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PART III

**COMMISSION STAFF WORKING DOCUMENT**

***Annex to the:***

**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT**

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

{COM (2007) 675 final}

### **Important notice**

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

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

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# 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 Italian authorities

The collected data are entered in the “*harmonised EU statistical tables*” agreed by the competent national authorities of the EU in 1997.

They generally confirm the downward trend in the total number of animals used in experiments, which has remained below the one million mark since 1999.

**93.61%** of the animals used were rodents and rabbits.

The tables also include data on animals used for in vitro studies (euthanised to remove organs, tissues and cells).

**44.08%** of the animals were used in basic biological studies.

**27.42%** of the animals were used in the research and development of products and devices for human medicine, dentistry and veterinary medicine.

**15.38%** of the animals were used in the production and quality control of products and devices for human medicine, dentistry and veterinary medicine.

**8.9%** of the animals were used in toxicological studies.

**4.22%** of the animals were used for diagnosis of disease, education and other purposes.

**98.67%** of the animals were used to study human diseases, while **1.33%** were used to study animal diseases.

Article 24 of Directive 86/609/EEC has allowed tighter rules to be introduced into Italian law, particularly regarding the use of non-human primates, cats and dogs, as may be seen from Article 3(2) of Legislative Decree 116/92, which states that “**with regard to non-human primates, cats and dogs, the authorisation stipulated by Article 8(1)(b) is also required.**”

Special attention was also paid to the use of horses in experiments.

All in all, this means that horses, non-human primates, cats and dogs together account for **0.17%** of all animals used.

Cats are used in experiments in Italy only in investigations of diseases affecting cats themselves. Since 2003 no animals have been used to test finished cosmetic products.

**Signed: Prof. Sergio Papalia**

**Director, Office**

**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> )	534614	516400	6073	97	12044	
1.b. Rats ( <i>Rattus norvegicus</i> )	279774	276681	2758	4	331	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	11533	6879	4613	15	26	
1.d. Hamsters ( <i>Mesocricetus</i> )	1537	1473	0	0	64	
1.e. Other Rodents (other <i>Rodentia</i> )	2303			0	0	
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	9916	9842	74	0	0	351
1.g. Cats ( <i>Felis catus</i> )	30	0	30	0	0	0
1.h. Dogs ( <i>Canis familiaris</i> )	1064	601	0	93	370	68
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> )	63					
1.l. Pigs ( <i>Sus</i> )	2579					
1.m. Goats ( <i>Capra</i> )	20					
1.n. Sheep ( <i>Ovis</i> )	584					
1.o. Cattle ( <i>Bos</i> )	1174					
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	17	12	5	0	0	87
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	395	7	343	3	42	85
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	68				0	0
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i> )	31697					
1.w. Reptiles ( <i>Reptilia</i> )	378					
1.x. Amphibians ( <i>Amphibia</i> )	4636					
1.y. Fish ( <i>Pisces</i> )	14584					
1.z. TOTAL	896966					

**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	292138	146808	26561	4744	34518	24245	403	5197	534614
2.b. Rats	79546	83690	81993	170	30818	1115	317	2125	279774
2.c. Guinea-Pigs	1778	4040	3740	451	1444	53	15	12	11533
2.d. Hamsters	1092	76	0	0	57	312	0	0	1537
2.e. Other Rodents	400	1043	0	0	0	860	0	0	2303
2.f. Rabbits	1766	1228	4195	855	1626	38	0	208	9916
2.g. Cats	0	30	0	0	0	0	0	0	30
2.h. Dogs	12	59	0	0	993	0	0	0	1064
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 breds	34	3	24	0	0	0	0	2	63
2.l. Pigs	758	405	18	71	333	0	249	745	2579
2.m. Goats	13	4	0	0	0	1	0	2	20
2.n. Sheep	187	257	51	75	14	0	0	0	584
2.o. Cattle	1024	62	1	73	0	10	0	4	1174
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	9	8	0	0	0	0	0	0	17
2.r. Old World Monkeys	20	11	37	0	327	0	0	0	395
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	58	0	0	10	0	0	0	0	68
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	6915	2519	15	14621	6102	3	0	1522	31697
2.w. Reptiles	348	0	0	0	0	0	0	30	378
2.x. Amphibians	4495	30	0	0	42	69	0	0	4636
2.y. Fish	4820	5674	0	310	3520	0	0	260	14584
2.z. TOTAL	395413	245947	116635	21380	79794	26706	984	10107	896966

**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	12523	69	290	0	0	390	182	2782	18282	34518
3.b. Rats	20550	288	2424	0	0	766	0	4830	1960	30818
3.c. Guinea-Pigs	959	70	397	0	0	0	0	0	18	1444
3.d. Hamsters	57	0	0	0	0	0	0	0	0	57
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1479	0	129	0	0	0	0	0	18	1626
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	929	0	64	0	0	0	0	0	0	993
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	313	0	0	0	0	0	0	0	20	333
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	12	0	0	0	0	0	0	0	2	14
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	327	0	0	0	0	0	0	0	0	327
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	6082	0	0	0	0	0	0	0	20	6102
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	42	42
3.y. Fish	255	0	0	0	0	0	0	3265	0	3520
3.z. TOTAL	43486	427	3304	0	0	1156	182	10877	20362	79794



**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	13061	61492	113322	132766	4449	325090
4.b. Rats	7290	49905	9863	37583	196	104837
4.c. Guinea-Pigs	632	966	0	2891	189	4678
4.d. Hamsters	100	659	144	12	6	921
4.e. Other Rodents	0	986	0	196	727	1909
4.f. Rabbits	378	195	19	1030	120	1742
4.g. Cats	0	0	0	0	30	30
4.h. Dogs	6	141	268	49	6	470
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	165	2	0	103	25	295
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	11	0	40	18	32	101
4.o. Cattle	0	0	0	7	0	7
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	12	0	0	0	12
4.r. Old World Monkeys	0	3	125	6	0	134
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	22	70	92
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	131	0	451	0	582
4.y. Fish	0	0	221	0	0	221
4.z. TOTAL	21643	114492	124002	175134	5850	441121

**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	4176	7816	0	40	15405	3868	31305
5.b. Rats	425	1789	0	0	78237	1712	82163
5.c. Guinea-Pigs	1326	29	0	0	2630	206	4191
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	1112	3297	0	0	460	181	5050
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	24	0	0	0	0	0	24
5.l. Pigs	50	39	0	0	0	0	89
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	119	7	0	0	0	0	126
5.o. Cattle	57	17	0	0	0	0	74
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	37	0	37
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	10	0	0	0	0	0	10
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	1607	13029	0	0	0	0	14636
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	310	310
5.z. TOTAL	8906	26023	0	40	96769	6277	138015

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	23592	6728	0	390	3259	549	34518
6.b. Rats	8821	8374	0	941	12359	323	30818
6.c. Guinea-Pigs	199	491	0	0	754	0	1444
6.d. Hamsters	0	48	0	0	9	0	57
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	110	555	0	0	874	87	1626
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	137	272	0	0	584	0	993
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	20	313	0	0	0	0	333
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	2	12	0	0	0	0	14
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	327	0	327
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	4840	1262	0	0	0	0	6102
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	42	0	0	0	0	0	42
6.y. Fish	3450	0	0	0	0	70	3520
6.z. TOTAL	41213	18055	0	1331	18166	1029	79794

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	1201	11332	6873	234	71	0	1298	3596	155	589	389	0	8780	34518
7.b. Rats	667	960	8144	0	0	0	7813	4807	1619	420	1352	0	5036	30818
7.c. Guinea-Pigs	0	0	37	97	1222	0	84	0	0	0	0	0	4	1444
7.d. Hamsters	0	0	48	0	0	0	0	0	0	0	0	0	9	57
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	400	147	5	38	64	0	514	0	264	0	194	1626
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	4	285	0	0	0	657	0	0	0	0	0	47	993
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	134	0	0	0	92	0	0	0	0	0	107	333
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	2	0	0	0	0	0	0	0	0	0	12	14
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	1	93	0	0	0	158	0	0	0	0	0	75	327
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	4840	1000	0	0	0	0	0	0	0	0	262	6102
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	42	0	0	0	0	42
7.y. Fish	2035	0	170	0	0	0	1100	0	0	0	0	215	0	3520
7.z. TOTAL	3903	12297	21026	1478	1298	38	11266	8403	2330	1009	2005	215	14526	79794

**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	1317	1673	16992	1444	759	29	9240	1433	1519	712	1688	185	6495	43486
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	40	0	70	0	0	0	0	0	317	0	0	427
8.c. Products/substances used or intended to be used mainly in industry	0	58	1053	34	468	9	466	0	769	297	0	0	150	3304
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	1006	0	0	0	150	0	0	0	0	0	0	1156
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	182	0	0	0	0	0	0	0	0	0	0	0	182
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	2035	400	128	0	0	0	1100	6970	0	0	0	30	214	10877
8.i. Other toxicological or safety evaluations	551	9984	1807	0	1	0	310	0	42	0	0	0	7667	20362
8.j. TOTAL	3903	12297	21026	1478	1298	38	11266	8403	2330	1009	2005	215	14526	79794

## **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> )	10480	10480				
1.b. Rats ( <i>Rattus norvegicus</i> )	2376	2376				
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	297	297				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	166	166				
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	13319	13319				

**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	2352	3068	2800			1494	766		10480
2.b. Rats	265	1105	613		90	126	177		2376
2.c. Guinea-Pigs	57					240			297
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	121					45			166
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0



2.z.	TOTAL	2795	4173	3413	0	90	1905	943	0	13319
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**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									90	90
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										0
3.z. TOTAL	0	0	0	0	0	0	0	0	90	90

**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						0
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	0	0	0	0	0

**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					2800		2800
5.b. Rats					613		613
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	3413	0	3413

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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						90	90
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							0
6.z. TOTAL	0	0	0	0	0	90	90

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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											90			90
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits														0
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	0	0	0	0	0	0	0	0	0	90	0	0	90

**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											90			90
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	0	0	0	0	0	0	0	90	0	0	90



# **LITHUANIA**

## **Statistical data submitted**

The statistical data have been submitted by the State Food and Veterinary service – Animal welfare department - Siesiku 19 LT-2010 Vilnius

## **Comments of Lithuanian 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> )	5116	5116				
1.b. Rats ( <i>Rattus norvegicus</i> )	493	493				
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> )	158	158				
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	5767					

**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	1773				330	2583	430		5116
2.b. Rats	323				120		50		493
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	96				62				158
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0

2.z.	TOTAL	2192	0	0	0	512	2583	480	0	5767
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**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		330								330
3.b. Rats		120								120
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	62									62
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	62	450	0	0	0	0	0	0	0	512

**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				2583		2583
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	0	0	2583	0	2583

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

**Regulatory requirements versus species**

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross 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	0	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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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		330					330
6.b. Rats		120					120
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		62					62
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	512	0	0	0	0	512

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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			100										230	330
7.b. Rats			60										60	120
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													62	62
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	0	160	0	0	0	0	0	0	0	0	0	352	512

**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													62	62
8.b. Products/substances used or intended to be used mainly in agriculture			160										290	450
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	160	0	0	0	0	0	0	0	0	0	352	512

# 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)

## Comments of Luxembourg authorities

Comments on statistical data on the use of laboratory animals in the Grand Duchy of Luxembourg in 2005

To DG Environment D.1.

- 2 experimentation projects were registered in Luxembourg in 2005 compared to 1 project in 2004.
- In comparison with 2004, a 62% decrease in the number of laboratory animals used has been recorded (280 more mice, but 500 fewer chicks and 1 800 fewer cotton rats).
- Responsibility for monitoring animal welfare lies with a veterinary inspector, who carries out at least 2 inspections per year per requested experimentation project.
- Detection infrastructure and the handling of laboratory animals comply with animal welfare requirements.
- The experiments are intended for:
  - a) an immunological study of the protective efficiency and the antigenicity of antigens to improve vaccination strategies and diagnostic procedures for specific diseases;
  - b) projects relating to immunology and immunodeficiency.

Director of the Veterinary

Services Administration

Dr Arthur Besch

### Remark:

Please note that only relevant EU tables containing data are included in this report. No uses of animals were reported in Tables 3-8.

**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> )	720	720				
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> )						
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> )						
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	4120	4120				

**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	280	3000							3280
2.b. Rats	320	400							720
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	600	3520	0	0	0	0	0	0	4120
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## **MALTA**

No animals were used in Malta in 2005 for experimental or other scientific purposes.



# 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)

## Comments of the Dutch authorities

### National vs EU statistics

Since the first national report was published in 1978 the total number of animal experiments has never been as low as in 2005. After a faster decline the first 10-15 years the decrease slowed down the last 10 years. However the overall tendency still seems to be decreasing though in a slower pace.

The national statistics are published annually including the eight tables constructed in accordance with the EU system. The latest reports can be found at [www.vwa.nl](http://www.vwa.nl). The Dutch national statistics differ slightly from the Dutch EU-contribution. The numbers in the national statistics are higher due to the following:

1. In addition to the EU statistics, killing animals solely for harvesting tissues or organs is considered to be an experiment and contributes to the statistics. In 2005 a total number of 55.144 animals (i.e. 7% of the total number of animals used) were killed for this purpose, without any procedures or techniques connected with the experiment performed on them before their death.
2. Furthermore the Dutch statistics are based on the number of experiments performed and not so much on the number of animals involved. Therefore re-use is included as well. It clearly influences the statistics, hence each and every time the animal was used will contribute to the total number of experiments. In 2005 28.717 animal experiments were conducted on animals that had already been used. These animals were not included in the EU statistics.

The national statistics include 19 tables relating species to different topics. Like e.g. origin of the animal, type of experiment, severity score, mandatory testing, anaesthesia, pain alleviation, etc. Furthermore 14 tables on type of experiment versus species and their origin, safety testing and special techniques, etc are published. Special tables are made per university (hospital and academia alike) 15 in total and 2 tables on research performed for the ministry of Defence.

### Severity scoring

All animal experiments have to go through a procedure of ethical reviewing prior to the start of the experiment. Part of the ethical reviewing is assessing by the responsible researcher, proposed expected severity score. During the experiment the animals are closely watched also to assess the actually experienced discomfort, harm, distress, etc. The experienced severity score is the one that is registered. The Dutch law recognises 6 severity bands:

- minor (35.5% of the experiments in 2005)

- minor/moderate (29.2% of the experiments in 2005)
- moderate (22.0% of the experiments in 2005)
- moderate/severe (8.8% of the experiments in 2005)
- severe (4.5% of the experiments in 2005)
- very severe (0.1% of the experiments in 2005)

## Primates

In 2005 327 primates were used (50 new world primates and 277 old world primates) for the first time, which is 0.62%. A further 5 new world primates and 372 old world primates were re-used, taking the total number of animal experiments conducted on primates up to 704 (0.11% of the total number of animal experiments).

Since 2003 it has been prohibited to perform animal experiments on great apes (behaviour-studies consisting solely of observing the animals in their normal surroundings and which do not include any discomfort, harm, distress, etc. is not considered to be an experiment. Therefore these studies are exempted from the prohibition). In 2004 the last 6 experiments were conducted on chimpanzees, hence in 2005 no experiments on great apes were performed nor will there be any in the foreseeable future.

## Inspectorate and inspections

The Food and Consumer Product Safety Authority (VWA) is responsible for enforcement of the legislation concerning laboratory animal welfare. The VWA conducted a total of 554 inspections in 2005 of which approximately 40% was unannounced beforehand. These inspections clearly showed that the regulations with direct regard to the welfare of the animals were in general well abided by.

In several cases infringements were detected. Depending on the severity of the infringement appropriate action was taken. In six cases the licence-holder received a written warning including a deadline for solving the problem. These licence-holders were told to solve the indicated infringement before a certain date. In every case the problems were solved when the inspector re-visited the licence-holder after the notified deadline. These infringements consisted of:

- housing of animals;
- entering remarks in a so-called welfare diary (which has to be present at the animal room to be used for recording all relevant welfare remarks);
- handling of and caring for the animals by not yet licensed personnel;
- conducting experiments on animals not bred/delivered by a licensed breeder without an exoneration by the VWA
- Conducting an experiment not according to the project plan, which had received a positive advice of the ethical review committee.

## Comparing 2005 with 2004

In 2005 fewer experiments were conducted than in 2004. Nearly half of the drop in number of animal experiments was due to a lower number of chicken experiments. This still was the result of the aftermath of the Avian Influenza outbreak in 2003. Many projects were postponed in 2003 due to the restrictions on transport of animals and eggs, hence a low number of chickens appeared in the 2003 statistics. In 2004 making up leeway led to a steep increase in use of chickens. In 2005 the situation was back to normal, thus the number dropped to normal levels.

## Type of experiments

Most animal experiments were conducted for developing, producing, checking or verifying of sera, vaccines, drugs, medical or veterinary products (47.3%). Fundamental research was responsible for 44.2% of the total number of animal experiments. Potentially harming effects of substances covered 5.1%, diagnostic procedures 1.4% and education and training 2.0%. (These percentages are all based on the national statistics, hence including re-use and organ harvesting.)

## Licence holding establishments

A licence to perform animal experiments is obliged in order to perform any experiment. In 2005 a total of 80 licence-holding establishments were registered by VWA. Three new licences were issued and one licence was terminated on request of the licence-holder.

In order to be allowed to breed an/or deliver laboratory animals a licence is mandatory as well. In 2005 41 establishments were licensed to breed a/o deliver laboratory animals. Most of which also have a licence to perform animal experiments.

**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> )	240048	228666	0	7733	3649	5695
1.b. Rats ( <i>Rattus norvegicus</i> )	116608	111973	0	4423	212	3357
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	7479	4319	0	3150	10	46
1.d. Hamsters ( <i>Mesocricetus</i> )	5322	4961	0	357	4	13
1.e. Other Rodents (other <i>Rodentia</i> )	3089	1798	0	1167	124	521
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	8251	7556	0	665	30	663
1.g. Cats ( <i>Felis catus</i> )	334	233	0	30	71	14
1.h. Dogs ( <i>Canis familiaris</i> )	1049	528	0	98	423	194
1.i. Ferrets ( <i>Mustela putorius furo</i> )	256	21	0	50	185	0
1.j. Other Carnivores (other <i>Carnivora</i> )	151	0	0	0	151	0
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	1705	541	0	0	1164	858
1.l. Pigs ( <i>Sus</i> )	9853	4113	540	65	5135	63
1.m. Goats ( <i>Capra</i> )	328	114	0	0	214	65
1.n. Sheep ( <i>Ovis</i> )	2667	184	0	10	2473	152
1.o. Cattle ( <i>Bos</i> )	4410	2602	3	81	1724	429
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	50	32	0	18	0	5
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	277	223	0	35	19	185
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	13	0	0	0	13	0
1.u. Quail ( <i>Coturnix coturnix</i> )	152	0	0	152	0	0
1.v. Other birds (other <i>Aves</i> )	111081	15137	26	0	95918	603
1.w. Reptiles ( <i>Reptilia</i> )	7	2	0	0	5	0
1.x. Amphibians ( <i>Amphibia</i> )	3231	2877	0	7	347	0
1.y. Fish ( <i>Pisces</i> )	14838	6906	683	1250	5999	119
1.z. TOTAL	531199	392786	1252	19291	117870	12982

**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	143937	47957	14519	16107	6114	8704	2710	0	240048
2.b. Rats	34904	20931	32029	2769	23100	0	2875	0	116608
2.c. Guinea-Pigs	609	1553	1223	3621	429	3	41	0	7479
2.d. Hamsters	811	94	5	4356	45	0	11	0	5322
2.e. Other Rodents	197	2781	0	0	0	0	111	0	3089
2.f. Rabbits	751	1211	88	2222	3920	15	44	0	8251
2.g. Cats	129	33	0	83	6	0	83	0	334
2.h. Dogs	166	157	0	287	401	0	38	0	1049
2.i. Ferrets	136	108	0	0	0	0	12	0	256
2.j. Other Carnivores	151	0	0	0	0	0	0	0	151
2.k. Horses, donkeys and cross breds	2	163	65	1473	0	0	2	0	1705
2.l. Pigs	5336	2482	82	1725	56	0	172	0	9853
2.m. Goats	221	43	0	0	0	0	64	0	328
2.n. Sheep	211	194	2179	74	0	0	9	0	2667
2.o. Cattle	2930	875	53	322	0	0	230	0	4410
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	13	23	0	0	14	0	0	0	50
2.r. Old World Monkeys	196	71	10	0	0	0	0	0	277
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	13	0	0	0	0	0	0	13
2.u. Quail	0	0	0	0	152	0	0	0	152
2.v. Other birds	34618	28022	333	47775	24	3	306	0	111081
2.w. Reptiles	6	0	0	0	0	0	1	0	7
2.x. Amphibians	3151	0	0	0	0	0	80	0	3231
2.y. Fish	7919	739	280	0	5384	0	516	0	14838

2.z.	TOTAL	236394	107450	50866	80814	39645	8725	7305	0	531199
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**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	2819	92	2382	0	0	322	0	247	252	6114
3.b. Rats	6140	5574	8389	0	0	1558	479	0	960	23100
3.c. Guinea-Pigs	276	0	131	0	0	19	0	0	3	429
3.d. Hamsters	45	0	0	0	0	0	0	0	0	45
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	2554	885	371	0	0	6	104	0	0	3920
3.g. Cats	6	0	0	0	0	0	0	0	0	6
3.h. Dogs	301	100	0	0	0	0	0	0	0	401
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	0	0	0	0	0	56	0	0	0	56
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	14	0	0	0	0	0	0	0	0	14
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	152	0	0	0	0	0	0	0	152
3.v. Other birds	0	24	0	0	0	0	0	0	0	24
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	350	180	0	0	0	0	4854	0	5384
3.z. TOTAL	12155	7177	11453	0	0	1961	583	5101	1215	39645



**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	15137	13750	48651	77344	12479	167361
4.b. Rats	3922	8641	2910	29959	50	45482
4.c. Guinea-Pigs	0	24	0	1794	145	1963
4.d. Hamsters	0	19	125	588	76	808
4.e. Other Rodents	0	0	0	2781	0	2781
4.f. Rabbits	340	5	28	1181	212	1766
4.g. Cats	0	1	0	24	69	94
4.h. Dogs	68	0	0	52	178	298
4.i. Ferrets	0	0	0	152	71	223
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	165	165
4.l. Pigs	277	0	21	511	3673	4482
4.m. Goats	89	0	0	142	2	233
4.n. Sheep	13	0	0	162	230	405
4.o. Cattle	0	0	0	61	1265	1326
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	5	0	27	0	32
4.r. Old World Monkeys	0	0	0	201	0	201
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	13	0	13
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	482	33870	34352
4.w. Reptiles	0	0	0	0	1	1
4.x. Amphibians	0	0	7	0	0	7
4.y. Fish	0	0	0	271	933	1204
4.z. TOTAL	19846	22445	51742	115745	53419	263197

**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	11126	0	1768	14929	2803	30626
5.b. Rats	0	3650	0	72	30483	593	34798
5.c. Guinea-Pigs	0	1139	7	0	2234	1464	4844
5.d. Hamsters	0	0	0	0	4354	7	4361
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	34	0	0	1996	280	2310
5.g. Cats	0	13	0	0	52	18	83
5.h. Dogs	0	0	0	0	149	138	287
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	136	1402	1538
5.l. Pigs	0	127	0	9	1248	423	1807
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	8	0	0	0	26	2219	2253
5.o. Cattle	7	0	26	10	161	171	375
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	10	10
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	40	0	0	0	37024	11044	48108
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	280	280
5.z. TOTAL	55	16089	33	1859	92792	20852	131680

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	0	0	84	4125	1905	6114
6.b. Rats	86	0	0	272	21161	1581	23100
6.c. Guinea-Pigs	0	0	0	0	400	29	429
6.d. Hamsters	0	0	0	0	45	0	45
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	3914	6	3920
6.g. Cats	0	0	0	6	0	0	6
6.h. Dogs	0	0	0	0	401	0	401
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	56	0	56
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	14	14
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	152	0	152
6.v. Other birds	0	0	0	0	0	24	24
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	321	0	0	0	3830	1233	5384
6.z. TOTAL	407	0	0	362	34084	4792	39645

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	10	839	0	2077	0	134	236	0	2435	0	0	383	6114
7.b. Rats	0	1009	3818	611	0	0	3242	0	6661	471	4852	0	2436	23100
7.c. Guinea-Pigs	0	0	18	0	290	0	23	0	0	0	0	0	98	429
7.d. Hamsters	0	0	45	0	0	0	0	0	0	0	0	0	0	45
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	140	330	0	167	24	0	60	0	1719	0	1480	3920
7.g. Cats	0	0	6	0	0	0	0	0	0	0	0	0	0	6
7.h. Dogs	0	0	169	0	0	0	224	0	0	0	0	0	8	401
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	56	0	0	0	0	0	0	56
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	14	14
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	152	0	0	0	0	0	0	0	0	0	0	0	0	152
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	24	24
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	1278	535	1713	0	0	0	790	0	804	0	0	264	0	5384
7.z. TOTAL	1430	1554	6748	941	2367	167	4493	236	7525	2906	6571	264	4443	39645

**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	119	3200	228	419	6	1469	0	1275	1600	961	0	2878	12155
8.b. Products/substances used or intended to be used mainly in agriculture	152	74	6	57	66	12	446	0	5338	26	843	0	157	7177
8.c. Products/substances used or intended to be used mainly in industry	144	826	1761	653	1759	146	864	0	108	830	4179	0	183	11453
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	68	3	79	3	1150	0	0	231	165	0	262	1961
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	160	0	0	0	423	0	0	583
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	1 134	535	1713	0	0	0	404	28	804	219	0	264	0	5101
8.i. Other toxicological or safety evaluations	0	0	0	0	44	0	0	208	0	0	0	0	963	1215
8.j. TOTAL	1430	1554	6748	941	2367	167	4493	236	7525	2906	6571	264	4443	39645

## **POLAND**

### **Statistical data submitted**

The statistical data have been submitted by the Ministry of Science and Higher Education, Department of Scientific Research.

### **Comments of the Polish authorities**

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Poland are regulated by the Experiments on Animals Act (Act of 21 January 2005 on experiments on live animals, Dz.U. Nr 33, poz. 289). The Minister of Science and Higher Education is responsible for enforcing the act.

Every animal experiment to be performed has to be recommended by a recognized ethical review committee (Local Commission for Ethics in Animal Experiments (LKE)). At the moment 18 ethical review committees are recognized. They are supervised by National Commission for Ethics in Animal Experiments (KKE). Members of KKE and LKE are independent on public administration institutions and user establishments. Licenses to perform animal experiments in individual user establishments are issued by the Minister of Science and Higher Education after receiving positive National Commission's (KKE) opinion.

The data on the use of experimental animals in Poland in 2005 was collected for the first time, so the number of animals used cannot be compared with the figures for the preceding years. The data collected comply with the procedure agreed by the Member States and the Commission of the European Communities pursuant to Article 26 of Directive 86/609/EEC.

The total number of animals used in experiments in Poland in 2005 was 358,829.

No animals were re-used.

Rodents accounted for 56,6% of all animals used – 202,983 animals.

No primates were used.

Cold-blooded animals (fish and amphibians) represented 15,7% of the animals used – 56,292 animals.

For the species which should be obtained from registered breeding or supplying establishments within Poland, over 95% of animals listed were so sourced and less than 4,5% were sourced outside of EC or Council of Europe member countries.

53,23 % of the animals were used in biological studies.

31,67 % of the animals were used in the research, development, production and quality control of products and devices for human medicine, dentistry and veterinary medicine.

6,18 % of the animals were used in toxicological studies.

8,93 % of the animals were used for diagnosis of disease, education and other purposes.

No animals were used in the testing of cosmetics products. Using animals for the purpose of testing of cosmetics products is prohibited by Polish law.

Poland was also asked to provide some feed back to the following specific question:

*Question: Could PL provide some background information which could **explain the reasons** for the significant use of other carnivores, other mammals, cattle, other rodents, quails, horses etc., pigs and other birds in comparison to other Member States?*

Almost 80% of 'other rodents' used for experiments in Poland are conducted at one of the largest academic centres, which collaborates with international universities and research institutes. Many experiments within the framework of international research projects are performed in Poland. It is important to emphasize that these research studies chiefly concern environmental research and the procedures used in these studies have the lowest level of invasiveness. The other 20% are used for environmental research much of which is unique to Poland and Central Europe.

Other carnivores are used in environmental studies, the study of endangered species and the process of re-introducing indigenous species to Poland (eg, wolves, bears etc).

The number of horses, donkeys and crossbreeds used in experiments is higher than in other Member States due to the Polish tradition of horse-breeding. These include studying new breeding programmes, assessment of transport conditions and nutrition, for example.

Poland produces a large amount of pork, beef and milk, therefore scientific research on pigs and cows is undertaken to maintain and improve the quality of these products.

Use of other mammals is necessary because agriculture is a big industry in Poland and animal testing is needed to monitor the effects of modern farming on the environment. These experiments involve mainly boars, bats and European bison.

Quails are used for toxicology tests for national as well as European companies. Other birds are also used for toxicological tests of pharmacological substances (required by Polish law), and ecological field studies on bird populations and the influence of agriculture on the bird population.



**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> )	126492	119158	2772	790	3772	
1.b. Rats ( <i>Rattus norvegicus</i> )	51558	50988	0	32	538	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	10763	10731	0	0	32	
1.d. Hamsters ( <i>Mesocricetus</i> )	243	194	0	0	49	
1.e. Other Rodents (other <i>Rodentia</i> )	10826					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	3101	2879	0	0	222	0
1.g. Cats ( <i>Felis catus</i> )	121	67	0	0	54	0
1.h. Dogs ( <i>Canis familiaris</i> )	618	419	0	0	199	0
1.i. Ferrets ( <i>Mustela putorius furo</i> )	19	14	0	0	5	0
1.j. Other Carnivores (other <i>Carnivora</i> )	6970					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	681					
1.l. Pigs ( <i>Sus</i> )	7358					
1.m. Goats ( <i>Capra</i> )	130					
1.n. Sheep ( <i>Ovis</i> )	2023					
1.o. Cattle ( <i>Bos</i> )	13834					
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	0	0	0	0	0	0
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0	0	0	0	0	0
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	5061					
1.u. Quail ( <i>Coturnix coturnix</i> )	1470	1470	0	0	0	
1.v. Other birds (other <i>Aves</i> )	61148					
1.w. Reptiles ( <i>Reptilia</i> )	121					
1.x. Amphibians ( <i>Amphibia</i> )	13216					
1.y. Fish ( <i>Pisces</i> )	43076					
1.z. TOTAL	358829					

**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	45285	28377	20196	3676	13370	14217	860	511	126492
2.b. Rats	33154	4018	5754	105	3709	3877	767	174	51558
2.c. Guinea-Pigs	579	0	7158	996	1557	444	21	8	10763
2.d. Hamsters	138	31	0	0	0	70	4	0	243
2.e. Other Rodents	10250	0	0	0	356	20	34	166	10826
2.f. Rabbits	754	68	1174	439	147	233	72	214	3101
2.g. Cats	24	0	45	50	0	0	2	0	121
2.h. Dogs	319	9	0	21	29	133	77	30	618
2.i. Ferrets	5	0	0	14	0	0	0	0	19
2.j. Other Carnivores	6970	0	0	0	0	0	0	0	6970
2.k. Horses, donkeys and cross breds	611	0	0	0	5	30	35	0	681
2.l. Pigs	6978	8	0	0	20	13	19	320	7358
2.m. Goats	60	6	0	0	0	36	27	1	130
2.n. Sheep	1796	61	0	0	72	0	63	31	2023
2.o. Cattle	12969	40	0	41	88	48	53	595	13834
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	5058	0	0	0	0	0	3	0	5061
2.u. Quail	1033	0	0	0	372	0	65	0	1470
2.v. Other birds	17194	40126	472	758	120	302	529	1647	61148
2.w. Reptiles	80	0	0	0	0	0	41	0	121
2.x. Amphibians	12200	0	0	0	0	0	1016	0	13216
2.y. Fish	35536	0	0	0	2315	300	515	4410	43076
2.z. TOTAL	190993	72744	34799	6100	22160	19723	4203	8107	358829

**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	9186	24				40		100	4020	13370
3.b. Rats	1450	460	665	31				128	975	3709
3.c. Guinea-Pigs	1459	98								1557
3.d. Hamsters										0
3.e. Other Rodents		28	28					300		356
3.f. Rabbits	126	9	6	6						147
3.g. Cats										0
3.h. Dogs								29		29
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds		5								5
3.l. Pigs						20				20
3.m. Goats										0
3.n. Sheep								72		72
3.o. Cattle	8						80			88
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		372								372
3.v. Other birds							120			120
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish	200	2079						36		2315
3.z. TOTAL	12429	3075	699	37	0	60	200	665	4995	22160

**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	2924	37604	7473	10829	3546	62376
4.b. Rats	3110	16646	550	6604	86	26996
4.c. Guinea-Pigs		4			444	448
4.d. Hamsters				70		70
4.e. Other Rodents		389		20		409
4.f. Rabbits	60		5	228		293
4.g. Cats				18	9	27
4.h. Dogs			9		148	157
4.i. Ferrets						0
4.j. Other Carnivores					35	35
4.k. Horses, donkeys and cross breeds	8				36	44
4.l. Pigs	45				40	85
4.m. Goats					5	5
4.n. Sheep	4			21	42	67
4.o. Cattle					135	135
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				152	490	642
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					500	500
4.z. TOTAL	6151	54643	8037	17942	5516	92289

**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	7474	8615		705	2398	4680	23872
5.b. Rats		5412		129	318		5859
5.c. Guinea-Pigs	1408	5813		20	10	903	8154
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	596	300		16	501	200	1613
5.g. Cats	76	11			8		95
5.h. Dogs	21						21
5.i. Ferrets	14						14
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		41					41
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	1230						1230
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	10819	20192	0	870	3235	5783	40899

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	3818	8290		20		1242	13370
6.b. Rats	1836	1357				516	3709
6.c. Guinea-Pigs		1557					1557
6.d. Hamsters							0
6.e. Other Rodents						356	356
6.f. Rabbits		147					147
6.g. Cats							0
6.h. Dogs		29					29
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds		5					5
6.l. Pigs						20	20
6.m. Goats							0
6.n. Sheep						72	72
6.o. Cattle	8					80	88
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		372					372
6.v. Other birds						120	120
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish		2279				36	2315
6.z. TOTAL	5662	14036	0	20	0	2442	22160

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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 Carcinog- enicity	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	306	7370	152				364						5178	13370
7.b. Rats	165		385				1651		316		371		821	3709
7.c. Guinea-Pigs		420	756	60	313								8	1557
7.d. Hamsters														0
7.e. Other Rodents	56						300							356
7.f. Rabbits				72		36							39	147
7.g. Cats														0
7.h. Dogs											29			29
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds													5	5
7.l. Pigs													20	20
7.m. Goats														0
7.n. Sheep									35		37			72
7.o. Cattle													88	88
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	180										192			372
7.v. Other birds													120	120
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish	2179										36	100		2315
7.z. TOTAL	2886	7790	1293	132	313	36	2315	0	351	0	665	100	6279	22160

**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 Carcinog- enicity	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	531	7750	946	123	215	24	711		316			100	1713	12429
8.b. Products/substances used or intended to be used mainly in agriculture	2302		21	3	98	6	224				416		5	3075
8.c. Products/substances used or intended to be used mainly in industry	33		315	3		3	198				147			699
8.d. Products/substances used or intended to be used mainly in the household	20		11	3		3								37
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption		40											20	60
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption													200	200
8.h. Potential or actual contaminants in the general environment which do not appear in other columns							528		35		102			665
8.i. Other toxicological or safety evaluations							654						4341	4995
8.j. TOTAL	2886	7790	1293	132	313	36	2315	0	351	0	665	100	6279	22160



# PORTUGAL

## Statistical data submitted

The statistical data have been submitted by the “Ministério da Agricultura, Desenvolvimento Rural e das Pescas – Direcção Geral de Veterinária” (Ministry of Agriculture, Rural Development and Fisheries – General Direction of Veterinary – Directorate for Animal Medicines and Products, Animal Welfare and Feed)

## Comments of Portuguese authorities

### 1. Total number of animals used by species

In 2005, the total number of animals used for experimental and other scientific purposes in Portugal was 41621.

Compared to the data of 2002, where the total number of used animals was 44577, it means that with regard to 2005 it was a slight decrease on the use of animals of 6,6%.

As in the previous report, Mice are the most commonly used species representing 68,04% of the total number of animals.

The second most used group of animals was Rats (16,32%), the third is represented by the cold-blooded animals (11,53%) and the fourth by the rabbits with 1,43%. The group of Artio and Perissodactyla represent 1,11% of the total number of animals used and Carnivores represent only 0,09%.

Rodents with rabbits represent 87,01% of the total number of animals used.

As in other previous reports, in Portugal, non-human primates were not used.

### *Comparison with the data of the previous report (data of 2002)*

The percentages of classes of animals used in 2002 (44577 animals) and in 2005 (41621 animals) are represented in the following table:

Class of animals (%)	2002	2005
Mice	62	68,04
Rats	27,6	16,32
Guinea-pigs	1,42	0,91
Hamsters and other rodents	0,21	0,31
Rabbits	2,04	1,43
Cold-blooded animals	5,38	11,53

Quail and other birds	0,44	0,27
Artio Perissodactyla	0,88	1,11
Carnivores	0,08	0,09

Looking at the data by groups of species, the two major increases that happened in 2005 are in the use of Cold-blooded animals and of Mice.

On the other hand, the biggest decrease was in the use of Rats.

The percentage of Rabbits decreased in 2005 but the percentage of Hamsters slightly increased.

Among the group of the Cold-blooded animals, the general increase was due to the increase on the use of Fish, as the numbers of Reptiles and Amphibians both decreased.

The use of Birds decreased too and this decrease was due to the reduction on the use of Quail but also on Other Birds too.

The use of Artio and Perisodactyla animals increased in 2005. The species that its use decreased among this group was only Goats but all the others increased.

## **2. Number of animals used by purposes of experiments**

In 2005, the percentage of animals (total 41621) used by purposes of experiments was the following:

78,78% of animals were used in Fundamental biology;

6,78% in Research and development for human medicine, veterinary medicine, dentistry;

5,09% in Production and quality control of products and devices in human medicine and dentistry (1,72%) and veterinary medicine (3,37%);

3,02% in Education and training;

2,68% in Diagnosis of disease;

2,26% in Toxicological and other safety evaluation;

1,39% in Other purposes;

Referring to the use of species versus experimental purposes, the highest amount of use of Mice and of Rats is in Fundamental biology and in Research and development for human medicine, veterinary medicine, dentistry.

### ***Comparison with the data of the previous report (data of 2002).***

The most significant increase in 2005 is the number of animals that were used for Fundamental biology, which increased from 64,11% in 2002, to 78,78% in 2005.

The other increase that occurred was in the percentage of animals used in Production and quality control of products and devices in human medicine and dentistry, which increased from 0,8% in 2002, to 1,72% in 2005.

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

The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92% to 2,26% (from 1301 to 939 animals);

The percentage of animals used for Education and training decreased from 4,78% to 3,02% (from 2132 to 1258 animals);

The percentage of animals used for Other purposes decreased from 2,41% to 1,39% (from 1075 to 577 animals)

## **1. Number of animals used for Toxicological and safety evaluation by type of products**

In 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

Products or devices for human medicine and dentistry and for veterinary medicine represents 52,08% of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represents 21,30% and Other toxicological or safety evaluations represent 26,62%.

### ***Comparison with the data of the previous report (data of 2002).***

Compared to the data of 2002, in 2005 there was a decrease on the use of animals in Toxicological and other safety evaluation. The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92% to 2,26% (from 1301 to 939 animals).

The data of 2002 refers to the same category of products that were tested in 2005.

Products or devices for human medicine and dentistry and for veterinary medicine represented, in 2002, 20,67% of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represented 12,45% and Other toxicological or safety evaluations represent 66,88%.

As in 2002, in 2005 the other groups of products/substances were not tested which means that, for example, there were no animals used for the purpose of evaluating the safety of Cosmetics or Additives in food for animal consumption.

In Portugal, in 2005, there happened a decrease in the number of animals used for Other toxicological or safety evaluation compared to 2002. In 2002, the number of animals used were 870 (66,88%) and in 2005, 250 (26,62%).

## **2. Number of animals used for the study of diseases**

In 2005, the number of animals used for the Studies on humans and animals diseases was 19372, which represents 46,54% of the total number of animals (41621 animals) that were used.

The percentages of animals per type of diseases were:

3,28% in Human cardiovascular diseases;

24,89% in Human nervous and mental disorders;

2,28% in Human cancer (excl. evaluation of carcino hazards);

68,15% in Other human diseases;

1,40% in Specific animal diseases.

The percentage of the number of animals used for studies of human diseases represents 98,6% (19101 animals) of the total number of animals used for all studies of diseases (19372 animals).

In 2005, the number of animals used to study animal diseases was only 271 (1,40%) while in 2002, that number had been 1922, which means that in 2005, there was a decrease on the use of animals for the study of animal diseases.

In general terms, the proportion of animals used for the studies of diseases showed a slight change when compared to the 2002 data.

In 2005, Cold-blooded animals were not used to study any diseases

### **3. Number of animals used for Toxicological and other safety evaluations by the types of tests**

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

#### ***Comparison with the data of the previous report (data of 2002).***

The percentages of animals used in toxicity tests for Toxicological and other safety evaluation in 2002 (1301 animals) and in 2005 (939 animals) are represented in the following table:

Type of tests (%)	2002	2005
Acute and sub-acute toxicity testing methods (including limit test)	14,37	37,6
Irritation/sensitization tests	6,53	27,8
Sub-chronic and chronic toxicity	0	0
Mutagenicity and carcinogenicity	8,84	32
Reproductive and developmental toxicity	49,19	0

Toxicity of aquatic vertebrates not included in other columns	0	0
Other	21,1	2,7

In 2005, the biggest percentage of use of animals is due to acute and sub-acute toxicity, which represents 37,6% and means that there was an increase of this type of tests related to the previous report (data 2002).

The use of animals used for Reproductive and developmental toxicity tests decreased from 49,19% in 2002, to 0% in 2005.

Contrary to what happened for the 25 Member States, the use of animals in 2005 for “Other tests” decreased from 21,1% in 2002, to 2,7% in 2005.

#### **4. Type of toxicity tests carried out for Toxicological and other safety evaluations of products**

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

#### ***Comparison with the data of the previous report (data of 2002)***

The numbers of animals used for Toxicological and other safety evaluation per types of products in 2002 (1301 animals) and in 2005 (939 animals) are represented in the following tables:

Types of products (%)	2002	2005
Products/substances or devices for human medicine and dentistry and for veterinary medicine	269	689
Potential or actual contaminants in the general environment which do not appear in other columns	162	0
Other toxicological or safety evaluations	870	250

In 2005, the number of animals used to test Products/substances or devices for human medicine and dentistry and for veterinary medicine were the following:

300 animals in Carcinogenicity and Mutagenicity (in 2002, they were 100 animals);

261 animals in Irritation/sensitisation tests (in 2002, they were 85 animals);

103 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 40 animals).

25 animals in Other tests (in 2002, they were 44 animals).

In 2005, the number of animals used in the category Other toxicological or safety evaluations were 250 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 230 animals in Acute and sub-acute toxicity testing methods (including limit test) and 640 animals in Reproductive and developmental toxicity tests).

**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> )	28318	19975	5838	49	2456	50
1.b. Rats ( <i>Rattus norvegicus</i> )	6793	2362	4236		195	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	379	102			277	
1.d. Hamsters ( <i>Mesocricetus</i> )	129	18	111			
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	594	349			245	20
1.g. Cats ( <i>Felis catus</i> )						
1.h. Dogs ( <i>Canis familiaris</i> )	36				36	10
1.i. Ferrets ( <i>Mustela putorius furo</i> )						
1.j. Other Carnivores (other <i>Carnivora</i> )						
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	8					
1.l. Pigs ( <i>Sus</i> )	113					
1.m. Goats ( <i>Capra</i> )	4					
1.n. Sheep ( <i>Ovis</i> )	290					
1.o. Cattle ( <i>Bos</i> )	45					
1.p. Prosimians ( <i>Prosimia</i> )						
1.q. New World Monkeys ( <i>Ceboidea</i> )						
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )						
1.s. Apes ( <i>Hominoidea</i> )						
1.t. Other Mammals (other <i>Mammalia</i> )	1					
1.u. Quail ( <i>Coturnix coturnix</i> )						
1.v. Other birds (other <i>Aves</i> )	112					
1.w. Reptiles ( <i>Reptilia</i> )						12
1.x. Amphibians ( <i>Amphibia</i> )	51				1	
1.y. Fish ( <i>Pisces</i> )	4748					
1.z. TOTAL	41621					

**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	23396	1075	700	977	440	994	471	265	28318
2.b. Rats	4249	1612			200	113	561	58	6793
2.c. Guinea-Pigs	65			110	2	8	25	169	379
2.d. Hamsters		115						14	129
2.e. Other Rodents									
2.f. Rabbits	3	19	15	245	261	1	25	25	594
2.g. Cats									
2.h. Dogs					36				36
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							8		8
2.l. Pigs	33						78	2	113
2.m. Goats							4		4
2.n. Sheep	272			4			8	6	290
2.o. Cattle	37						8		45
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals		1							1
2.u. Quail									
2.v. Other birds	6			69				37	112
2.w. Reptiles									
2.x. Amphibians							50	1	51
2.y. Fish	4728						20		4748
2.z. TOTAL	32789	2822	715	1405	939	1116	1258	577	41621



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

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	190								250	440
3.b. Rats								200		
3.c. Guinea-Pigs	2									2
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits	261									261
3.g. Cats										
3.h. Dogs	36									36
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breeds										
3.l. Pigs										
3.m. Goats										
3.n. Sheep										
3.o. Cattle										
3.p. Prosimians										
3.q. New World Monkeys										
3.r. Old World Monkeys										
3.s. Apes										
3.t. Other Mammals										
3.u. Quail										
3.v. Other birds										
3.w. Reptiles										
3.x. Amphibians										
3.y. Fish										
3.z. TOTAL	489							200	250	939

**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	66	2126	436	12509	247	15384
4.b. Rats	459	2696	3	658		3816
4.c. Guinea-Pigs				2		2
4.d. Hamsters	111			14		125
4.e. Other Rodents						
4.f. Rabbits						
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breeds						
4.l. Pigs			2		2	4
4.m. Goats						
4.n. Sheep					4	4
4.o. Cattle						
4.p. Prosimians						
4.q. New World Monkeys						
4.r. Old World Monkeys						
4.s. Apes						
4.t. Other Mammals						
4.u. Quail						
4.v. Other birds				19	18	37
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	636	4822	441	13202	271	19372

**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	977					700	1677
5.b. Rats							
5.c. Guinea-Pigs	110						110
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits	220	40					260
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breeds							
5.l. Pigs							
5.m. Goats							
5.n. Sheep	4						4
5.o. Cattle							
5.p. Prosimians							
5.q. New World Monkeys							
5.r. Old World Monkeys							
5.s. Apes							
5.t. Other Mammals							
5.u. Quail							
5.v. Other birds	69						69
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL	1380	40				700	2120

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine**

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	25	315				100	440
6.b. Rats	200						200
6.c. Guinea-Pigs		2					2
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits		261					261
6.g. Cats							
6.h. Dogs		36					36
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breeds							
6.l. Pigs							
6.m. Goats							
6.n. Sheep							
6.o. Cattle							
6.p. Prosimians							
6.q. New World Monkeys							
6.r. Old World Monkeys							
6.s. Apes							
6.t. Other Mammals							
6.u. Quail							
6.v. Other birds							
6.w. Reptiles							
6.x. Amphibians							
6.y. Fish							
6.z. TOTAL	225	614				100	939

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	100	215								100			25	440
7.b. Rats								200						200
7.c. Guinea-Pigs		2												2
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits						261								261
7.g. Cats														
7.h. Dogs			36											36
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breds														
7.l. Pigs														
7.m. Goats														
7.n. Sheep														
7.o. Cattle														
7.p. Prosimians														
7.q. New World Monkeys														
7.r. Old World Monkeys														
7.s. Apes														
7.t. Other Mammals														
7.u. Quail														
7.v. Other birds														
7.w. Reptiles														
7.x. Amphibians														
7.y. Fish														
7.z. TOTAL	100	217	36			261		200		100			25	939

**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		103				261		200		100			25	689
8.b. Products/substances used or intended to be used mainly in agriculture														
8.c. Products/substances used or intended to be used mainly in industry														
8.d. Products/substances used or intended to be used mainly in the household														
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														
8.i. Other toxicological or safety evaluations	100	150												250
8.j. TOTAL	100	253				261		200		100			25	939

## **FINLAND**

### **Statistical data submitted**

The statistical data have been submitted by the “*Maa – ja metsätalousministeriö Elintarvike- ja terveysosasto*” (Ministry of Agriculture and Forestry, Veterinary and Food Department).

### **Comments of Finnish authorities**

#### **Report from Finland 2005**

In year 2005, 256826 experimental animals were used in Finland. Fish were used 20 % more than in 2004. The total amount of animals of other species used in experiments remained essentially unchanged from the previous year.

Due to the increase in fish use there was a 6 % increase in the total number of experimental animals in 2005 in comparison to 2004. In recent years fish use has varied greatly from more than 500 000 in years 2001 and 2002 to 78 000 in year 2004 causing a great yearly variation in total number of experimental animals used in Finland.

The number of mice used in 2005 was 19 % higher than the yearly average in 2000-2004, but of rats 12% lower, respectively. Of all experimental animals used 60 % were rodents, and 93 % of fish are excluded from the total, respectively. No cats were used in Finland in 2005, but the number of dogs used was increasing third year in row, the number being 103 in 2005 which is 60 % higher than the average yearly use of previous 5 years. Cattle was in 2005 used also increasingly in comparison to previous 5 years. In other species no tendency was seen.

No cats, monkeys and reptiles were reported used as experimental animals in Finland in 2005.

Major part (87 %) of the animals were used for biological studies of a fundamental nature. Animal use in 2005 for human and veterinary medicine research and quality control was 9,3 %, for toxicological and other safety evaluations 0,9 %, for diagnosis of disease 0,2 %, for education and training 1,8 % and other uses 0,9 % of the total number of experimental animals used, respectively. No major differences in comparison to the previous year were observed.

Preparations for a revision of the Finnish legislation concerning use of experimental animals proceeded to final drafts during year 2005 and was planned to be passed in 2006.

Ministry of Agriculture and Forestry funded Finnish research for studies to replace existing techniques using experimental animals with alternative methods with 27 000 € in year 2005.



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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	120636	87684	32362	247	343	
1.b. Rats ( <i>Rattus norvegicus</i> )	28358	10869	17365		124	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	563		563			
1.d. Hamsters ( <i>Mesocricetus</i> )	126	6	120			
1.e. Other Rodents (other <i>Rodentia</i> )	3187					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	1214	500	714			
1.g. Cats ( <i>Felis catus</i> )	0	0				
1.h. Dogs ( <i>Canis familiaris</i> )	103	8	95			
1.i. Ferrets ( <i>Mustela putorius furo</i> )	80	80				
1.j. Other Carnivores (other <i>Carnivora</i> )	5					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	125					
1.l. Pigs ( <i>Sus</i> )	1471					
1.m. Goats ( <i>Capra</i> )	73					
1.n. Sheep ( <i>Ovis</i> )	445					
1.o. Cattle ( <i>Bos</i> )	455					
1.p. Prosimians ( <i>Prosimia</i> )	0	0				
1.q. New World Monkeys ( <i>Ceboidea</i> )	0	0				
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0	0				
1.s. Apes ( <i>Hominoidea</i> )	0	0				
1.t. Other Mammals (other <i>Mammalia</i> )	972	0				
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0				
1.v. Other birds (other <i>Aves</i> )	5773					
1.w. Reptiles ( <i>Reptilia</i> )	0					
1.x. Amphibians ( <i>Amphibia</i> )	20					
1.y. Fish ( <i>Pisces</i> )	93220					
1.z. TOTAL	256826	100617	51229	247	468	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 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	111502	7761	100		585	25	581	82	120636
2.b. Rats	13749	11885	100		1374	17	791	442	28358
2.c. Guinea-Pigs		352	24		79		24	84	563
2.d. Hamsters	126								126
2.e. Other Rodents	3187								3187
2.f. Rabbits	514	467	54		75	1	85	18	1214
2.g. Cats									0
2.h. Dogs		47			56				103
2.i. Ferrets	80								80
2.j. Other Carnivores	5								5
2.k. Horses, donkeys and cross breds	110	15							125
2.l. Pigs	445	141	203				82	600	1471
2.m. Goats		4					69		73
2.n. Sheep	22	43	380						445
2.o. Cattle	277						178		455
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	972								972
2.u. Quail									0
2.v. Other birds	2515	8		2209			41	1000	5773
2.w. Reptiles									0
2.x. Amphibians							20		20
2.y. Fish	90011				72	317	2820		93220
2.z. TOTAL	223515	20723	861	2209	2241	360	4691	2226	256826

**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	265								320	585
3.b. Rats	758								616	1374
3.c. Guinea-Pigs	79									79
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	75									75
3.g. Cats										0
3.h. Dogs	56									56
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								72		72
3.z. TOTAL	1233	0	0	0	0	0	0	72	936	2241

**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	3629	6400	8652	18885		37566
4.b. Rats	3408	9683	266	4118		17475
4.c. Guinea-Pigs	332					332
4.d. Hamsters				120		120
4.e. Other Rodents						0
4.f. Rabbits	195	15		362		572
4.g. Cats						0
4.h. Dogs	75	12				87
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	218					218
4.m. Goats						0
4.n. Sheep				39	22	61
4.o. Cattle					6	6
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals					6	6
4.u. Quail						0
4.v. Other birds					8	8
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					385	385
4.z. TOTAL	7857	16110	8918	23524	427	56836

**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		80	20				100
5.b. Rats						100	100
5.c. Guinea-Pigs						24	24
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		4				50	54
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					171	32	203
5.m. Goats							0
5.n. Sheep					380		380
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						2209	2209
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	84	20	0	551	2415	3070

**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 Hungarian requirement  
5.5 – Sweden 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.

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**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	40	55			490		585
6.b. Rats		127			1151	96	1374
6.c. Guinea-Pigs					79		79
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		8			67		75
6.g. Cats							0
6.h. Dogs		56					56
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						72	72
6.z. TOTAL	40	246	0	0	1787	168	2241

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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			375				40						170	585
7.b. Rats			520				17				100		737	1374
7.c. Guinea-Pigs													79	79
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits							8						67	75
7.g. Cats														0
7.h. Dogs							56							56
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish												72		72
7.z. TOTAL	0	0	895	0	0	0	121	0	0	0	100	72	1053	2241

**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			895				121				100		957	2073
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												72		72
8.i. Other toxicological or safety evaluations													96	96
8.j. TOTAL	0	0	895	0	0	0	121	0	0	0	100	72	1053	2241



# **SLOVENIA**

## **Statistical data submitted**

The statistical data have been submitted by the "Veterinary Administration of the Republic of Slovenia"

## **Comments of Slovenian authorities**

The Slovenian national legislation on the protection of experimental animals has been harmonised with the relevant EU legislation. Experimental animals have been regulated under the Protection of Animals Act (UPB-1, UL RS<sup>1</sup> 20/04), under the Rules on conditions for experiments on animals (UL RS 88/06), and under the Rules on the Ethical Commission for experiments on animals (UL RS 84/00).

On the basis of annual reports submitted by organisations conducting experiments on animals, the Veterinary Administration of the Republic of Slovenia (VARs) has been keeping statistical records including the data on quantities and species of animals used in experiments and types of experiments as laid down in Article 24 (2) of the Protection of Animals Act. Each user organisation employs an animal welfare expert, who is responsible for compiling on a specifically prescribed form a collective annual report on experiments conducted during the year and for submitting the report by the end of February to VARs. The form envisaged for annual reporting includes eight tables and as Annex 5 constitutes an integral part of the Rules on conditions for experiments on animals.

In the Republic of Slovenia, data on the use of animals in experiments have been collected since 1992. In the period 1992 – 1996, the collective number of animals used in experiments ranged on average up to 33,000 animals, in the period 1997 – 1999 up to 21,000 animals, in the period 2000 – 2001 up to 16,000 animals, and in the period 2002 – 2004 on average up to 13,500 animals. In the light of the above it may be stated with certainty that the use of animals in experiments in the Republic of Slovenia has been showing a downward trend.

In 2005, a collective number of animals used for experimental and other scientific purposes totalled 11,991 animals. As compared to 2004, where 13,538 animals were used in experiments, the number of animals used in experiments in 2005 decreased by 1,547 animals (11.4 %). This collective number of animals mostly included laboratory rodents (mice, rats) and rabbits.

In 2005, 11,344 laboratory rodents were used, amounting to 94.6 % of all experimental animals used, whilst more laboratory rodents were used in 2004, i.e. 12,145 animals or 89.7 % of all experimental animals used. In 2005, 533 rabbits were used in experiments, amounting to 8.5 % less rabbits as compared to 2004. In 2005, a collective number of 114 other animals were used, including in particular sheep, birds, pigs and a horse.

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<sup>1</sup> UL RS – *Uradni list Republike Slovenija* – Official Gazette of the Republic of Slovenia

It is evident from **Table 1** showing the number and species of animals used in relation to their place of origin that nearly all laboratory experimental animals in 2005 came from breeding organisations established within the Republic of Slovenia. Mostly used were laboratory rodents (94.6 %). From the collective number of experimental animals, the animals reused in experiments included the rabbits and dogs.

As regards animals used in experiments for selected purposes as shown in **Table 2**, in 2005, most animals were used in pharmaceutical industry in the Republic of Slovenia. For the purposes of research and development of products and devices for human medicine, and for dentistry and veterinary medicine, for the production and quality control of products and devices for human and veterinary medicine, and for toxicological and other safety evaluations, a total of 9,420 animals, or 78.5 % of all animals used (94 % laboratory rodents, 5.4 % rabbits and 0.4 % sheep), were used in such experiments in 2005.

**Table 3** shows that a total of 1,054 animals were used in the toxicological and other safety evaluations. A total of 1,009 animals (975 laboratory rodents and 34 sheep) were used for testing products/substances or devices for human medicine, dentistry and veterinary medicine, and 45 rabbits for other toxicological or safety evaluations.

**Table 7** details the use of animals in the toxicological and other safety evaluations. In 2005, 965 laboratory rodents were used in the acute and sub-acute toxicity testing methods, or in LD 50 and LC 50 determination, and 10 laboratory rats, 45 rabbits and 34 sheep in other toxicological and safety evaluations.

**Table 8** shows that 965 animals were used in the toxicological and other safety evaluations for products/substances or devices for human medicine, dentistry and veterinary medicine, and 34 animals for other purposes of toxicological or safety evaluations, whilst 55 animals were used in tests of reproduction toxicity of products/substances intended for use in agriculture.

Quality control of products and devices for human medicine, dentistry and veterinary medicine, and toxicological and other safety evaluations of substances are conducted in accordance with the applicable legislation, the requirements of relevant Pharmacopoeias, and in accordance with the international regulations.

**Table 5** shows that in accordance with EU legislation, including the requirements of the European Pharmacopoeia, 5,916 animals in total were used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine, which amounts to 49.3 % of all experimental animals used in 2005. Laboratory rodents and rabbits were used for these purposes.

The institutes and laboratories of the faculties of human medicine, veterinary medicine, biology and zootechnics use animals in the baseline biological research studies and/or in the research and development studies, and a total of 1,888 animals were used for these purposes in 2005, which amounts to 15.7 % of all animals used, including in particular laboratory rodents (98.9 %), some dogs, sheep and birds.

In 2005, animals were used to a lesser extent for diagnosing diseases (3.1 %), educational and training purposes (2.3 %), and other purposes (0.1 %).

Table 4 shows the number and species of animals used in experiments for studies of diseases in humans and in animals. A total of 1,786 animals were used for these purposes, all for studies of diseases in humans. A total of 735 animals were used for studies of nervous and mental disorders in humans, 422 animals for studies of cardiovascular diseases, and 629 animals for studies of other diseases. Laboratory rodents were used predominantly, and some rabbits and sheep.

An important role in decreasing the number of animals used in experiments plays in particular the legislation, and the substitution of animals by alternative methods where so required by law, the requirement for specific authorisations of experiments, appropriate staff training, successful cooperation between the institutes and researchers at the national and international levels, as well as the active involvement of animal protection and welfare societies. A further important contribution to decreasing the number of animals used in experiments is the responsibility on the part of researchers and their improved attitude towards experimental animals as the plans and protocols of experiments are more precise and detailed, methods more carefully selected and experiments more precisely conducted. Further important factors in decreasing the number of animals used in experiments particularly in the pharmaceutical industry include the interstate/international recognition of results obtained in experiments on animals, the improved biometric methods, improved initial research phases of new substances and the use of cell cultures, tissues or smaller groups of animals.

Dr. Dragica Ornik,

Inspector – Counsellor

Dr. Vida Čadonič Špelič,

Chief Veterinary Officer

**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> )	8556	8556				
1.b. Rats ( <i>Rattus norvegicus</i> )	2732	2727	5			
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	38	38				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )	18					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	533	533				466
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	15	15				6
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> )	1					
1.l. Pigs ( <i>Sus</i> )	16					
1.m. Goats ( <i>Capra</i> )	0					
1.n. Sheep ( <i>Ovis</i> )	57					
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> )	22					
1.w. Reptiles ( <i>Reptilia</i> )	3					
1.x. Amphibians ( <i>Amphibia</i> )	0					
1.y. Fish ( <i>Pisces</i> )	0					
1.z. TOTAL	11991					

**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	760	2157	4467	240	478	334	104	16	8556
2.b. Rats	1087	293	743		497		112		2732
2.c. Guinea-Pigs	22					9	7		38
2.d. Hamsters									
2.e. Other Rodents						16	2		18
2.f. Rabbits			466		45	1	21		533
2.g. Cats									
2.h. Dogs	7						2	6	15
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							1		1
2.l. Pigs							16		16
2.m. Goats									
2.n. Sheep	5				34	18			57
2.o. Cattle									
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals									
2.u. Quail									
2.v. Other birds	7						15		22
2.w. Reptiles							3		3
2.x. Amphibians									
2.y. Fish									
2.z. TOTAL	1888	2450	5676	240	1054	378	283	22	11991

**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	478									478
3.b. Rats	497									497
3.c. Guinea-Pigs										
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits									45	45
3.g. Cats										
3.h. Dogs										
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breeds										
3.l. Pigs										
3.m. Goats										
3.n. Sheep	34									34
3.o. Cattle										
3.p. Prosimians										
3.q. New World Monkeys										
3.r. Old World Monkeys										
3.s. Apes										
3.t. Other Mammals										
3.u. Quail										
3.v. Other birds										
3.w. Reptiles										
3.x. Amphibians										
3.y. Fish										
3.z. TOTAL	1009								45	1054

**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	99			426		525
4.b. Rats	323	735		157		1215
4.c. Guinea-Pigs				22		22
4.d. Hamsters						
4.e. Other Rodents				16		16
4.f. Rabbits						
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breeds						
4.l. Pigs						
4.m. Goats						
4.n. Sheep				8		8
4.o. Cattle						
4.p. Prosimians						
4.q. New World Monkeys						
4.r. Old World Monkeys						
4.s. Apes						
4.t. Other Mammals						
4.u. Quail						
4.v. Other birds						
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	422	735		629		1786

**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		4707					4707
5.b. Rats		743					743
5.c. Guinea-Pigs							
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits		466					466
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breeds							
5.l. Pigs							
5.m. Goats							
5.n. Sheep							
5.o. Cattle							
5.p. Prosimians							
5.q. New World Monkeys							
5.r. Old World Monkeys							
5.s. Apes							
5.t. Other Mammals							
5.u. Quail							
5.v. Other birds							
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL		5916					5916

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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		478					478
6.b. Rats		487			0	10	497
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents						45	45
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						34	34
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	965	0	0	0	89	1054

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	478													478
7.b. Rats	487												10	497
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													45	45
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep													34	34
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	965	0	0	0	0	0	0	0	0	0	0	0	89	1054

**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	965												34	999
8.b. Products/substances used or intended to be used mainly in agriculture											55			55
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	965	0	0	0	0	0	0	0	0	0	55	0	34	1054

## **SLOVAKIA**

### **Statistical data submitted**

The statistical data have been submitted by the State Veterinary and Food Administration of the Slovak Republic, Botanická 17, 842 13 Bratislava

### **Comments of Slovakian authorities**

National comments to the statistical evaluation of data concerning the number of experimental animals used in experiments in the year 2005 in the Slovak Republic.

The State Veterinary and Food Administration of the Slovak Republic (hereinafter "SVFA SR") as a competent authority of the Slovak Republic in the matter of approval of establishments for breeding and use of animals for experimental and other scientific purposes is comprised of **8** Regional Veterinary and Food Administrations (hereinafter RVFA) and **40** District Veterinary and Food Administrations (hereinafter DVFA). All the workers of the veterinary administration in the field of animal welfare are veterinarians.

The SVFA SR approves in compliance with Article 6 of the Act No.488/2002 Coll. on Veterinary Care and on Amendment to Some Laws as later amended ( hereinafter Act No. 488/2002 Coll.) and in compliance with Article 7 and Article 13 and 17 of the Ordinance of the Government of Slovak Republic No. 289/2003 Coll., laying down requirements for the protection of animals used for experimental purposes or other scientific purposes as later amended (hereinafter "Ordinance of the Government of the Slovak Republic No. 289/2003 Coll."), experimental, breeding and supplying establishments and all the experiments performed using animals. Each approved establishment is kept by the SVFA SR on the list of approved establishments on the website of SVFA SR [www.svssr.sk](http://www.svssr.sk) in compliance with Article 37 of the Act No. 488/2002 Coll.

Approval of all kinds of establishments is performed by the SVFA SR based on affirmative standpoint on assessment of the suitability of establishment for housing, breeding, care and the use of animals for experiments, issued by the RVFA) in compliance with Article 12 and 16 of the Ordinance of the Government of the Slovak Republic No.289/2003 Coll. The RVFA issues a standpoint based on results of a control performed directly in the establishment for the purpose of assessment of observance of requirements for approved establishment, which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. and Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year non-discriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA SR, as a competent authority, trained theoretically and also practically all the animal welfare

inspectors for the performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

The SVFA SR approved in the year 2005, based on applicant's applications a total of 7 new experimental establishments, 1 breeding establishment for breeding of experimental animals.

Total number of establishments in the Slovak Republic in the year 2005

Kind of establishment	Number
Experimental establishment	43
Experimental establishment with breeding of animals for own use	20
Breeding establishment	7
Supplying establishment	1
<b>Total:</b>	<b>71</b>

The SVFA SR approves the experiments performed upon animals based on the application for approval of the experiment submitted by an applicant - approved experimental establishment. Each application for approval of an experiment shall be submitted by an applicant in compliance with Article 20 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. in order to be judged by the ETHIC COMMISSION. Each approved experimental establishment shall have established its own ethic commission comprised of minimum 5 members, out of which 1/3 must not be dependent from the experimental establishment. Ethic commission, on the submitted project of an experiment, shall assess justification of each experiment, use of the animals in the experiment and specification of species and number of animals in the experiment. An applicant may submit his/her project of an experiment for approval by the SVFA SR only after recommendation for submission, issued by the ethic commission. The SVFA SR has in compliance with the Act No. 71/1967 Coll. On Administrative Proceedings (Administrative Codex) minimum 30 days for assessment of an application for approval of the experiment. The SVFA SR, as a competent authority shall issue a decision by which the performance of the experiment may be approved or refused. In approval of the experiment, the SVFA SR shall assess the conformity of purpose of the experiment (3R), methods of performance of the experiment, origin of experimental animals, handling, care and housing of experimental animals with provision laid down in the Ordinance of the Government No. 289/2003 Coll., in compliance with the valid legislation in the Slovak Republic and in the European Union. The SVFA SR established, based on the Article 8 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. advisory body of the chief veterinary officer the members of which are scientific workers in the said branch. The SVFA SR in case of the need of professional consultation concerning the aim of the experiment, the need of use of the animals in

the experiment and the number of used animals shall ask the members of the advisory body for opinion - to the submitted application for approval of the experiment- with observance of rules of personal data protection and protection of data with signs of trade secret or intellectual property.

**To the Table No. 1** most of experimental animals originate in domestic breeding establishments or in experimental establishments with breeding of animals for own use. As far as foreign suppliers are concerned, the animals originate mainly in the Czech Republic, Hungary, Germany, Poland and France.

**To the Table No. 2** The SVFA SR approved 273 experiments with use of experimental animals and suspended the proceeding in 10 applications for approval of the experiment in the year 2005. The total number of used animals does not reflect the number of approved experiments, because in number of used experimental animals also the animals are included which were used in the year 2005 from the experiments, approved in the year 2003, 2004 for the period of 2-3 years. In the column 2.8, in total 7 experiments as pre-experiments for introduction of surgical methods and practices in the course of performance of main experiments were approved.

#### **Number of approved experiments in the Slovak Republic for the year 2005**

Dividing of experiments based on the Table No.2 (number of animals used in the experiment for a various purpose) from the statistical notification of the number of used animals

<b>Kind of experiment– purpose of the experiment</b>	<b>Number of experiments performed</b>
2.2. Basic research	70
2.3. Research and development of products and devices for human medicine and veterinary medicine and dentistry	79
2.4. Production and control of quality of products and devices for human medicine and dentistry	5
2.5. Production and control of quality of products and devices for veterinary medicine	10
2.6. Toxicological and other safety evaluations including evaluation of safety of products and devices for human and veterinary medicine and dentistry	62
2.7. Disease diagnostics	25

2.8. Education and training	7
2.9. Other	15
<b>Total</b>	<b>273</b>

**To the Table No.3** In the column 3.2 most animals were used for evaluation of products and substances for human medicine. In the column 3.3 the animal was used for control of products/substances used in agriculture- mainly pesticide, herbicide products. In the column 3.4 the animals used for control of various chemical products/substances being a part of oils, lubricants and rude materials are indicated.

**To the Table No. 4** Explanation to the column 4.5. Animals were used for the purpose of investigation of immune systems, infectious diseases, and metabolism disorders in man and in the column 4.6 in animals.

**To the Table No. 5** In the Slovak Republic the experiments upon animals are performed in compliance with the valid Slovak legislation, in which the legal acts of the European Communities and the European Union are incorporated. The experiments are performed in compliance with the valid legislation of the European Pharmacopoeia, in the column 5.5 the experiments were performed according to the valid national legislation e.g. STN EN ISO standards. In the column 5.7 the methods in control of human products/substances were used that were created by the experimental establishment as a modified method based on the approved pharmacopoeial methods or as a new individual method.

**To the Table No. 6** The Slovak Republic has elaborated the valid legislation for the control of drugs - Act No. 140/1998 Coll. Act On Medicinal Products and Medical Devices as amended, for the control of chemical substances and preparations the Act No. 163/2001 Coll. On Chemical Substances and Preparations, Decree of the Ministry of Economy No. 2/2005 Annex 5 Part B Methods B, that are analogous to OECD methods. In the column 6.3 the number of animals used in compliance with the European Pharmacopoeia are indicated, in the column 6.4 a total of 4 rabbits were used in the experiment of eye irritation in control of a substance used mainly in agriculture.

**To the Table No. 7** In the column 7.2.1. the animals were used only in limit test. Tests were performed mainly by methods OECD TG 402, 403. In the column 7.2.2. the tests OECD TG 423, B.1 tris were performed. In the column 7.2.3 mainly tests in compliance with OECD TG 407, 420, tolerance studies were performed.

In compliance with Article 17 para 4 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. each approved establishment shall be obliged, in order to maintain the approval, to submit yearly by the end of January for the previous year to the SVFA SR a notification on the form according to the specimen laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. on the number of used animals. Approved establishments shall be obliged to keep records about the number of used GMO animals in the experiment. Based on collected data the SVFA SR shall yearly work out a notification about the activity of the SVFA SR in which the numbers of approved establishments and approved or refused

experiments as well as numbers and species of used animals in the experiment for the respective year are published.

Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. And Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year non-discriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA, as a competent authority, has trained theoretically and also practically all the animal welfare inspectors for performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

Control of animal welfare in approved establishments is performed by animal welfare inspectors – veterinarians in compliance with Article 8 para 3 letter b) and Article 21 of the Act No. 488/2002 Coll. and of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of animal welfare are non-discriminatory, performed minimum once a year in each approved establishment. The competent authority trained all the inspectors for performance of animal welfare inspection and worked out the methodical instruction according to which the animal welfare inspections are performed. The purpose of animal welfare control in approved establishments is a control of observance of requirements laid down in the Act No. 488/2002 Coll, Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Animal welfare inspectors shall control conformity of the test performance in an approved experimental establishment with a decision issued by the SVFA SR on the approval of the experiment. Finding of infringements laid down in the Act No. 488/2002 Coll., Article 21 and 44 and in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. is classified as an administrative delict for which a penalty may be imposed on a legal or natural person in compliance with Article 45 of the Act No. 488/2002 Coll.

The SVFA SR performs theoretical and practical trainings of all workers of veterinary administration in performance of control with regard to housing, care and protection of experimental animals.

The competent authority performs consulting services for public in the field of animal welfare, organizes trainings for workers of approved establishments the purpose of which is interpretation of the valid legislation of the Slovak Republic in the field of animal welfare. The SVFA SR organizes also seminars and lectures aimed at protection of experimental animals used for experimental purposes. In compliance with the Article 35 of the Act. No. 488/2002 Coll. the animal owner, keeper and dealer shall be obliged to educate demonstrably the persons handling the animals so that such persons must avoid from any acts that might cause injury or any other damage to the health of animals or unnecessary suffering thereof.

Prof. Jozef Bireš, DVM, DrSc



Chief Veterinary Officer

**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> )	14975	9246		5729		
1.b. Rats ( <i>Rattus norvegicus</i> )	6761	4942	51	1768		
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	594	514		80		
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )						
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	782	632		150		126
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	6			6		
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> )	251	251				
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	23369					

**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	7415	2433	117	482	440	3766	100	222	14975
2.b. Rats	4857	341			1015	292	50	206	6761
2.c. Guinea-Pigs	252	122	116		84		3	17	594
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	133	39	161	91	159	178	3	18	782
2.g. Cats									0
2.h. Dogs					6				6
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds	251								251
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	12908	2935	394	573	1704	4236	156	463	23369

**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	270	50	120							440
3.b. Rats	296	121	514			6	75		3	1015
3.c. Guinea-Pigs	84									84
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	66	10	71				9		3	159
3.g. Cats										0
3.h. Dogs	6									6
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	722	181	705	0	0	6	84	0	6	1704

**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	29	2787	623	8677	1497	13613
4.b. Rats	1944	1573	181	1792		5490
4.c. Guinea-Pigs	38			336		374
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits		59	8	283		350
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				251		251
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	2011	4419	812	11339	1497	20078

**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		460		77		62	599
5.b. Rats							0
5.c. Guinea-Pigs				116			116
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		107			5	140	252
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	567	0	193	5	202	967

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, ‘the former Yugoslav Rep. of Macedonia’, Turkey, Ukraine

**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	120	320					440
6.b. Rats	669	346					1015
6.c. Guinea-Pigs		84					84
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	89	66	4				159
6.g. Cats							0
6.h. Dogs	6						6
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	884	816	4	0	0	0	1704

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	100	60								160			120	440
7.b. Rats	6	285	222	218	159		100						25	1015
7.c. Guinea-Pigs			4		80									84
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits			43	16		88							12	159
7.g. Cats														0
7.h. Dogs			6											6
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	106	345	275	234	239	88	100	0	0	160	0	0	157	1704



**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	50	320	89	11	80					160			12	722
8.b. Products/substances used or intended to be used mainly in agriculture	50	25	8	46	14	19							19	181
8.c. Products/substances used or intended to be used mainly in industry			124	147	145	69	100						120	705
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	6													6
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption			54	30										84
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													6	6
8.j. TOTAL	106	345	275	234	239	88	100	0	0	160	0	0	157	1704

## **SWEDEN**

### **Statistical data submitted**

The statistical data have been submitted by the National Board for Laboratory Animals.

### **Comments of Swedish authorities**

#### **Additional comments and remarks on the Swedish statistical records over used laboratory animals 2005.**

The deadline for submitting the statistical records covering the use of laboratory animals during 2005 to the EU commission was in July 2006. Most researchers were prompt and submitted their reports in March, although some were as late as May-June despite several reminders from the Swedish Animal Welfare Agency (SAWA).

#### *Electronical statistical form and database*

During 2006 SAWA has developed an electronically statistical reporting form that will give the researcher a possibility to submit the statistical records electronically to a computer base. SAWA's goal is that this will make it easier for the researcher to submit the statistical records and also that it will give the authority an excellent opportunity to handle, analyze and present the statistical records more easily.

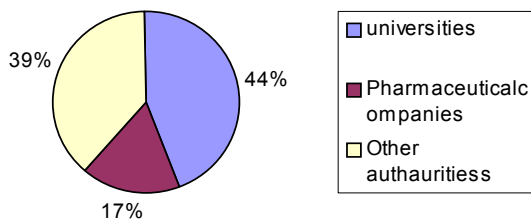
### **86/609/EEC Directive**

According to the EU definition (directive 86/609/EEC) the number of laboratory animals used during 2005 in Sweden reached about 505 600. This is approx. a 12 % increase (about 58 000 animals) compared to 2004. Three kinds of animals were predominately used in animal experimentation, the mice, the rat and fish. Indeed, these three groups comprised about 90 % of all laboratory animals used during 2005. The increase in the use of mice is probably due to increased use of genetically modified animals. The large number of fish used is mainly explained by tagging of fish in assessment studies. The increase in the use of mice as a laboratory animal is an ongoing trend that has been consistent during the last 10 year period.

Whereas, a clear decrease can be seen in the use of guinea pigs and rabbits throughout the 1990s, this may be due to new techniques of producing antibodies, using *in vitro* production instead of whole animals.

### **Diagram 1.**

Illustrating the use of laboratory animals in Sweden during 2005 according to the EU directive. Sorted in different reporting categories.



### Specific use of animals

As in previous years most laboratory animals were used in either fundamental biological research (43%) or in development of product/devices (17%) used in human or veterinary medicine. During 2005, 3% of the animals were used in toxicological research, and finally, less than 1% of the total numbers of laboratory animals were used for diagnosing diseases. The most common animals used in toxicological research are mice, rats and fish and to lesser extent dogs and rabbits. Mammals were mostly used in experiments concerning products/substances or devices relating to human medicine, dentistry and veterinary medicine, fish are mainly used in the evaluation of hazardous environmental substances.

### Reused animals

During 2005, 209 animals were reused in experiments according to the EU directive. This is a slight increase compared to 2004 when 168 animals were reused. Of the animals reused approx. 90 % were dogs (150 animals). To a much lesser extent old world monkeys and rabbits were reused, 28 and 31 respectively.

### Tendencies in Sweden

From 1990 until 2002 the mean number of laboratory animals used in Sweden was about 315 000 with the highest number 1994 (approx. 351 000) and the lowest 1997 (267 000). From 2003-2005 there has been a large increase in the number of animals used. This is mainly due to the fact that tagging of fish for assessment studies has been included as an animal experiment. After discussions with the Swedish Board of Fisheries, SAWA decided to include tagging of fish as an animal experiment. The mean number during 2003-2005 is about 489 000 animals where the mean number of tagged fish is approx. 160 000.

The reasons behind these fluctuations during the last decade are hard to speculate about. It may just be due to natural fluctuations and/or reflect the status of high or low economy in Sweden. However, one clear tendency is the decrease of rats throughout the 1990s. In 1990 approx. 160 000 rats were used according to the EU directive. Whereas, during the year 2005 the number of rats in experiments is down to 83 000, an almost 50 % decrease. On the other hand, the use of mice as laboratory animals has

increased throughout the 1990s; this rise is probably due to the increased use of transgenic technique(s).

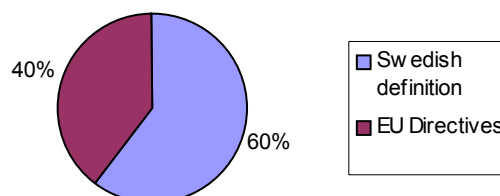
### **Swedish definition**

Apart from the information, Sweden also collects its own statistical data on other use of laboratory animals. According to Swedish legislation all use of animals, which have a scientific purpose, should be recorded. Therefore, this statistical data includes all animals used in behaviour studies, feeding trials or animals being euthanized for the use of their tissues and organs. During 2005 about 767 000 animals were reported according to this definition. The dominating animals were bird, mice, rats, fish and pigs. This is an increase with nearly 208 000 animals compared with the figures in the year 2004 and is mainly due to increased use of birds and fish. The increase in birds is due to a large behavioural study on hens and the use of roosters, i.e. comb from roosters for the production of hyaloronic acids. The reason behind the increase in fish is that the Swedish Board of Fisheries performed a large feeding study with the goal of increasing the survival of fish released from hatcheries.

### ***Fish assessment***

Apart from the categories described above, Sweden also collects statistical records on fish used in assessment studies. That is fish that are caught by trawling, netting etc. During 2005 the number of fish in this category was approx. 6 356 000

Diagram 2. The use of laboratory animals in Sweden according to 86/609/EEC directive 40% (approx. 505 000) and the Swedish definition 60% (approx. 767 000)



### **Transgenic animals**

The Swedish statistical records do not separate the use of transgenic animals from other laboratory animals. In agreement with EU directive, Sweden does not regard breeding of transgenic stocks as an experiment in it self. However, it is regarded as an experiment when transgenic animals are used in experiments or when new transgenic strains are created.

### **Conclusions**

The overall impression is that the use of laboratory animals according to the EU directive shows an increase when comparing the year 2005 with the numbers used during 2004. The effect(s) is most obviously when comparing the use of animals by the universities and other authorities. This is probably due to the fact that the new animal facilities were ready and in full operation during 2005 and of course the tagging of fish. During the same period the Swedish pharmaceutical industries also show a slight increase in the use of laboratory animals (approx: 7000 animals). The reason behind these fluctuations difficult speculate about it may just be a fact of natural fluctuations.

**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> )	213 727	152 004	58 954	0	2 769	
1.b. Rats ( <i>Rattus norvegicus</i> )	83 321	51 536	31 692	0	93	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	2 014	1 923	91	0	0	
1.d. Hamsters ( <i>Mesocricetus</i> )	167	63	104	0	0	
1.e. Other Rodents (other <i>Rodentia</i> )	1 269					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	2 112	1 690	422	0	0	28
1.g. Cats ( <i>Felis catus</i> )	220	175	0	0	45	0
1.h. Dogs ( <i>Canis familiaris</i> )	1 166	1 035	47	0	84	150
1.i. Ferrets ( <i>Mustela putorius furo</i> )	47	47	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i> )	163					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	650					
1.l. Pigs ( <i>Sus</i> )	2 722					
1.m. Goats ( <i>Capra</i> )	23					
1.n. Sheep ( <i>Ovis</i> )	256					
1.o. Cattle ( <i>Bos</i> )	727					
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	12	12	0	0	0	0
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	63	1	18	0	44	31
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	639					
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0	0	0	0	
1.v. Other birds (other <i>Aves</i> )	7 838					
1.w. Reptiles ( <i>Reptilia</i> )	0					
1.x. Amphibians ( <i>Amphibia</i> )	5 496					
1.y. Fish ( <i>Pisces</i> )	183 049					
1.z. TOTAL	505 681					

**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	152 796	54 941	68	54	2 246	65	1 128	2 429	213 727
2.b. Rats	47 396	30 220	80	0	4 460	0	943	222	83 321
2.c. Guinea-Pigs	578	956	443	17	0	0	6	14	2 014
2.d. Hamsters	53	104	0	0	0	0	10	0	167
2.e. Other Rodents	401	868	0	0	0	0	0	0	1 269
2.f. Rabbits	1 053	472	46	2	347	2	35	155	2 112
2.g. Cats	138	9	0	0	0	51	0	22	220
2.h. Dogs	370	317	0	0	441	15	3	20	1 166
2.i. Ferrets	47	0	0	0	0	0	0	0	47
2.j. Other Carnivores	71	0	0	0	0	0	0	92	163
2.k. Horses, donkeys and cross breds	13	0	0	0	0	7	570	60	650
2.l. Pigs	1 495	241	0	0	0	260	375	351	2 722
2.m. Goats	0	0	0	0	0	0	0	23	23
2.n. Sheep	132	27	0	0	0	0	1	96	256
2.o. Cattle	315	33	0	0	0	29	340	10	727
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	12	0	0	0	12
2.r. Old World Monkeys	52	11	0	0	0	0	0	0	63
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	489	0	0	0	0	0	0	150	639
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	5 689	245	15	0	0	0	1 011	878	7 838
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	5 419	77	0	0	0	0	0	0	5 496
2.y. Fish	3 146	0	0	0	8 667	0	577	170 659	183 049
2.z. TOTAL	219 653	88 521	652	73	16 173	429	4 999	175 181	505 681

**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	1 042	0	0	0	0	0	0	159	1 045	2 246
3.b. Rats	4 460	0	0	0	0	0	0	0	0	4 460
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	347	0	0	0	0	0	0	0	0	347
3.g. Cats										0
3.h. Dogs	441	0	0	0	0	0	0	0	0	441
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	12	0	0	0	0	0	0	0	0	12
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	300	0	0	0	0	0	8 367	0	8 667
3.z. TOTAL	6 302	300	0	0	0	0	0	8 526	1 045	16 173



**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	33 843	27 196	30 212	81 523	19 919	192 693
4.b. Rats	2 877	6 771	27 216	39 155	0	76 019
4.c. Guinea-Pigs	0	344	485	760	17	1 606
4.d. Hamsters	0	66	0	91	0	157
4.e. Other Rodents	0	77	0	1 192	0	1 269
4.f. Rabbits	22	373	115	900	2	1 412
4.g. Cats	0	0	52	0	145	197
4.h. Dogs	0	128	18	145	392	683
4.i. Ferrets	0	0	33	14	0	47
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	0	534	0	978	370	1 882
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	17	0	0	40	0	57
4.o. Cattle	0	10	0	0	358	368
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	1	0	56	0	57
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	80	545	625
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	30	87	0	0	117
4.y. Fish	0	0	0	1 020	1 000	2 020
4.z. TOTAL	36 759	35 530	58 218	125 954	22 748	279 209

**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					68	54	122
5.b. Rats		80					80
5.c. Guinea-Pigs					406	54	460
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits					42	6	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						15	15
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	80	0	0	516	129	725

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	842					1 404	2 246
6.b. Rats	4 460						4 460
6.c. Guinea-Pigs							
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits	347						347
6.g. Cats							
6.h. Dogs	441						441
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breeds							
6.l. Pigs							
6.m. Goats							
6.n. Sheep							
6.o. Cattle							
6.p. Prosimians							
6.q. New World Monkeys					12		
6.r. Old World Monkeys							
6.s. Apes							
6.t. Other Mammals							
6.u. Quail							
6.v. Other birds							
6.w. Reptiles							
6.x. Amphibians							
6.y. Fish	7 510					1 157	8 667
6.z. TOTAL	13 600				12	2 561	16 173

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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.			462		1 045		35	200		165			339	2 246
7.b. Rats		265	3 229				113		165	405	51		232	4 460
7.c. Guinea-Pigs														
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits			36						263		48			347
7.g. Cats														
7.h. Dogs			383				40						18	441
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breds														
7.l. Pigs														
7.m. Goats														
7.n. Sheep														
7.o. Cattle														
7.p. Prosimians														
7.q. New World Monkeys							12							
7.r. Old World Monkeys														
7.s. Apes														
7.t. Other Mammals														
7.u. Quail														
7.v. Other birds														
7.w. Reptiles														
7.x. Amphibians														
7.y. Fish									3 570		2 850	2 112	135	8 667
7.z. TOTAL	0	265	4 110	0	1 045	0	200	200	3 998	570	2 949	2 112	724	16 173

**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		265	4 110				165	200	428	446	99		589	6 302
8.b. Products/substances used or intended to be used mainly in agriculture											300			300
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											1 045			1 045
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							35		3 570	124	2 550	2 112	135	8 526
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	0	265	4 110	0	0	0	200	200	3 998	570	3 994	2 112	724	16 173

## **UNITED KINGDOM**

### **Statistical data submitted**

The United Kingdom statistical data for 2005 were prepared, quality assured and submitted by the "Home Office".

Within the United Kingdom (UK), Great Britain (GB) and Northern Ireland (NI) publish separate, annual statistical reports based largely on the number of procedures started rather than numbers of animals used. The 2005 data collection process was 100% complete.

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

### **Comments of United Kingdom authorities**

In the UK, just over 1.87 million animals were used for the first time in procedures started in 2005, a rise of 57,000 on the number reported for 2002.

1,463,565 (78%) of the animals used were mice and rats.

Cold-blooded animals (fish, amphibia, and reptiles) accounted for 203,173 animals, 11% of the animals used.

Cats, dogs, equidae and non-human primates are accorded special protection in the UK and collectively amounted to 9,104 animals, 0.5% of the animals used – a reduction of 841 compared with 2002.

Non-human primates accounted for 3,115 animals, 0.16% of animals used – 58 fewer than in 2002.

99% of the animals that must be sourced from approved breeders or suppliers originated from UK registered breeding or supplying establishments. Less than 0.5% were sourced outside of EC or Council of Europe member countries.

974,046 animals (52%) were used for fundamental biological studies, research and development relating to human medicine, dentistry and veterinary medicine.

Toxicological or other safety evaluation used 248,610 animals (13%) – a reduction of 73,323 since 2002.

There was a marked reduction in the number of animals used to satisfy national legislation specific to a single member state, with the majority of the animal use (72%) being to fulfil multinational regulatory requirements.

110,384 animals (6%) were used for the production and quality control of products and devices for human medicine, dentistry or veterinary medicine – over 45,000 fewer than in 2002.

Approximately 40% of animals used received some form of anaesthesia. For the other animals the use of anaesthesia would have been deemed to increase the severity of the procedure.

As in 2002 no animals were used to evaluate the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2005 for monoclonal antibody production using the ascites method.

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	1 052 064	1 048 052	690	40	3 282	
1.b. Rats ( <i>Rattus norvegicus</i> )	411 501	408 104	1 183	-	2 214	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	28 918	28 918	-	-	-	
1.d. Hamsters ( <i>Mesocricetus</i> )	3 746	2 219	1 256	271	-	
1.e. Other Rodents (other <i>Rodentia</i> )	8 216					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	15 523	15 063	410	2	48	2 315
1.g. Cats ( <i>Felis catus</i> )	308	205	103	-	-	175
1.h. Dogs ( <i>Canis familiaris</i> )	5 373	4 294	194	-	885	907
1.i. Ferrets ( <i>Mustela putorius furo</i> )	1 004	970	-	-	34	18
1.j. Other Carnivores (other <i>Carnivora</i> )	938					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	308					
1.l. Pigs ( <i>Sus</i> )	4 127					
1.m. Goats ( <i>Capra</i> )	274					
1.n. Sheep ( <i>Ovis</i> )	11 772					
1.o. Cattle ( <i>Bos</i> )	6 306					
1.p. Prosimians ( <i>Prosimia</i> )	-	-	-	-	-	-
1.q. New World Monkeys ( <i>Ceboidea</i> )	643	501	108	34	-	148
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	2 472	135	6	-	2 331	590
1.s. Apes ( <i>Hominoidea</i> )	-	-	-	-	-	-
1.t. Other Mammals (other <i>Mammalia</i> )	2 541					
1.u. Quail ( <i>Coturnix coturnix</i> )	140	140	-	-	-	
1.v. Other birds (other <i>Aves</i> )	114 860					
1.w. Reptiles ( <i>Reptilia</i> )	84					
1.x. Amphibians ( <i>Amphibia</i> )	10 585					
1.y. Fish ( <i>Pisces</i> )	192 504					
1.z. TOTAL	1 874 207					

**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	55 660	92 488	63 461	18 280	81 113	8 016	896	432 150	<b>1 052 064</b>
2.b. Rats	115 092	143 212	4 061	-	110 005	10	1 427	37 694	<b>411 501</b>
2.c. Guinea-Pigs	3 235	11 578	7 396	1 273	2 890	448	118	1 980	<b>28 918</b>
2.d. Hamsters	1 656	30	60	480	1 304	-	-	216	<b>3 746</b>
2.e. Other Rodents	5 266	2 794	-	-	40	-	2	114	<b>8 216</b>
2.f. Rabbits	1 488	768	338	990	8 456	1 737	32	1 714	<b>15 523</b>
2.g. Cats	237	71	-	-	-	-	-	-	<b>308</b>
2.h. Dogs	119	748	4	-	4 248	15	-	39	<b>5 373</b>
2.i. Ferrets	172	94	6	-	-	35	13	684	<b>1 004</b>
2.j. Other Carnivores	502	-	-	-	-	-	-	436	<b>938</b>
2.k. Horses, donkeys and cross breds	38	31	-	50	25	68	8	88	<b>308</b>
2.l. Pigs	2 046	445	36	716	541	-	-	343	<b>4 127</b>
2.m. Goats	233	6	-	-	3	11	-	21	<b>274</b>
2.n. Sheep	5 681	136	-	169	223	408	5	5 150	<b>11 772</b>
2.o. Cattle	4 312	523	-	718	345	9	-	399	<b>6 306</b>
2.p. Prosimians	-	-	-	-	-	-	-	-	<b>-</b>
2.q. New World Monkeys	114	86	8	-	334	16	-	85	<b>643</b>
2.r. Old World Monkeys	89	110	-	-	2 257	-	-	16	<b>2 472</b>
2.s. Apes	-	-	-	-	-	-	-	-	<b>-</b>
2.t. Other Mammals	1 937	-	-	-	15	-	-	589	<b>2 541</b>
2.u. Quail	140	-	-	-	-	-	-	-	<b>140</b>
2.v. Other birds	29 119	687	-	5 746	4 000	2 470	6	72 832	<b>114 860</b>
2.w. Reptiles	70	-	-	-	12	-	-	2	<b>84</b>
2.x. Amphibians	8 943	-	-	-	-	-	-	1 642	<b>10 585</b>
2.y. Fish	106 445	2 275	-	6 592	32 799	163	-	44 230	<b>192 504</b>

2.z. TOTAL	642 594	256 082	75 370	35 014	248 610	13 406	2 507	600624	1 874 207
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**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	49965	3335	6955	21	-	-	-	3	20834	81113
3.b. Rats	70890	18134	10621	-	-	-	-	324	10036	110005
3.c. Guinea-Pigs	2366	120	128	-	-	-	-	-	276	2890
3.d. Hamsters	721	551	16	-	-	-	-	-	16	1304
3.e. Other Rodents	-	40	-	-	-	-	-	-	-	40
3.f. Rabbits	5378	1120	1742	-	-	-	-	-	216	8456
3.g. Cats	-	-	-	-	-	-	-	-	-	-
3.h. Dogs	4012	91	3	-	-	-	-	-	142	4248
3.i. Ferrets	-	-	-	-	-	-	-	-	-	-
3.j. Other Carnivores	-	-	-	-	-	-	-	-	-	-
3.k. Horses, donkeys and cross breeds	25	-	-	-	-	-	-	-	-	25
3.l. Pigs	409	90	-	-	-	-	-	-	42	541
3.m. Goats	-	3	-	-	-	-	-	-	-	3
3.n. Sheep	213	10	-	-	-	-	-	-	-	223
3.o. Cattle	297	48	-	-	-	-	-	-	-	345
3.p. Prosimians	-	-	-	-	-	-	-	-	-	-
3.q. New World Monkeys	297	-	-	-	-	-	-	-	37	334
3.r. Old World Monkeys	1961	-	-	-	-	-	-	-	296	2257
3.s. Apes	-	-	-	-	-	-	-	-	-	-
3.t. Other Mammals	15	-	-	-	-	-	-	-	-	15
3.u. Quail	-	-	-	-	-	-	-	-	-	-
3.v. Other birds	1240	2620	-	-	-	-	-	131	9	4000
3.w. Reptiles	-	-	-	-	-	-	-	-	12	12
3.x. Amphibians	-	-	-	-	-	-	-	-	-	-
3.y. Fish	3326	6579	4398	-	-	-	-	16109	2387	32799
3.z. TOTAL	141115	32741	23863	21	-	-	-	16567	34303	248610

**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	22260	99729	86802	459327	22392	<b>690510</b>
4.b. Rats	16176	145474	5694	187929	1464	<b>356737</b>
4.c. Guinea-Pigs	975	1884	-	23963	1564	<b>28386</b>
4.d. Hamsters	-	740	76	1707	639	<b>3162</b>
4.e. Other Rodents	38	4517	85	3470	-	<b>8110</b>
4.f. Rabbits	1005	99	63	9944	1337	<b>12448</b>
4.g. Cats	-	98	-	139	71	<b>308</b>
4.h. Dogs	466	3	10	4502	280	<b>5261</b>
4.i. Ferrets	102	140	-	749	-	<b>991</b>
4.j. Other Carnivores	2	-	-	500	403	<b>905</b>
4.k. Horses, donkeys and cross breeds	-	12	-	94	192	<b>298</b>
4.l. Pigs	278	62	-	2205	1543	<b>4088</b>
4.m. Goats	31	-	-	232	8	<b>271</b>
4.n. Sheep	116	474	-	6244	4864	<b>11698</b>
4.o. Cattle	135	1788	-	2398	1914	<b>6235</b>
4.p. Prosimians	-	-	-	-	-	<b>-</b>
4.q. New World Monkeys	33	50	-	547	-	<b>630</b>
4.r. Old World Monkeys	41	76	-	2097	-	<b>2214</b>
4.s. Apes	-	-	-	-	-	<b>-</b>
4.t. Other Mammals	240	182	-	1697	15	<b>2134</b>
4.u. Quail	-	140	-	-	-	<b>140</b>
4.v. Other birds	1377	5456	-	25010	80509	<b>112352</b>
4.w. Reptiles	-	70	-	12	-	<b>82</b>
4.x. Amphibians	472	53	745	7673	-	<b>8943</b>
4.y. Fish	-	3282	-	105746	25538	<b>134566</b>
4.z. TOTAL	<b>43747</b>	<b>264329</b>	<b>93475</b>	<b>846185</b>	<b>142733</b>	<b>1390469</b>

**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	1924	6000	-	136	66574	7107	<b>81741</b>
5.b. Rats	-	1920	-	-	567	1574	<b>4061</b>
5.c. Guinea-Pigs	5711	1399	-	122	1137	300	<b>8669</b>
5.d. Hamsters	-	480	-	-	-	60	<b>540</b>
5.e. Other Rodents	-	-	-	-	-	-	-
5.f. Rabbits	116	-	-	-	1202	10	<b>1328</b>
5.g. Cats	-	-	-	-	-	-	-
5.h. Dogs	-	-	-	-	-	4	<b>4</b>
5.i. Ferrets	-	-	-	-	-	6	<b>6</b>
5.j. Other Carnivores	-	-	-	-	-	-	-
5.k. Horses, donkeys and cross breeds	-	-	-	-	50	-	<b>50</b>
5.l. Pigs	24	716	-	-	-	12	<b>752</b>
5.m. Goats	-	-	-	-	-	-	-
5.n. Sheep	-	98	-	-	71	-	<b>169</b>
5.o. Cattle	49	265	-	-	352	52	<b>718</b>
5.p. Prosimians	-	-	-	-	-	-	-
5.q. New World Monkeys	-	-	-	-	-	8	<b>8</b>
5.r. Old World Monkeys	-	-	-	-	-	-	-
5.s. Apes	-	-	-	-	-	-	-
5.t. Other Mammals	-	-	-	-	-	-	-
5.u. Quail	-	-	-	-	-	-	-
5.v. Other birds	-	68	-	-	5185	493	<b>5746</b>
5.w. Reptiles	-	-	-	-	-	-	-
5.x. Amphibians	-	-	-	-	-	-	-
5.y. Fish	-	2621	-	-	3971	-	<b>6592</b>
5.z. TOTAL	<b>7824</b>	<b>13567</b>	-	<b>258</b>	<b>79109</b>	<b>9626</b>	<b>110384</b>

**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 Hungarian requirement  
5.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

- 2) **Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	566	8683	-	1921	57004	12939	<b>81113</b>
6.b. Rats	1000	3862	-	3869	92289	8985	<b>110005</b>
6.c. Guinea-Pigs	4	165	-	256	2076	389	<b>2890</b>
6.d. Hamsters	-	-	-	-	1022	282	<b>1304</b>
6.e. Other Rodents	-	-	-	-	-	40	<b>40</b>
6.f. Rabbits	29	2114	-	539	5662	112	<b>8456</b>
6.g. Cats	-	-	-	-	-	-	-
6.h. Dogs	-	24	-	-	4051	173	<b>4248</b>
6.i. Ferrets	-	-	-	-	-	-	-
6.j. Other Carnivores	-	-	-	-	-	-	-
6.k. Horses, donkeys and cross breeds	-	-	-	-	25	-	<b>25</b>
6.l. Pigs	-	181	-	-	305	55	<b>541</b>
6.m. Goats	-	-	-	-	3	-	<b>3</b>
6.n. Sheep	-	36	-	-	181	6	<b>223</b>
6.o. Cattle	4	151	-	-	178	12	<b>345</b>
6.p. Prosimians	-	-	-	-	-	-	-
6.q. New World Monkeys	-	-	-	-	297	37	<b>334</b>
6.r. Old World Monkeys	-	-	-	-	2207	50	<b>2257</b>
6.s. Apes	-	-	-	-	-	-	-
6.t. Other Mammals	-	15	-	-	-	-	<b>15</b>
6.u. Quail	-	-	-	-	-	-	-
6.v. Other birds	50	950	-	522	2306	172	<b>4000</b>
6.w. Reptiles	12	-	-	-	-	-	<b>12</b>
6.x. Amphibians	-	-	-	-	-	-	-
6.y. Fish	3581	7148	-	1144	15110	5816	<b>32799</b>
6.z. TOTAL	<b>5246</b>	<b>23329</b>	-	<b>8251</b>	<b>182716</b>	<b>29068</b>	<b>248610</b>

**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 Hungarian requirement  
6.5 – Sweden 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, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom  
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, 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	6784	384	7497	6	2496	-	4424	7549	769	3247	-	-	47957	<b>81113</b>
7.b. Rats	3636	2309	30789	-	-	-	11778	8654	4556	5565	25216	-	17502	<b>110005</b>
7.c. Guinea-Pigs	217	-	86	12	278	-	-	-	-	-	-	-	2297	<b>2890</b>
7.d. Hamsters	-	-	482	-	-	-	-	-	-	-	-	-	822	<b>1304</b>
7.e. Other Rodents	-	-	-	-	-	-	-	-	-	-	-	-	40	<b>40</b>
7.f. Rabbits	-	12	532	1302	-	837	244	-	3141	-	123	-	2265	<b>8456</b>
7.g. Cats	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.h. Dogs	-	-	2279	-	-	-	1541	-	-	-	-	-	428	<b>4248</b>
7.i. Ferrets	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.j. Other Carnivores	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.k. Horses, donkeys and cross breds	-	-	-	-	-	-	-	-	-	-	-	-	25	<b>25</b>
7.l. Pigs	-	-	52	-	-	-	-	-	-	-	-	-	489	<b>541</b>
7.m. Goats	-	-	-	-	-	-	-	-	-	-	-	-	3	<b>3</b>
7.n. Sheep	-	-	24	-	-	-	-	-	-	-	-	-	199	<b>223</b>
7.o. Cattle	-	-	39	-	-	-	-	-	-	-	-	-	306	<b>345</b>
7.p. Prosimians	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.q. New World Monkeys	-	13	112	-	-	-	155	-	-	-	-	-	54	<b>334</b>
7.r. Old World Monkeys	-	-	1035	-	-	-	838	-	-	-	-	-	384	<b>2257</b>
7.s. Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.t. Other Mammals	-	-	-	-	-	-	-	-	-	-	-	-	15	<b>15</b>
7.u. Quail	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.v. Other birds	920	140	400	-	-	-	-	-	-	-	-	-	2540	<b>4000</b>
7.w. Reptiles	-	-	-	-	-	-	-	-	-	-	-	-	12	<b>12</b>
7.x. Amphibians	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.y. Fish	9192	7157	6963	-	-	-	752	-	-	226	710	-	7799	<b>32799</b>
7.z. TOTAL	<b>20749</b>	<b>10015</b>	<b>50290</b>	<b>1320</b>	<b>2774</b>	<b>837</b>	<b>19732</b>	<b>16203</b>	<b>8466</b>	<b>9038</b>	<b>26049</b>	-	<b>83137</b>	<b>248610</b>

**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- genicit y	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	-	383	32535	103	428	18	16045	14662	7260	5558	14797	-	49326	<b>141115</b>
8.b. Products/substances used or intended to be used mainly in agriculture	3213	2703	7461	280	365	240	2214	1377	832	839	7915	-	5302	<b>32741</b>
8.c. Products/substances used or intended to be used mainly in industry	2288	1824	7050	937	1775	579	577	60	264	1720	2357	-	4432	<b>23863</b>
8.d. Products/substances used or intended to be used mainly in the household	-	-	-	-	21	-	-	-	-	-	-	-	-	<b>21</b>
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	4268	3927	2504	-	-	-	-	-	-	226	980	-	4662	<b>16567</b>
8.i. Other toxicological or safety evaluations	10980	1178	740	-	185	-	896	104	110	695	-	-	19415	<b>34303</b>
8.j. TOTAL	<b>20749</b>	<b>10015</b>	<b>50290</b>	<b>1320</b>	<b>2774</b>	<b>837</b>	<b>19732</b>	<b>16203</b>	<b>8466</b>	<b>9038</b>	<b>26049</b>	-	<b>83137</b>	<b>248610</b>