
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	176	305	0	0	396	0	877
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	435	0	0	0	0	435
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	23	0	0	0	0	23
6.o. Cattle	0	9	0	0	0	0	9
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	238	0	238
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	6171	0	0	0	450	6621
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	1650	158	0	0	0	210	2018
6.z. TOTAL	24023	22732	0	0	20798	1453	69006

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

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

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

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

**Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	590	5698	7128	110	0	0	5666	77	177	344	743	0	13617	34150
7.b. Rats	104	453	3884	38	2	0	10261	2	507	363	717	0	1399	17730
7.c. Guinea-Pigs	0	0	23	80	4630	0	0	0	0	0	0	0	18	4751
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	145	145
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	371	250	0	90	130	0	235	0	0	0	933	2009
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	179	0	0	0	681	0	0	0	0	0	17	877
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	56	0	0	0	40	0	0	0	0	0	339	435
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	23	23
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	9	9
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	57	0	0	0	122	0	0	0	0	0	59	238
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	4595	1020	0	0	0	0	0	0	0	0	1006	6621
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	930	0	368	0	0	0	720	0	0	0	0	0	0	2018
7.z. TOTAL	1624	6151	16661	1498	4632	90	17620	79	919	707	1460	0	17565	69006

**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	184	350	12772	1469	4330	69	11879	79	625	513	701	0	2838	35809
8.b. Products/substances used or intended to be used mainly in agriculture	0	120	65	3	87	6	0	0	0	0	100	0	499	880
8.c. Products/substances used or intended to be used mainly in industry	0	224	361	26	215	15	200	0	244	194	189	0	96	1764
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	35	0	0	0	174	0	50	0	0	0	0	259
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	169	0	0	0	0	0	0	0	0	0	0	768	937
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	930	0	0	0	0	0	3099	0	0	0	470	0	1233	5732
8.i. Other toxicological or safety evaluations	510	5288	3428	0	0	0	2268	0	0	0	0	0	12131	23625
8.j. TOTAL	1624	6151	16661	1498	4632	90	17620	79	919	707	1460	0	17565	69006

## **CYPRUS**

### **Statistical data submitted**

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

Remark: Cyprus reported data only in tables 1, 2, 4 and 5. The remaining tables are not applicable.

### **Comments of the Cypriot authorities**

At present only rodents (mice) are used in animal experimentation in Cyprus. The use of experimental mice concentrates mainly on the generation and use of genetically modified mice to study basic biological processes like:

- Development of the central nervous system and early development of the mouse embryo.
- Generation of mouse models of inherited diseases or diseases with a genetic component and study of disease progression. These include haemoglobinopathies and neurodegenerative diseases.
- Testing of genetically engineered molecules as putative anti-neoplastic agents on genetically immunocompromised animals, challenged with carcinogenic cells.
- Testing of modified forms of natural vitamins as potential antioxidants on induced models of diabetes.
- Use of mice to study the effect of various agents on heart physiology.

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

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	2114	2114				
1.b. Rats ( <i>Rattus norvegicus</i> )	0					
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	0					
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	0					
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )						
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )						
1.l. Pigs ( <i>Sus</i> )						
1.m. Goats ( <i>Capra</i> )						
1.n. Sheep ( <i>Ovis</i> )						
1.o. Cattle ( <i>Bos</i> )						
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0					
1.s. Apes ( <i>Hominioidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )						
1.u. Quail ( <i>Coturnix coturnix</i> )	0					
1.v. Other birds (other <i>Aves</i> )						
1.w. Reptiles ( <i>Reptilia</i> )						
1.x. Amphibians ( <i>Amphibia</i> )						
1.y. Fish ( <i>Pisces</i> )						
1.z. TOTAL	2114					

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

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



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

**Purpose versus species**

2.1 Species	2.2 Biological studies of a fundamenta l nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	1701		320				93		2114
2.b. Rats									0
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits									0
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	1701	0	320	0	0	0	93	0	2114

**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		205	70	165		440
4.b. Rats						0
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	205	70	165	0	440

**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						320	320
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 breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	0	320	320

**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

## **LATVIA**

### **Statistical data submitted**

The statistical data have been submitted by the Ministry of Agriculture – State Food and veterinary service

### **Comments of Latvian authorities**

None

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	6912	6912				
1.b. Rats ( <i>Rattus norvegicus</i> )	2407	2407				
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	32	32				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	48	48				
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )						
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )						
1.l. Pigs ( <i>Sus</i> )						
1.m. Goats ( <i>Capra</i> )						
1.n. Sheep ( <i>Ovis</i> )						
1.o. Cattle ( <i>Bos</i> )						
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0					
1.s. Apes ( <i>Hominoidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )						
1.u. Quail ( <i>Coturnix coturnix</i> )	0					
1.v. Other birds (other <i>Aves</i> )						
1.w. Reptiles ( <i>Reptilia</i> )						
1.x. Amphibians ( <i>Amphibia</i> )						
1.y. Fish ( <i>Pisces</i> )						
1.z. TOTAL	9399					

**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	1032	1952	2710			668	550		6912
2.b. Rats	325	460	1037			280	305		2407
2.c. Guinea-Pigs					32				32
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits			48						48
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	1357	2412	3795	0	32	948	855	0	9399

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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice										0
3.b. Rats										0
3.c. Guinea-Pigs	32									32
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 breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	32	0	0	0	0	0	0	0	0	32

**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	995	634	1353	548	122	3652
4.b. Rats	394	195	360	116		1065
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	1389	829	1713	664	122	4717



**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					2710		2710
5.b. Rats					1037		1037
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits					48		48
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	3795	0	3795

**Examples:**  
 5.2 – France is testing due to a UK (or FR) specific requirement  
 5.3 - UK is testing according to EC legislation  
 5.4 – Spain is testing due to a Norwegian requirement  
 5.5 – Poland is testing due to a US specific requirement  
 5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice							0
6.b. Rats							
6.c. Guinea-Pigs					32		32
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 breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	0	0	0	0	32	0	32

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

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

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

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

**Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total	
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods												
7.a. Mice															0
7.b. Rats															
7.c. Guinea-Pigs				32											32
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 breeds															0
7.l. Pigs															0
7.m. Goats															0
7.n. Sheep															0
7.o. Cattle															0
7.p. Prosimians															0
7.q. New World Monkeys															0
7.r. Old World Monkeys															0
7.s. Apes															0
7.t. Other Mammals															0
7.u. Quail															0
7.v. Other birds															0
7.w. Reptiles															0
7.x. Amphibians															0
7.y. Fish															0
7.z. TOTAL	0	0	0	32	0	0	0	0	0	0	0	0	0	0	32

**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				32										32
8.b. Products/substances used or intended to be used mainly in agriculture														0
8.c. Products/substances used or intended to be used mainly in industry														0
8.d. Products/substances used or intended to be used mainly in the household														0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	0	0	0	32	0	0	0	0	0	0	0	0	0	32

# LITHUANIA

## Statistical data submitted

The statistical data have been submitted by the Animal Health and Welfare Department of the State Food and Veterinary Service of the Republic of Lithuania.

## Comments of Lithuanian authorities

The legal basis for the collection of statistics on the number and use of vertebrate animals for experimental and other scientific purposes in Lithuania is provided by the State Food and Veterinary Service Director Decree No B1-639 (Government Gazette 2009-01-22, No 8-287) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC and European Convention on the protection of animals used for experimental and other scientific purposes

The total number of animals used in experiments in Lithuania in 2008 was 5,582 of which 100% animals came from registered breeding or supplying establishments within the reporting country.

Rodents accounted for 91,61% of all animals used – 5,114 animals (3,827 mice – accounting for 68,56%, 1,194 rats - accounting for 21,39%, 93 guinea pigs – accounting for 1,67%)

A further 3,56% (199 animals) were rabbits.

Cold-blooded animals (fish and amphibians) represented 2,67% of the animals used, 149 animals, of which 28,86% were used for research and development of medical, dental and veterinary products and appliances, 71,14% for education and training purposes.

Pigs accounted for 1,43% of the animals used (80 animals), of which 37,5% were used for research and development of medical, dental and veterinary products and appliances, 62,5% for education and training purposes.

Birds accounted for 0,71% (40 animals), of which 100% were used for research and development of medical, dental and veterinary products and appliances.

No animals were re-used.

No primates were used.

No animals were used in the testing of cosmetic products.

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	3827	3827				
1.b. Rats ( <i>Rattus norvegicus</i> )	1194	1194				
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	93	93				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	199	199				
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )						
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )						
1.l. Pigs ( <i>Sus</i> )	80					
1.m. Goats ( <i>Capra</i> )						
1.n. Sheep ( <i>Ovis</i> )						
1.o. Cattle ( <i>Bos</i> )						
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0					
1.s. Apes ( <i>Hominoidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )						
1.u. Quail ( <i>Coturnix coturnix</i> )	0					
1.v. Other birds (other <i>Aves</i> )	40					
1.w. Reptiles ( <i>Reptilia</i> )						
1.x. Amphibians ( <i>Amphibia</i> )	149					
1.y. Fish ( <i>Pisces</i> )						
1.z. TOTAL	5582					

**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	718	1367	525		1213		4		3827
2.b. Rats	44	1070	33		26		21		1194
2.c. Guinea-Pigs	41	40		5	7				93
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	8	148		5	7		31		199
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs		30					50		80
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		40							40
2.w. Reptiles									0
2.x. Amphibians		43					106		149
2.y. Fish									0
2.z. TOTAL	811	2738	558	10	1253	0	212	0	5582

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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	239						200		774	1213
3.b. Rats							26			26
3.c. Guinea-Pigs							7			7
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits							7			7
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	239	0	0	0	0	0	240	0	774	1253



**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	189		300	1496	100	2085
4.b. Rats	22		33	959	100	1114
4.c. Guinea-Pigs	39			22	20	81
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	30	24		82	20	156
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	30					30
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				20	20	40
4.w. Reptiles						0
4.x. Amphibians		43				43
4.y. Fish						0
4.z. TOTAL	310	67	333	2579	260	3549

**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	525						525
5.b. Rats	33						33
5.c. Guinea-Pigs	5						5
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	5						5
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	568	0	0	0	0	0	568

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement  
5.3 - UK is testing according to EC legislation  
5.4 – Spain is testing due to a Norwegian requirement  
5.5 – Poland is testing due to a US specific requirement  
5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a.	1013	200					1213
6.b.		26					26
6.c.		7					7
6.d.							0
6.e.							0
6.f.		7					7
6.g.							0
6.h.							0
6.i.							0
6.j.							0
6.k.							0
6.l.							0
6.m.							0
6.n.							0
6.o.							0
6.p.							0
6.q.							0
6.r.							0
6.s.							0
6.t.							0
6.u.							0
6.v.							0
6.w.							0
6.x.							0
6.y.							0
6.z.	1013	240	0	0	0	0	1253

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

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

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

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

**Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	172									246		200	595	1213
7.b. Rats												26		26
7.c. Guinea-Pigs												7		7
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits												7		7
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	172	0	0	0	0	0	0	0	0	246	0	240	595	1253

**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	172													67	239
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														240	240
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										246				528	774
8.j. TOTAL	172	0	0	0	0	0	0	0	0	246	0	0	835	1253	

# LUXEMBOURG

## Statistical data submitted

The statistical data have been submitted by the “*Ministère de l’Agriculture, de la viticulture et du développement rural. Administration des Services Vétérinaires*” (Ministry of Agriculture, viticulture and rural development. Administration of Veterinary Services)

Remark: Luxembourg reported data only in tables 1, 2 and 4 with the remaining tables not applicable.

## Comments of Luxembourg authorities

None

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	3280	3280				
1.b. Rats ( <i>Rattus norvegicus</i> )	430	430				
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	100	100				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )	0					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	20	20				
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )	0					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	0					
1.l. Pigs ( <i>Sus</i> )	0					
1.m. Goats ( <i>Capra</i> )	0					
1.n. Sheep ( <i>Ovis</i> )	0					
1.o. Cattle ( <i>Bos</i> )	0					
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0					
1.s. Apes ( <i>Hominoidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )	0					
1.u. Quail ( <i>Coturnix coturnix</i> )	0					
1.v. Other birds (other <i>Aves</i> )	0					
1.w. Reptiles ( <i>Reptilia</i> )	0					
1.x. Amphibians ( <i>Amphibia</i> )	0					
1.y. Fish ( <i>Pisces</i> )	0					
1.z. TOTAL	3830					

**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		3280							3280
2.b. Rats		430							430
2.c. Guinea-Pigs		100							100
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits		20							20
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	0	3830	0	0	0	0	0	0	3830



**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					3280	3280
4.b. Rats					430	430
4.c. Guinea-Pigs					100	100
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits					20	20
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	0	0	0	3830	3830

## **HUNGARY**

### **Statistical data submitted**

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

### **Comments of the Hungarian authorities**

None

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	158799	129817	26099	1131	1752	
1.b. Rats ( <i>Rattus norvegicus</i> )	89375	73336	15248	340	451	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	9743	6064	3669	10	0	
1.d. Hamsters ( <i>Mesocricetus</i> )	215	215	0	0	0	
1.e. Other Rodents (other <i>Rodentia</i> )	356					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	8134	7560	14	360	200	598
1.g. Cats ( <i>Felis catus</i> )	40	40	0	0	0	
1.h. Dogs ( <i>Canis familiaris</i> )	686	412	12	262	0	65
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )	0					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	40					
1.l. Pigs ( <i>Sus</i> )	1193					
1.m. Goats ( <i>Capra</i> )	92					
1.n. Sheep ( <i>Ovis</i> )	200					
1.o. Cattle ( <i>Bos</i> )	93					
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	5	5				
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	1	1				
1.s. Apes ( <i>Hominoidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )	16					
1.u. Quail ( <i>Coturnix coturnix</i> )	13	13				
1.v. Other birds (other <i>Aves</i> )	32554					
1.w. Reptiles ( <i>Reptilia</i> )	108					
1.x. Amphibians ( <i>Amphibia</i> )	1182					
1.y. Fish ( <i>Pisces</i> )	2077					
1.z. TOTAL	304922					

**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	50186	57384	23136	0	13495	3935	5706	4957	158799
2.b. Rats	24239	60144	0	0	2809	15	2143	25	89375
2.c. Guinea-Pigs	2304	629	3699	774	2006	0	235	96	9743
2.d. Hamsters	214	0	0	0	0	0	1	0	215
2.e. Other Rodents	356	0	0	0	0	0	0	0	356
2.f. Rabbits	1360	2183	0	618	3620	66	287	0	8134
2.g. Cats	6	34	0	0	0	0	0	0	40
2.h. Dogs	352	59	7	0	240	0	23	5	686
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	40	0	40
2.l. Pigs	399	292	0	159	156	130	57	0	1193
2.m. Goats	2	0	0	0	0	50	40	0	92
2.n. Sheep	10	26	0	82	0	0	82	0	200
2.o. Cattle	6	4	0	2	30	51	0	0	93
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	5	0	0	0	0	0	0	0	5
2.r. Old World Monkeys	1	0	0	0	0	0	0	0	1
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	16	0	0	0	0	0	0	16
2.u. Quail	13	0	0	0	0	0	0	0	13
2.v. Other birds	7558	8158	0	13390	462	10	576	2400	32554
2.w. Reptiles	0	50	0	0	0	0	58	0	108
2.x. Amphibians	120	0	0	0	0	0	1062	0	1182
2.y. Fish	345	0	0	0	1126	100	506	0	2077
2.z. TOTAL	87476	128979	26842	15025	23944	4357	10816	7483	304922

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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	11093	0	0	0	0	0	288	0	2114	13495
3.b. Rats	1129	0	0	0	0	78	0	0	1602	2809
3.c. Guinea-Pigs	1236	0	0	0	0	0	0	0	770	2006
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	3428	0	0	0	0	0	0	0	192	3620
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	240	0	0	0	0	0	0	0	0	240
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	122	0	0	0	0	0	0	34	0	156
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	30	0	0	0	0	0	0	0	0	30
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	462	0	0	0	0	0	0	0	0	462
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	126	0	0	0	0	0	1000	0	1126
3.z. TOTAL	17740	126	0	0	0	78	288	1034	4678	23944

**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	886	69114	8615	27448	5442	111505
4.b. Rats	2564	72436	1777	7621	0	84398
4.c. Guinea-Pigs	72	314	0	2482	65	2933
4.d. Hamsters	0	109	0	83	22	214
4.e. Other Rodents	0	290	0	66	0	356
4.f. Rabbits	447	613	0	1782	767	3609
4.g. Cats	0	30	0	0	10	40
4.h. Dogs	390	21	0	0	0	411
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	0	0
4.l. Pigs	194	0	0	0	627	821
4.m. Goats	2	0	0	0	50	52
4.n. Sheep	0	0	0	0	36	36
4.o. Cattle	0	0	0	0	61	61
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	5	0	0	0	0	5
4.r. Old World Monkeys	1	0	0	0	0	1
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	16	0	0	0	0	16
4.u. Quail	0	0	0	0	13	13
4.v. Other birds	0	0	0	0	15726	15726
4.w. Reptiles	0	50	0	0	0	50
4.x. Amphibians	0	120	0	0	0	120
4.y. Fish	0	0	0	0	445	445
4.z. TOTAL	4577	143097	10392	39482	23264	220812

**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	9363	13523	0	0	250	0	23136
5.b. Rats	0	0	0	0	0	0	0
5.c. Guinea-Pigs	586	3887	0	0	0	0	4473
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	40	578	0	0	0	0	618
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	7	0	0	0	0	0	7
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	159	0	0	0	0	159
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	6	76	0	0	0	0	82
5.o. Cattle	0	2	0	0	0	0	2
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	11	13379	0	0	0	0	13390
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	10013	31604	0	0	250	0	41867

**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	60	12533	0	0	460	442	13495
6.b. Rats	152	1657	0	0	910	90	2809
6.c. Guinea-Pigs	0	1236	0	0	770	0	2006
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	550	2878	0	0	192	0	3620
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	110	66	58	6	0	0	240
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	81	67	8	0	0	0	156
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	30	0	0	0	0	30
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	462	0	0	0	0	462
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	1000	126	0	0	0	0	1126
6.z. TOTAL	1953	19055	66	6	2332	532	23944

**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	3307	4492	3194	0	0	0	160	0	0	323	0	0	2019	13495
7.b. Rats	30	26	1200	0	85	0	400	24	190	30	218	0	606	2809
7.c. Guinea-Pigs	0	0	976	0	420	0	490	0	120	0	0	0	0	2006
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	3420	41	4	28	0	0	127	0	0	0	0	3620
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	108	0	0	0	132	0	0	0	0	0	0	240
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	77	0	0	0	20	0	0	0	0	0	59	156
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	30	30
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	72	0	390	0	0	0	0	0	0	0	0	0	0	462
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	626	0	0	0	0	0	0	0	0	0	0	500	0	1126
7.z. TOTAL	4035	4518	9365	41	509	28	1202	24	437	353	218	500	2714	23944

**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	3374	4492	6997	41	509	28	1202	0	437	353	218	0	89	17740
8.b. Products/substances used or intended to be used mainly in agriculture	126	0	0	0	0	0	0	0	0	0	0	0	0	126
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	26	28	0	0	0	0	24	0	0	0	0	0	78
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	288	288
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	500	0	34	0	0	0	0	0	0	0	0	500	0	1034
8.i. Other toxicological or safety evaluations	35	0	2306	0	0	0	0	0	0	0	0	0	2337	4678
8.j. TOTAL	4035	4518	9365	41	509	28	1202	24	437	353	218	500	2714	23944

## **MALTA**

### **Statistical data submitted**

The data were submitted by the Ministry of Resources and Rural Affairs

### **Comments of Malta authorities**

None

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	50		50			
1.b. Rats ( <i>Rattus norvegicus</i> )	44		44			
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	0					
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	0					
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )						
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )						
1.l. Pigs ( <i>Sus</i> )						
1.m. Goats ( <i>Capra</i> )						
1.n. Sheep ( <i>Ovis</i> )						
1.o. Cattle ( <i>Bos</i> )						
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0					
1.s. Apes ( <i>Hominoidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )						
1.u. Quail ( <i>Coturnix coturnix</i> )	0					
1.v. Other birds (other <i>Aves</i> )						
1.w. Reptiles ( <i>Reptilia</i> )						
1.x. Amphibians ( <i>Amphibia</i> )						
1.y. Fish ( <i>Pisces</i> )	600					
1.z. TOTAL	694					

**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		50							50
2.b. Rats			44						44
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits									0
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish					600				600
2.z. TOTAL	0	50	44	0	600	0	0	0	694

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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice										0
3.b. Rats										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 breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish	600									600
3.z. TOTAL	600	0	0	0	0	0	0	0	0	600

**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		50				50
4.b. Rats			44			44
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	50	44	0	0	94

**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	44						44
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 breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL							0

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement  
5.3 - UK is testing according to EC legislation  
5.4 – Spain is testing due to a Norwegian requirement  
5.5 – Poland is testing due to a US specific requirement  
5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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



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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice							0
6.b. Rats							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 breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	600						600
6.z. TOTAL	600	0	0	0	0	0	600

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

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

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

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

**Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total	
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods												
7.a. Mice															0
7.b. Rats															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 breeds															0
7.l. Pigs															0
7.m. Goats															0
7.n. Sheep															0
7.o. Cattle															0
7.p. Prosimians															0
7.q. New World Monkeys															0
7.r. Old World Monkeys															0
7.s. Apes															0
7.t. Other Mammals															0
7.u. Quail															0
7.v. Other birds															0
7.w. Reptiles															0
7.x. Amphibians															0
7.y. Fish	600														600
7.z. TOTAL	600	0	0	0	0	0	0	0	0	0	0	0	0	0	600

**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	600														600
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations															0
8.j. TOTAL	600	0	0	0	0	0	0	0	0	0	0	0	0	0	600

# THE NETHERLANDS

## Statistical data submitted

The statistical data have been submitted by the “*Keuringsdienst van Waren, Ministerie voor Volksgezondheid, Welzijn en Sport*” (Inspectorate for Goods, Ministry for Public Health, Welfare and Sports

The statistical data were prepared, quality assured and submitted by the Voedsel en Waren Autoriteit, (Dutch Food and Consumer Product Safety Authority

## Comments of the Dutch authorities

On 5 February 1997, the revised version of the **Experiments on Animals Act (1977)** entered into force.

The provisions of the European Directive on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC) have been implemented.

In addition, among others the following provisions have been issued:

- Animal experiments using LD<sub>50</sub>/LC<sub>50</sub> methods are prohibited. However, for acute dermal and acute respiratory toxicity tests a general exemption is granted, due to the lack of validated alternative methods.
- Animal experiments for new or existing cosmetics are prohibited.
- Since 2003 animal experiments on great apes are prohibited.
- Every animal experiment to be performed has to be recommended by a recognised ethical review committee. Such a committee comprises at least seven members, one of whom is the chairperson. In addition, such a committee comprises in equal numbers experts in the fields of animal experiments, experts in the field of alternative methods, experts in the field of animal welfare and protection and experts in the field of ethical assessment. At least two of these experts are not involved in the conduct of experiments on animals. The chairperson and at least two members are not in the employment of any licence holder applying to the committee. The animal welfare officer is involved already at an early stage in the review of experiments and acts as a permanent advisor for the ethical review committee. At this moment 23 ethical review committees are recognized.

**Licenses** to perform animal experiments are issued by the Minister of Public Health, Welfare and Sport to a natural or legal person who is a mandated representative of an establishment for animal use. So licensed, those people are responsible for assuring that the legal requirements are complied with. The welfare of the experimental animals is supervised by a qualified veterinarian or another competent person in charge of the licensee.

A **Standing Committee** advises the Minister on the administration of the Act and other related issues. The Committee consists of experts in the field of animal experimentation, laboratory animal science and animal welfare.

The **enforcement** of the Act has been commissioned to the *Food and Consumer Product Safety Authority*.

## **The creation of transgenic animals**

Within the framework of the *Animal Health and Welfare Act (1992)* a system of licensing has entered into force with respect to experiments aiming at a genetic modification of animals. A national committee on ethical evaluation of genetic modification of animals, called the Committee on Animal Biotechnology will advise the Minister of Agriculture, Nature Management and Fisheries on the ethical aspects of the creation and the use of transgenic animals in general and on the admissibility of proposed projects.

In addition, such projects have to be evaluated within the framework of the Experiments of Animals Act and the Environmental Conservation Act.

The Inspectorate of the Food and Consumer Product Safety Authority is in charge of the supervision of these licences to create genetically modified animals.

In 2008 12,186 animals (12,052 mice, 72 rats and 62 fish) were used for the creation of transgenic animals.

### **Collection of data**

87 establishments completed the 2008 registration form.

These establishments can be categorized as follows:

a)	Universities and university hospitals	15
b)	Other hospitals, regional public health laboratories	1
c)	Public health research institutes	8
d)	Agricultural and veterinary research institutes	8
e)	Other research institutes	4
f)	Industries and companies	40
g)	Schools for vocational training	8
h)	Breeders	3

### **The killing of an animal without any previous intervention & re-use of animals**

In the Netherlands, the killing of an animal without any previous intervention in the framework of research or testing, e.g. for organ/blood collection, is considered to be an experiment. The rationale of this is that the Inspectorate must have the power to supervise the killing of laboratory animals.

This is in contrast to the Council of Europe Convention ETS 123 and Directive 86/609/EEC, where the use of an animal for an experimental or other scientific purpose is not considered an experiment if the least painful method of killing accepted in modern practice ('humane' methods') is used.

In 2008, 60,391 animals were killed without previous intervention.

Re-use of the animals (in 2008 17,220 animals) is included as well in the Dutch statistics.

## **Total number of animals used**

In 2008, according to the EU Tables, the total number of animals used was 501,056.

This is 1,6% (10,060) less than the number of animals used in 2007 (513,423).

The total number of genetically modified animals that was used was 83,097. When split up into species, the numbers of genetically modified animals used are: 81,089 mice, 284 rats, 81 rabbits, 225 amphibians and 1,418 fish.

In 2008 the number of animals used for toxicological and other safety evaluation was decreased with 24,7% (13,431) compared to the number used in 2007.

## **Discomfort**

### General

Data has to be registered after an experiment has been performed. This includes data on the degree of discomfort; i.e. experienced discomfort.

As a consequence of the animal experiments performed in 2008:

- 33,66% of the animals experienced minor discomfort;
- 28,52% of the animals experienced minor/moderate discomfort;
- 25,05% of the animals experienced moderate discomfort;
- 9,11% of the animals experienced moderate/severe discomfort;
- 3,63% of the animals experienced severe discomfort and
- 0,03% of the animals experienced very severe discomfort.

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	237681	228113	8160	0	1408	2164
1.b. Rats ( <i>Rattus norvegicus</i> )	105780	105300	231	0	249	2716
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	6062	2939	3123	0	0	130
1.d. Hamsters ( <i>Mesocricetus</i> )	3358	3077	281	0	0	54
1.e. Other Rodents (other <i>Rodentia</i> )	2439	1642	73	0	724	0
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	7418	6755	646	0	17	109
1.g. Cats ( <i>Felis catus</i> )	253	100	0	0	153	23
1.h. Dogs ( <i>Canis familiaris</i> )	1244	464	208	0	572	268
1.i. Ferrets ( <i>Mustela putorius furo</i> )	472	0	193	0	279	20
1.j. Other Carnivores (other <i>Carnivora</i> )	10	0	0	0	10	0
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	2562	3	0	0	2559	164
1.l. Pigs ( <i>Sus</i> )	11729	4192	216	0	7321	125
1.m. Goats ( <i>Capra</i> )	229	52	0	0	177	80
1.n. Sheep ( <i>Ovis</i> )	3486	67	0	0	3419	470
1.o. Cattle ( <i>Bos</i> )	2236	232	35	0	1969	187
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	73	73	0	0	0	8
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	82	62	16	0	4	202
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	202	0	0	0	202	7
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i> )	90890	12995	472	0	77423	4119
1.w. Reptiles ( <i>Reptilia</i> )	121	100	0	0	21	28
1.x. Amphibians ( <i>Amphibia</i> )	870	785	0	0	85	482
1.y. Fish ( <i>Pisces</i> )	23859	8518	126	0	15215	270
1.z. TOTAL	501056	0	0	0	0	0

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

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

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

**Purpose versus species**

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	152304	40617	5624	15653	7522	8859	7102	0	237681
2.b. Rats	31930	15348	28320	2700	23284	0	4198	0	105780
2.c. Guinea-Pigs	488	373	767	4181	183	0	70	0	6062
2.d. Hamsters	444	330	0	2539	30	0	15	0	3358
2.e. Other Rodents	2222	217	0	0	0	0	0	0	2439
2.f. Rabbits	727	393	16	1653	4543	5	81	0	7418
2.g. Cats	0	45	0	85	44	0	79	0	253
2.h. Dogs	157	285	11	187	519	0	85	0	1244
2.i. Ferrets	28	414	0	0	0	0	30	0	472
2.j. Other Carnivores	10	0	0	0	0	0	0	0	10
2.k. Horses, donkeys and cross breeds	65	377	110	2007	0	0	3	0	2562
2.l. Pigs	5138	3693	3	2283	188	0	424	0	11729
2.m. Goats	135	50	0	0	0	0	44	0	229
2.n. Sheep	133	639	2576	85	0	0	53	0	3486
2.o. Cattle	248	1012	129	598	0	0	249	0	2236
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	28	45	0	0	0	0	0	0	73
2.r. Old World Monkeys	21	61	0	0	0	0	0	0	82
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	202	0	0	0	0	0	0	0	202
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	51806	17171	4	20684	0	395	830	0	90890
2.w. Reptiles	108	0	0	0	0	0	13	0	121
2.x. Amphibians	788	0	0	0	0	0	82	0	870
2.y. Fish	19503	0	0	0	3383	0	973	0	23859
2.z. TOTAL	266485	81070	37560	52655	39696	9259	14331	0	501056



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

**Products versus species**

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	3224	201	1499	0	0	2598	0	0	0	7522
3.b. Rats	5838	4193	11700	48	0	1286	177	0	42	23284
3.c. Guinea-Pigs	134	0	49	0	0	0	0	0	0	183
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	2222	634	1681	0	0	6	0	0	0	4543
3.g. Cats	44	0	0	0	0	0	0	0	0	44
3.h. Dogs	471	48	0	0	0	0	0	0	0	519
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	26	0	0	0	0	0	162	0	0	188
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	353	0	365	0	0	0	0	2665	0	3383
3.z. TOTAL	12342	5076	15294	48	0	3890	339	2665	42	39696

**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	16595	13267	47276	84369	11454	172961
4.b. Rats	4070	11472	1554	20855	46	37997
4.c. Guinea-Pigs	0	98	0	463	40	601
4.d. Hamsters	0	9	0	263	240	512
4.e. Other Rodents	0	27	0	619	0	646
4.f. Rabbits	369	5	56	476	38	944
4.g. Cats	0	0	0	6	39	45
4.h. Dogs	61	0	0	28	269	358
4.i. Ferrets	0	0	0	355	87	442
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	37	350	387
4.l. Pigs	293	0	36	263	3784	4376
4.m. Goats	106	0	0	75	4	185
4.n. Sheep	32	0	0	271	467	770
4.o. Cattle	0	0	0	129	997	1126
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	9	0	64	0	73
4.r. Old World Monkeys	0	0	0	72	0	72
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	1160	39694	40854
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	148	210	1003	95	1456
4.z. TOTAL	21526	25035	49132	110508	57604	263805

**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	2725	0	1978	15087	1487	21277
5.b. Rats	0	4000	0	758	26194	68	31020
5.c. Guinea-Pigs	0	543	0	160	2400	1845	4948
5.d. Hamsters	0	0	0	0	2539	0	2539
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	1	0	0	1582	86	1669
5.g. Cats	27	0	0	0	58	0	85
5.h. Dogs	22	0	0	0	165	11	198
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	60	2057	2117
5.l. Pigs	0	0	0	0	1610	676	2286
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	2	0	0	0	10	2649	2661
5.o. Cattle	16	0	0	6	359	346	727
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	75	0	60	0	15474	5079	20688
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	142	7269	60	2902	65538	14304	90215

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement  
5.3 - UK is testing according to EC legislation  
5.4 – Spain is testing due to a Norwegian requirement  
5.5 – Poland is testing due to a US specific requirement  
5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	4	0	0	0	6870	648	7522
6.b. Rats	77	0	0	0	22654	553	23284
6.c. Guinea-Pigs	4	0	0	0	57	122	183
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	0	0	0	4540	3	4543
6.g. Cats	0	0	0	0	44	0	44
6.h. Dogs	0	0	0	0	519	0	519
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	13	175	188
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	77	0	0	0	2898	408	3383
6.z. TOTAL	162	0	0	0	37625	1909	39696

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

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

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

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

**Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	251	396	0	2020	0	40	106	2293	1026	360	0	1030	7522
7.b. Rats	0	960	4486	391	0	0	3231	0	7844	553	4512	0	1307	23284
7.c. Guinea-Pigs	0	0	114	18	49	0	0	0	0	0	0	0	2	183
7.d. Hamsters	0	0	0	22	0	0	0	0	0	0	0	0	8	30
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	508	249	0	186	428	0	0	0	2084	0	1088	4543
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	44	44
7.h. Dogs	0	0	227	0	0	0	250	0	0	0	0	0	42	519
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	13	0	0	0	0	0	0	0	0	0	175	188
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	1198	421	1344	119	0	0	301	0	0	0	0	0	0	3383
7.z. TOTAL	1198	1632	7088	799	2069	186	4250	106	10137	1579	6956	0	3696	39696

**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	0406	03.645	0182	0832	028	02.490	0106	0	0673	0994	0	02.986	12342
8.b. Products/substances used or intended to be used mainly in agriculture	0	034	0390	030	044	03	0120	0	0703	0184	03.568	0	0	5076
8.c. Products/substances used or intended to be used mainly in industry	0365	0749	01.833	0465	01.193	0152	0288	0	07.141	0375	02.227	0	0506	15294
8.d. Products/substances used or intended to be used mainly in the household	0	016	032	0	0	0	0	0	0	0	0	0	0	48
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	06	0120	03	0	03	0951	0	02.293	0305	0167	0	042	3890
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	077	0	0	0	0100	0	0	0	0	0	0162	339
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0833	0421	0991	0119	0	0	0301	0	0	0	0	0	0	2665
8.i. Other toxicological or safety evaluations	0	0	0	0	0	0	0	0	0	042	0	0	0	42
8.j. TOTAL	1198	1632	7088	799	2069	186	4250	106	10137	1579	6956	0	3696	39696