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**COMMISSION STAFF WORKING DOCUMENT**

**DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES**

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

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

**COM(2010) 511 final**

### **Important notice**

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

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THE MEMBER STATES**

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# **SLOVENIA**

## **Statistical data submitted**

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

## **Comments of Slovenian authorities**

In the Republic of Slovenia, data on the use of animals in experiments are collected on the basis of Article 24 of the Animal Protection Act (ZZZiv-UPB2; UL RS 43/2007). Competent administrative authority for data collection is the Veterinary Administration of the Republic of Slovenia (VARŠ), a body within the Ministry of Agriculture, Forestry and Food. Organisations using animals in experiments prepare annual statistical reports in the form of tables required by the Rules on conditions for experiments on animals (UL RS 88/2006, 81/2009). These Rules are requiring data presentation on the number, species and origin of animals used in experiments, the number and species of animals used in experiments as to the purpose of use, including details on the use of animals in experiments for the human and animal disease study purposes, for manufacturing and assessing the quality of products and preparations intended for human medicine, dentistry and veterinary medicine, and toxicological testing. Data collection takes place for every calendar year in the form of eight EU tables, which have been harmonised within the EU as to form and scope. Animals actually involved in experiments within the data collection year only shall be presented in the tables. As required by the Animal Protection Act, the final statistical data on the number and species of animals used in experiments and on the types of experiments on animals have been made available to the public as information of public character ever since 2000.

As defined in the Protection of Animals Act, an experiment on an animal means a procedure on a live animal for experimental or other scientific purposes, which may cause pain, suffering, distress or lasting harm to the animal. An experiment on an animal includes other actions, which do or may lead to a birth of an animal in the circumstances as referred to above. The least painful methods of killing or the identification of animals shall not be regarded as experiments. An experiment commences, when an animal is prepared for use in an experiment for the first time, and ends at the point, where any subsequent observation is unnecessary. The use of animals shall be deemed an experiment in cases also, where anaesthetics, analgesics or other methods are used to prevent the suffering, distress or lasting harm to the animals. Before an experiment on animals may commence, the expert on animal welfare within the organisation conducting the experiment shall check whether an adequate animal species has been selected, and whether the test or method has been selected that requires the use of a minimum number of animals, animals with the lowest level of neurophysiological sensitivity, and which will cause the least pain, suffering or lasting harm, and yield satisfactory results. Scientific and research or educational procedures on organs, tissues and carcasses of animals, which had preliminarily been put to death using the required methods, shall not be defined as experiments on animals.

Experiments on animals shall be conducted by organisations only, which have been approved for conducting experiments on animals and duly authorised by VARS. Where in the search for results there are no other satisfactory scientific methods at hand, which would not require the use of animals in experiments, the use of animals shall be authorised for the following purposes: development, manufacture, and testing of quality, effectiveness and safety of medicinal products, foodstuffs and other substances or products for the purposes of avoiding, preventing, diagnosing or treating diseases, disorders and other anomalies or their effects on humans, animals or plants, and for the assessment, detection, remedy or improvement of physiological state in humans, animals and plants. Animals may further be used in experiments for the purposes of protecting the environment, in baseline research studies and, to a limited extent, for the educational and training purposes. VARS may authorise such experiments, provided that they are conducted within the higher education organisations and in accordance with the regulations governing higher education, or within the research organisations and in accordance with the regulations governing the research activities, and which are crucial for obtaining the expertise required by medical doctors in conducting surgery on humans, or by veterinary doctors in conducting surgery on animals, and provided that objectives attainable through experiments cannot be achieved through other teaching aids (videos, figures, models, preparations, etc.). Experiments for ethically inadmissible purposes, as testing of weapons, cosmetic preparations, tobacco or alcohol products, or for tests using muscle paralysing substances and conducted without anaesthesia shall be prohibited.

Where an experiment is absolutely necessary and all other requirements are complied with, VARS may grant an authorisation for conducting the particular experiment or a sequence of experiments on animals to the user organisation and to the particular experiment leader and staff involved, within a limited period of time. The Authorisation shall specify *inter alia* the purpose of use of animals and the species, number and origin of animals authorised for use in the experiment. In its reasoning, the Authorisation shall list the conditions which shall be complied with before the experiment may commence. Experiments on animals shall not be conducted in cases where there is another acceptable, feasible and scientifically satisfactory and proven method available that does not require the use of animals. Animal species, which shall be reared as laboratory animals in the approved laboratory-animal rearing establishments, and which may be used in experiments, shall include: the mouse (*Mus musculus*), rat (*Rattus norvegicus*), guinea pig (*Cavia porcellus*), golden hamster (*Mesocricetus auratus*), rabbit (*Oryctolagus cuniculus*), dog (*Canis familiaris*), cat (*Felis catus*), quail (*Coturnix coturnix*) and non-human primates. Experiments on farmed animals, dogs and cats shall be authorised in cases only, where the purpose of experiment cannot be attained through experiments on other animal species. In exceptional cases, where an experiment is absolutely necessary in order to conserve an animal species, and where the animal in question is the only appropriate one for conducting the experiment, or where such an animal cannot be raised, the authorisation for experiment may be granted by VARS even if such an animal does not come from an organised and registered rearing establishment. Experiments on abandoned animals shall be prohibited.

In 2008, the total number of animals used for experimental and other scientific purposes amounted to 12,438 animals. Most used were laboratory rodents, i.e. 96,4%, and there follow rabbits with 2,5%, birds with 1,0%, and other animals with 0,06%.

All laboratory rodents and rabbits used originate from the approved rearing establishments, where one half of approved rearing establishments are situated nationally and the other half in the other EU Member States. Most rodents were used in pharmaceutical industry within the applied research projects for the manufacture and quality control of products and devices intended for human medicine, dentistry and veterinary medicine and, to a lesser extent, within their research and development for the assessment of toxicity. Less rodents were used in biological studies of a fundamental nature. Only a minor number of laboratory rodents and rabbits were used for other purposes, such as educational purposes, other non-defined purposes of use, and for diagnosing diseases. Rabbits were the more frequently used animals in sequences of experiments within the scope of experiments required for the assessment of quality of products intended for human medicine, dentistry and veterinary medicine. As regards farmed animals, three pigs originating from an agricultural holding were used in experiments, based on a preliminary consensus obtained from the animal keeper/breeder, for the educational purposes and training of surgeons in human medicine.

In the Republic of Slovenia, the mean of animals used in experiments in the recent 5 years amounts to around 12,700 animals. Most used are laboratory rodents with around 95%. In the past 2 years, no cats or dogs were used in experiments. Non-human primates are not used in experiments in the Republic of Slovenia. On adoption of relevant legislation and taking into account the 3R principles, and conducting official controls, the use of animals in experiments has decreased. Following the specific training of staff involved in experiments on animals, the responsibility of researchers has increased, and their attitude towards animals used in experiments improved, which is reflected in the accurate experiment protocols, careful selection of methods and subsequent consistent implementation of experiments. The use of validated alternative methods and/or cell cultures and tissues has played an important part in decreasing the number of animals used in experiments particularly in pharmaceutical industry.

**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> )	10313	4974	5339			
1.b. Rats ( <i>Rattus norvegicus</i> )	1675	1142	533			
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	7	7				
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )	0					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	307	29	278			278
1.g. Cats ( <i>Felis catus</i> )	0					
1.h. Dogs ( <i>Canis familiaris</i> )	0					
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0					
1.j. Other Carnivores (other <i>Carnivora</i> )	0					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	0					
1.l. Pigs ( <i>Sus</i> )	3					
1.m. Goats ( <i>Capra</i> )	0					
1.n. Sheep ( <i>Ovis</i> )	4					
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>Hominioidea</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> )	129					
1.w. Reptiles ( <i>Reptilia</i> )	0					
1.x. Amphibians ( <i>Amphibia</i> )	0					
1.y. Fish ( <i>Pisces</i> )	0					
1.z. TOTAL	12438					

**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	763	3009	5742	285	446	2	36	30	10313
2.b. Rats	542	173	434		512		14		1675
2.c. Guinea-Pigs	7								7
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits			292		3		12		307
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							3		3
2.m. Goats									0
2.n. Sheep	4								4
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds	3			126					129
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	1319	3182	6468	411	961	2	65	30	12438

**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	50								396	446
3.b. Rats	512									512
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	3									3
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	565	0	0	0	0	0	0	0	396	961

**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		20	2764	268	366	3418
4.b. Rats		199	3	197	102	501
4.c. Guinea-Pigs				7		7
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	219	2767	472	468	3926

**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		6027					6027
5.b. Rats		434					434
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		292					292
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						126	126
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	6753	0	0	0	126	6879

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

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

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	314				50	82	446
6.b. Rats		512					512
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits						3	3
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	314	512	0	0	50	85	961

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

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

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

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		364											82	446
7.b. Rats	250						260			2				512
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				3										3
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	250	364	0	3	0	0	260	0	0	2	0	0	82	961

**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	250	50		3			260			2				565
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		314											82	396
8.j. TOTAL	250	364	0	3	0	0	260	0	0	2	0	0	82	961

## **SLOVAKIA**

### **Statistical data submitted**

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

### **Comments of Slovakian authorities**

The State Veterinary and Food Administration of the Slovak Republic (hereinafter “SVFA SR”) is a competent authority in the Slovak Republic in the area of protection of animals used for experimental purposes. The SVFA SR approves in compliance with Article 6(2) letter i), (3) and (4) of the Act No. 39/2007 Coll. on Veterinary Care and on Amendment to Some Laws as later amended (Act No. 299/2009 Coll.), (hereinafter „Act No. 39/2007 Coll.“) and in compliance with Articles 8, 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 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 39 of the Act No. 39/2007 Coll.

The SVFA SR is comprised of 8 Regional Veterinary and Food Administrations (hereinafter RVFA) and 40 District Veterinary and Food Administrations (hereinafter DVFA). All the employees of the veterinary administration in the field of animal welfare are veterinarians.

All kinds of establishments are approved by the SVFA SR based on results on assessment of the suitability of establishment in accordance with requirements of the Ordinance of the Government of Slovak Republic No. 289/2003 Coll. Animal welfare inspectors shall be obliged, in compliance with Articles 6, 7 and 8 of the Act 39/2007 Coll. to perform non-discriminatory controls of all approved establishments. The SVFA SR, as a competent authority, trained both theoretically and practically all the animal welfare inspectors (RVFA, DVFA) for the performance of the control. Controls are performed according to methodical instructions and checklists 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 39/2007 Coll.

Based on applicant's applications in the year 2008, the SVFA SR approved totally 3 new experimental establishments, from that 1 breeding establishment for breeding of experimental animals and 2 establishments for carrying out projects. 3 establishments were subjects of control due to increased number of animals in single-use capacity and another 3 establishments were subjects of control due to use of a new species of an experimental animal.

Total number of establishments in the Slovak Republic in the year 2008

Kind of establishment	Number
Experimental establishment	46
Experimental establishment with breeding of animals for own use	20
Breeding establishment	8
Supplying establishment	1
<b>Total:</b>	<b>75</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 founded 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 observance of 3R, existence of alternative method contrary to presented project, 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 and administrative proceeding may be approved, refused, suspended or stopped. 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 their opinion – to the submitted application for approval of the experiment – with observance of rules of personal data protection and protection of trade secret data or intellectual property.

**Table No. 1:** Most of experimental animals originate in domestic breeding establishments or in experimental establishments with breeding of animals for use within that establishment. As far as foreign suppliers are concerned, the animals originate mainly from the EU Member States (Czech Republic, Hungary, Germany, Poland and France) as well as from countries are signatories to ETS 123. The number of 25 fish marked in column 1.6 as "animals coming from other origins" was entered incorrectly – these fish originate from the Slovak republic. We do apologise incorrect information being provided.

**Table No. 2:** The SVFA SR approved **273** experiments with use of experimental animals; stopped the proceeding in 4 applications; refused 5 applications for approval of the experiment and suspended the proceeding in 36 applications in the year 2008. The total number of 19,260 animals used does not reflect the number of approved experiments in the year 2008, because within the total of the number of animals used are included also the animals which were used in the year 2008 from the experiments approved in the year 2005, 2006, 2007 and 2008. Number of animals used in preparatory studies for performed projects is listed in the column 2.8. Animals were used for introduction of new surgical methods practised during projects. Some preparatory studies were approved as individual projects. Numbers of animals used for training of persons involved in projects were approved as pre-experiment within the project in some cases.

**Table No. 3:** Most animals indicated in the column 3.2 were used for evaluation of products and substances for human medicine (testing of new drugs, medical supplies, surgical supplies – collagen surgical implants). In the column 3.3 the animals were used for control of products/substances used in agriculture – mainly pesticide, herbicide, rodenticide products, growth stimulators for plants and biocide substances. In the column 3.4 the animals used for control of various chemical products/substances being a part of oils, lubricants and rubber industry materials are indicated. The orders for re-test of the same substance produced in various batches were done in several establishments. In some cases, whole series of standard toxicological safety tests were carried out with the same substance, depending on EU legislation (REACH).

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

**Table No. 5:** In the Slovak Republic the experiments on 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 5.3 while 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 pharmacopoeia methods or as a new individual method.

**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 conformable to OECD methods. In the column 6.3 the number of animals used in compliance with the European Pharmacopoeia are indicated, in the column 6.7 a total of 4 rabbits and 70 mice were used in product quality testing: testing of efficiency on and harm to animals. These projects are usually carried out mainly according to European Pharmacopoeia 4 and Slovak Pharmacopoeia but this single project was performed in accordance with obligatory safety control test described in producer's documentation.

**Table No. 7:** In the column 7.2.1. the animals were used only in the 'limit test'. Tests were performed mainly by OECD methods TG 402 and 403 while in the column 7.2.2. the OECD tests TG 423, B.1 tris were performed. In the column 7.2.3 mainly tests in compliance with OECD TG 407, 420 and tolerance studies were performed; in the column 7.12 were animals used in studies for determination of minimal lethal and maximal non-lethal dose of certain substance (food additive); determination of MDT minimal comparative dose of certain substances; harvesting of hepatic S9 fraction for testing of metabolic activation in vitro genotoxicity.

In compliance with Article 17 paragraph 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 its authorisation, to submit yearly by the end of January for the previous year to the SVFA SR a notification on the number of animals used according to the specimen laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Approved establishments shall be obliged to keep records about the number of GMO animals used in procedures. Based on collected data the SVFA SR shall work out on an annual basis a notification concerning 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.

The purpose of inspections in approved establishments is to control the observance of requirements indicated in the Act No. 39/2007 Coll., in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and the compliance of the performed project in approved establishment with the project authorisation issued by SVFA SR. Finding of infringements laid down in the Act No. 39/2007 Coll. 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 the Act No. 39/2007 Coll.

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

The competent authority performs consulting services for the public in the field of animal welfare, organizes trainings for employees of approved establishments the purpose of which is interpretation of the valid legislation of the Slovak Republic in the field of animal welfare. The SVFA SR organizes also seminars and lectures aimed at protection of experimental animals used for experimental purposes. The owner, keeper and dealer of an animal – in compliance with the Article 37 of the Act. No. 39/2007 Coll. – shall be obliged to educate demonstrably the persons handling the animals so that such persons must avoid any acts that might cause injury or any other damage to the health of animals or unnecessary suffering thereof.

**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> )	6942	5229	1713			
1.b. Rats ( <i>Rattus norvegicus</i> )	9692	6767	2789	136		
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	982	536	446			
1.d. Hamsters ( <i>Mesocricetus</i> )	0					
1.e. Other Rodents (other <i>Rodentia</i> )	45	45				
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	679	646	33			
1.g. Cats ( <i>Felis catus</i> )	18		18			
1.h. Dogs ( <i>Canis familiaris</i> )	4		4			
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> )	22	22				1
1.m. Goats ( <i>Capra</i> )	5	5				
1.n. Sheep ( <i>Ovis</i> )	9	9				
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> )	21	21				
1.u. Quail ( <i>Coturnix coturnix</i> )	120	120				
1.v. Other birds (other <i>Aves</i> )	696	438	258			
1.w. Reptiles ( <i>Reptilia</i> )						
1.x. Amphibians ( <i>Amphibia</i> )						
1.y. Fish ( <i>Pisces</i> )	25				25	
1.z. TOTAL	19260					

**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	1199	2007		280	610	2716	80	50	6942
2.b. Rats	4284	2734	60		1371		25	1218	9692
2.c. Guinea-Pigs	176	344			421			41	982
2.d. Hamsters									0
2.e. Other Rodents	45								45
2.f. Rabbits	478	60	66	16	24			35	679
2.g. Cats	18								18
2.h. Dogs					4				4
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs	12	10							22
2.m. Goats								5	5
2.n. Sheep	9								9
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	21								21
2.u. Quail	120								120
2.v. Other birds	208			333	155				696
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish					25				25
2.z. TOTAL	6570	5155	126	629	2610	2716	105	1349	19260

**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	507	103								610
3.b. Rats	40	50	941			155	100	85		1371
3.c. Guinea-Pigs	15	406								421
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	12	12								24
3.g. Cats										0
3.h. Dogs	4									4
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	155									155
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish									25	25
3.z. TOTAL	733	571	941	0	0	155	100	85	25	2610

**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		115	1439	2411	1957	5922
4.b. Rats	2426	1822	584	2149	37	7018
4.c. Guinea-Pigs				520		520
4.d. Hamsters						0
4.e. Other Rodents		25			20	45
4.f. Rabbits		12		511	15	538
4.g. Cats				18		18
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs					22	22
4.m. Goats						0
4.n. Sheep				9		9
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				21		21
4.u. Quail				120		120
4.v. Other birds				88	120	208
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	2426	1974	2023	5847	2171	14441

**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		200				80	280
5.b. Rats	60						60
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	10					72	82
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	258	60				15	333
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	328	260	0	0	0	167	755

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

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

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

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

**Regulatory requirements versus species**

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		540				70	610
6.b. Rats	412	959					1371
6.c. Guinea-Pigs		421					421
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	12	8				4	24
6.g. Cats							0
6.h. Dogs		4					4
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		155					155
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	25						25
6.z. TOTAL	449	2087	0	0	0	74	2610

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

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

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

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	21		220		35					334				610
7.b. Rats		144	287				560		85	15			280	1371
7.c. Guinea-Pigs			15		406									421
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits			4	6		14								24
7.g. Cats														0
7.h. Dogs													4	4
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds			90			65								155
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish			25											25
7.z. TOTAL	21	169	616	6	441	79	560	0	85	349	0	0	284	2610

**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	21		329			73	40			266			4	733
8.b. Products/substances used or intended to be used mainly in agriculture		50			441					68			12	571
8.c. Products/substances used or intended to be used mainly in industry		54	157	6		6	450						268	941
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		40	30				70			15				155
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption			100											100
8.h. Potential or actual contaminants in the general environment which do not appear in other columns									85					85
8.i. Other toxicological or safety evaluations		25												25
8.j. TOTAL	21	169	616	6	441	79	560	0	85	349	0	0	284	2610

# FINLAND

## Statistical data submitted

The data were submitted by the Ministry of Agriculture and Forestry

## Comments of Finnish authorities

The years 2006-2008 have been a transition period after the new Act and Decree on Animal Experimentation for Finland (2006) came into force, and the national Animal Experiment Board took over the responsibility of granting authorisation for all the experiments with vertebrate animals in Finland. The number of animals used yearly in experiments has been reduced throughout these 3 years, partly due to change in authorisation practices.

In 2008 a total of 138,600 experimental animals were used in Finland, which is 17% less than in 2007. Of all experimental animals used 78% were rodents, and 74% mice (about 78,500 animals used) and rats (26,000, respectively). Fish accounted for about 21,000 animals, and birds other than quails about 5,500 animals. The use of other species was at the level 30 – 850 animals.

There was a decrease in the number of mice used in experiments in 2008 (-22%) in comparison to the previous year. Also use of rats was slightly decreased (-9%). The change was, however, at least partly due to change in authorisation practices.

When compared to year 2005, the total number of animals used was dropped from 256,826 (163,606 without fish) to 138,600 (117,522 without fish), which is 46% reduction (28% without fish). Here also, the reduction is mainly due to the change in authorisation practices.

As in previous years, a major part of the animals (77%) was used for biological studies of a fundamental nature (2005: 87%, 2007: 82%). Animal use in 2008 for human and veterinary medicine research and quality control was 20% (2005: 9,3%, 2007: 15%), for toxicological and other safety evaluations 1,1 % (2005: 0,9, 2007: 1,2 %), for diagnosis of disease 0,1 % (2005: 0,2%, 2007: 0,24%), for education and training 1,0 % (2005: 1,8%, 2007: 0,89%) and other uses 1,00 % (2005: 0,9%, 2007: 0,48%) of the total number of experimental animals used.

The national Animal Experiment Board evaluated and was responsible for granting authorisation for all the experiments with vertebrate animals in Finland. The Board works on two levels: the local level in the form of four local subcommittees having the authority to grant an experiment when unanimous. In case of disagreement the decision is taken by the full national Board. In 2008 a total of 362 authorisations were granted by the Board: 287 for new experiment and 75 for changes in ongoing experiment.

In 2008 the Ministry of Agriculture and Forestry provided 40,000€ to the Finnish research community for studies to replace existing techniques using experimental animals with alternative methods.

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

**Origin versus species**

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice ( <i>Mus musculus</i> )	78446	56285	18160	2464	1537	
1.b. Rats ( <i>Rattus norvegicus</i> )	26058	7989	16756	25	1288	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	215	4	211			
1.d. Hamsters ( <i>Mesocricetus</i> )	302		302			
1.e. Other Rodents (other <i>Rodentia</i> )	3142					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	814	250	564			32
1.g. Cats ( <i>Felis catus</i> )						
1.h. Dogs ( <i>Canis familiaris</i> )	54		54			
1.i. Ferrets ( <i>Mustela putorius furo</i> )						
1.j. Other Carnivores (other <i>Carnivora</i> )	761					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	37	37				
1.l. Pigs ( <i>Sus</i> )	819					
1.m. Goats ( <i>Capra</i> )						
1.n. Sheep ( <i>Ovis</i> )	571					
1.o. Cattle ( <i>Bos</i> )	300					
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>Hominioidea</i> )						
1.t. Other Mammals (other <i>Mammalia</i> )	84					
1.u. Quail ( <i>Coturnix coturnix</i> )						
1.v. Other birds (other <i>Aves</i> )	5568					
1.w. Reptiles ( <i>Reptilia</i> )	317					
1.x. Amphibians ( <i>Amphibia</i> )	34					
1.y. Fish ( <i>Pisces</i> )	21078					
1.z. TOTAL	138600					

**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	66628	11186	30		20	89	426	67	78446
2.b. Rats	12548	12317			608	34	382	169	26058
2.c. Guinea-Pigs	16	195						4	215
2.d. Hamsters	24	278							302
2.e. Other Rodents	3072	70							3142
2.f. Rabbits	518	248			12	10	10	16	814
2.g. Cats									0
2.h. Dogs		8			43			3	54
2.i. Ferrets									0
2.j. Other Carnivores	761								761
2.k. Horses, donkeys and cross breds	33			3			1		37
2.l. Pigs	267	149	318				39	46	819
2.m. Goats									0
2.n. Sheep	18	29	520					4	571
2.o. Cattle	19	10					203	68	300
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	84								84
2.u. Quail									0
2.v. Other birds	4779			265			54	470	5568
2.w. Reptiles	317								317
2.x. Amphibians	7						27		34
2.y. Fish	17344			2215	798		185	536	21078
2.z. TOTAL	106435	24490	868	2483	1481	133	1327	1383	138600

**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	20									20
3.b. Rats	608									608
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	12									12
3.g. Cats										0
3.h. Dogs	43									43
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									798	798
3.z. TOTAL	683	0	0	0	0	0	0	0	798	1481

**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	2935	12967	5328	8799		30029
4.b. Rats	3842	6958	1009	4938	1	16748
4.c. Guinea-Pigs	184	9				193
4.d. Hamsters	227	51				278
4.e. Other Rodents		70	24			94
4.f. Rabbits	463		41	201		705
4.g. Cats						0
4.h. Dogs					8	8
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	305			52		357
4.m. Goats						0
4.n. Sheep	18			11		29
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					647	647
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					2715	2715
4.z. TOTAL	7974	20055	6402	14001	3371	51803

**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	30						30
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						3	3
5.l. Pigs	318						318
5.m. Goats							0
5.n. Sheep	520						520
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				265			265
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish						2215	2215
5.z. TOTAL	868	0	0	265	0	2218	3351

**Examples:**

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

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

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

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	20						20
6.b. Rats	608						608
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	12						12
6.g. Cats							0
6.h. Dogs	43						43
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						798	798
6.z. TOTAL	683	0	0	0	0	798	1481

**Examples:**

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

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

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

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice							20							20
7.b. Rats	19						304						285	608
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													12	12
7.g. Cats														0
7.h. Dogs							43							43
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											798			798
7.z. TOTAL	19	0	0	0	0	0	367	0	0	0	798	0	297	1481

**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	19						367						297	683
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											798			798
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	19	0	0	0	0	0	367	0	0	0	798	0	297	1481

## SWEDEN

### Statistical data submitted

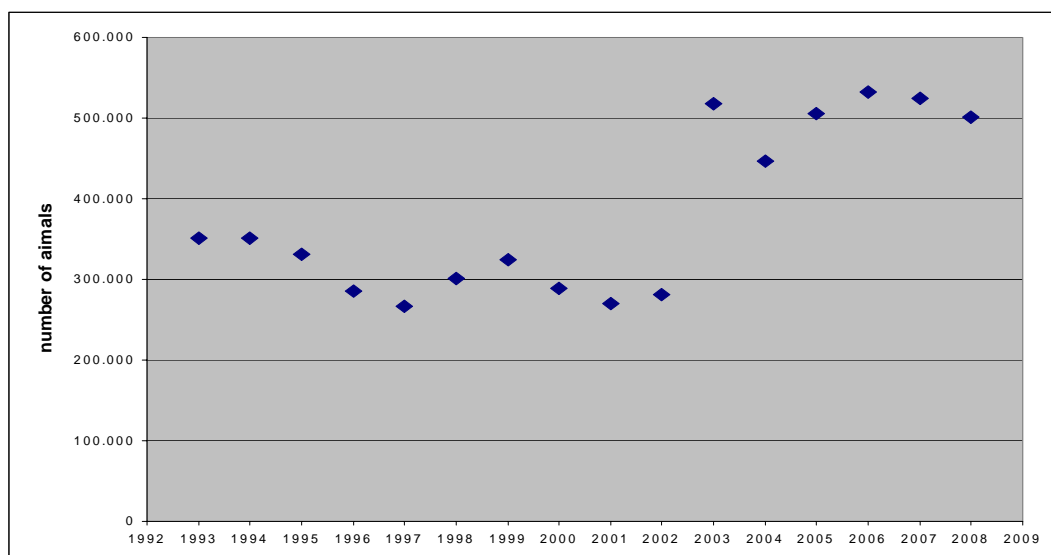
The statistical data have been submitted by the National Board for Laboratory Animals.

### Comments of Swedish authorities

The Swedish Board of Agriculture hereby submits comments on the statistical data regarding the use of laboratory animals in Sweden for 2008.

According to the EU definition (directive 86/609/EEC), the number of laboratory animals used during 2008 in Sweden was 501,499 including reused animals and 484,604 excluding reused animals. This is a small decrease compared to the 505,600 animals reported for 2005 and reflects well the minor fluctuation in the number of laboratory animals used in Sweden that has been seen during the last 5 years.

From 1990 until 2002, the mean number of laboratory animals used in Sweden was about 315,000 with the highest number 1994 (approximately 351,000) and the lowest 1997 (approximately 267,000). From 2003-2008, however, there has been an increase in the number of animals used due to the fact that tagging of fish for assessment studies have been included. During 2008, the number of fish used for this purpose was 200,243. Apart from fish, mice and rats are the animals predominately used in animal experimentation in Sweden. During the last 10 years the trend has been an increase in the use of mice whereas the use of rats, rabbits and guinea pigs has decreased. The increased use of mice as laboratory animals is most probably due to the increased use of transgenic technique(s).



### **Specific use of animals**

As in previous years, most laboratory animals used during 2008 were used for fundamental biological research. The large proportion of animals used for other purposes can be explained by the tagging of fish in assessment studies.

Only 2% of the animals were used in toxicological research, and the most common animals used in toxicological research were rats, mice and fish.

### **Swedish definition**

According to Swedish legislation, all use of animals with a scientific purpose is defined as animal experimentation. Sweden therefore also collects statistical data on for example animals used in behaviour studies, feeding trials and animals being killed for the use of their tissues and organs. During 2008, 528,663 animals were reported being used for these purposes. In addition, Sweden also keeps statistical records on fish used in assessment studies, caught by trawling, netting etc. During 2008 the number of fish in this category was approximately 6,806,700.

**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> )	203112	197709	2763		2640	
1.b. Rats ( <i>Rattus norvegicus</i> )	53141	25727	27348		66	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	1766	1766				
1.d. Hamsters ( <i>Mesocricetus</i> )	864		864			
1.e. Other Rodents (other <i>Rodentia</i> )	2033					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	1332	1332				13
1.g. Cats ( <i>Felis catus</i> )	149		21	7	121	
1.h. Dogs ( <i>Canis familiaris</i> )	1982	450	36	47	1449	222
1.i. Ferrets ( <i>Mustela putorius furo</i> )	39	39				0
1.j. Other Carnivores (other <i>Carnivora</i> )	53					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	423					
1.l. Pigs ( <i>Sus</i> )	1973					
1.m. Goats ( <i>Capra</i> )	5					
1.n. Sheep ( <i>Ovis</i> )	152					
1.o. Cattle ( <i>Bos</i> )	1379					
1.p. Prosimians ( <i>Prosimia</i> )	0					
1.q. New World Monkeys ( <i>Ceboidea</i> )	0					
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	35				35	11
1.s. Apes ( <i>Hominioidea</i> )	0					
1.t. Other Mammals (other <i>Mammalia</i> )	263					
1.u. Quail ( <i>Coturnix coturnix</i> )	201	201				
1.v. Other birds (other <i>Aves</i> )	3432					
1.w. Reptiles ( <i>Reptilia</i> )	170					
1.x. Amphibians ( <i>Amphibia</i> )	641					
1.y. Fish ( <i>Pisces</i> )	211459					
1.z. TOTAL	484604					

**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	127301	64066	140	516	2305	1685	689	6410	203112
2.b. Rats	22531	24299	0	10	5225	70	486	520	53141
2.c. Guinea-Pigs	276	1455	12	14	0	0	5	4	1766
2.d. Hamsters	6	661	0	0	135	0	62	0	864
2.e. Other Rodents	2033	0	0	0	0	0	0	0	2033
2.f. Rabbits	309	401	11	1	371	0	16	223	1332
2.g. Cats	32	0	0	0	0	105	0	12	149
2.h. Dogs	548	175	0	0	546	701	12	0	1982
2.i. Ferrets	39	0	0	0	0	0	0	0	39
2.j. Other Carnivores	0	0	0	0	0	0	0	53	53
2.k. Horses, donkeys and cross breeds	253	0	0	8	0	0	162	0	423
2.l. Pigs	951	265	0	0	0	0	757	0	1973
2.m. Goats	0	0	0	0	0	0	0	5	5
2.n. Sheep	19	40	0	12	0	0	53	28	152
2.o. Cattle	135	856	0	3	0	0	276	109	1379
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys	0	35	0	0	0	0	0	0	35
2.s. Apes									0
2.t. Other Mammals	208	0	0	0	0	0	0	55	263
2.u. Quail	151	0	0	0	0	0	0	50	201
2.v. Other birds	401	45	60	43	0	146	0	2737	3432
2.w. Reptiles	170	0	0	0	0	0	0	0	170
2.x. Amphibians	641	0	0	0	0	0	0	0	641
2.y. Fish	6852	1671	0	0	1370	0	42	201524	211459
2.z. TOTAL	162856	93969	223	607	9952	2707	2560	211730	484604

**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	636			1620				49		2305
3.b. Rats	5225									5225
3.c. Guinea-Pigs										0
3.d. Hamsters	135									135
3.e. Other Rodents										0
3.f. Rabbits	371									371
3.g. Cats										0
3.h. Dogs	546									546
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		250						1060	60	1370
3.z. TOTAL	6913	250	0	1620	0	0	0	1109	60	9952

**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	30075	33514	29932	89604	1627	184752
4.b. Rats	4439	20559	1365	17804	28	44195
4.c. Guinea-Pigs	88	1070	0	583	16	1757
4.d. Hamsters	636	0	0	31	0	667
4.e. Other Rodents	57	0	0	10	1966	2033
4.f. Rabbits	201	99	9	412	1	722
4.g. Cats	0	16	0	0	107	123
4.h. Dogs	90	12	0	73	1221	1396
4.i. Ferrets	0	39	0	0	0	39
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds	0	0	0	0	69	69
4.l. Pigs	467	65	0	430	145	1107
4.m. Goats						0
4.n. Sheep	40	0	0	17	14	71
4.o. Cattle	1	0	0	0	859	860
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys	0	6	6	23	0	35
4.s. Apes						0
4.t. Other Mammals	0	0	0	0	208	208
4.u. Quail	0	0	0	0	151	151
4.v. Other birds	2	0	45	218	203	468
4.w. Reptiles						0
4.x. Amphibians	15	36	0	590	0	641
4.y. Fish	0	0	0	0	1676	1676
4.z. TOTAL	36111	55416	31357	109795	8291	240970

**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					140	516	656
5.b. Rats						10	10
5.c. Guinea-Pigs						26	26
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits						12	12
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds						8	8
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep						12	12
5.o. Cattle						3	3
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						103	103
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	140	690	830

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

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

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

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

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	1620				636	49	2305
6.b. Rats					5225		5225
6.c. Guinea-Pigs							0
6.d. Hamsters						135	135
6.e. Other Rodents							0
6.f. Rabbits						371	371
6.g. Cats							0
6.h. Dogs					546		546
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	870					500	1370
6.z. TOTAL	2490	0	0	0	6407	1055	9952

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

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

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

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a.		1620								170			515	2305
7.b. Rats			2399						132	655	206		1833	5225
7.c. Guinea-Pigs														0
7.d. Hamsters			135											135
7.e. Other Rodents														0
7.f. Rabbits			34						337					371
7.g. Cats														0
7.h. Dogs			486										60	546
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											1180	190		1370
7.z. TOTAL	0	1620	3054	0	0	0	0	0	469	825	1386	190	2408	9952

**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			3054						469	825	206		2359	6913
8.b. Products/substances used or intended to be used mainly in agriculture											250			250
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		1620												1620
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											870	190	49	1109
8.i. Other toxicological or safety evaluations											60			60
8.j. TOTAL	0	1620	3054	0	0	0	0	0	469	825	1386	190	2408	9952

## **UNITED KINGDOM**

### **Statistical data submitted**

The United Kingdom statistical data for 2008 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.

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

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

In the UK, just over 2.26 million animals were used for the first time in procedures started in 2008, a rise of 393,000 (+21%) on the number reported for 2005. The increase was largely accounted for by increases in numbers of fish (+292,000) and mice (+160,000) along with a fall in the use of rats (-68,000).

2,039,577 (90%) of the animals used were mice (53%), rats (15%) or fish (21%).

Cold-blooded animals (fish, amphibia, and reptiles) accounted for 507,470 (22%) of the animals used.

Cats, dogs, equidae and non-human primates are accorded special protection in the UK and collectively amounted to 8,105 animals, 0,4% of the animals used – a reduction of 999 compared with 2005.

Non-human primates accounted for 3,354 animals, 0,15% of animals used, very slightly less as a percentage but 239 more as an absolute number than in 2005. (although there was a fall in the numbers of new world monkeys used, there was a larger rise in the number of old world monkeys used)

1,172,936, animals (52%) were used for fundamental biological studies, research and development and production and quality control relating to human medicine, dentistry and veterinary medicine.

Toxicological or other safety evaluation used 284,888 animals (13%) – an increase of 36,278 since 2005.

There was a marked increase in the number of toxicology and other safety evaluation experiments carried out in 2008 not to satisfy any regulatory requirements (94,185),

up 65,117 compared with 2005 (29,068) in 2005, largely due to an increases in such use of fish (+80,098).

176,362 animals (8%) were used for the production and quality control of products and devices for human medicine, dentistry or veterinary medicine – almost 66,000 more than in 2005. This increase was accounted for almost entirely by an increase in the number of mice (+48,000) and fish (+17,000).

Approximately 40% of animals used received some form of anaesthesia, hardly changed from 2005. For the other animals the use of anaesthesia would have been deemed to increase the severity of the procedure.

As in 2005 no animals were used in 2008 to evaluate the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2008 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> )	1212243	1.206.713	1.809	173	3.548	
1.b. Rats ( <i>Rattus norvegicus</i> )	343289	341.897	785	105	502	
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	29250	28.762	488	0	0	
1.d. Hamsters ( <i>Mesocricetus</i> )	2851	1.247	1.604	0	0	
1.e. Other Rodents (other <i>Rodentia</i> )	1.958					
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	12009	9.297	2.140	0	572	3.066
1.g. Cats ( <i>Felis catus</i> )	184	79	52	0	53	147
1.h. Dogs ( <i>Canis familiaris</i> )	4277	3.458	58	0	761	896
1.i. Ferrets ( <i>Mustela putorius furo</i> )	978	973	0	0	5	44
1.j. Other Carnivores (other <i>Carnivora</i> )	948					
1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> )	290					
1.l. Pigs ( <i>Sus</i> )	7.255					
1.m. Goats ( <i>Capra</i> )	487					
1.n. Sheep ( <i>Ovis</i> )	9.818					
1.o. Cattle ( <i>Bos</i> )	4.194					
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	262	262	0	0	0	82
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	3092	1.814	96	0	1.182	497
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	952					
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0	0	0	0	
1.v. Other birds (other <i>Aves</i> )	125.077					
1.w. Reptiles ( <i>Reptilia</i> )	109					
1.x. Amphibians ( <i>Amphibia</i> )	23.316					
1.y. Fish ( <i>Pisces</i> )	484.045					
1.z. TOTAL	2266884					

**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	374.109	88.038	115.790	13.721	56.951	13.683	829	549.122	1212243
2.b. Rats	92.466	115.862	7.135	0	100.777	419	1.386	25.244	343289
2.c. Guinea-Pigs	1.753	17.474	4.784	492	1.911	168	115	2.553	29250
2.d. Hamsters	828	31	0	576	873	0	0	543	2851
2.e. Other Rodents	931	512	30	0	191	0	0	294	1958
2.f. Rabbits	996	611	427	230	7.431	1.018	12	1.284	12009
2.g. Cats	61	41	0	0	53	0	0	29	184
2.h. Dogs	4	381	139	0	3.662	11	0	80	4277
2.i. Ferrets	319	6	556	6	0	41	12	38	978
2.j. Other Carnivores	507	0	0	27	296	0	0	118	948
2.k. Horses, donkeys and cross breds	54	44	0	21	22	19	0	130	290
2.l. Pigs	1.652	403	24	948	728	0	0	3.500	7255
2.m. Goats	65	0	1	4	10	12	0	395	487
2.n. Sheep	5.120	52	491	253	100	985	0	2.817	9818
2.o. Cattle	2.808	152	0	804	195	4	0	231	4194
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	82	4	33	0	123	0	0	20	262
2.r. Old World Monkeys	122	181	12	0	2.733	0	0	44	3092
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	825	0	0	0	0	0	0	127	952
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	22.221	201	16	6.472	1.783	2.168	154	92.062	125077
2.w. Reptiles	30	0	0	0	0	0	0	79	109
2.x. Amphibians	8.993	0	0	0	0	0	0	14.323	23316
2.y. Fish	230.664	54.477	20.418	2.952	107.049	0	117	68.368	484045
2.z. TOTAL	744610	278470	149856	26506	284888	18528	2625	761401	2266884

**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	38.288	1.803	5.351	132	0	0	0	78	11.299	56951
3.b. Rats	73.139	11.131	10.533	0	0	0	0	5	5.969	100777
3.c. Guinea-Pigs	1.822	0	0	0	0	0	0	0	89	1911
3.d. Hamsters	873	0	0	0	0	0	0	0	0	873
3.e. Other Rodents	0	164	0	0	0	0	0	0	27	191
3.f. Rabbits	5.658	330	1.241	0	0	0	0	0	202	7431
3.g. Cats	53	0	0	0	0	0	0	0	0	53
3.h. Dogs	3.323	116	8	0	0	0	0	0	215	3662
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	296	0	0	0	0	0	0	0	0	296
3.k. Horses, donkeys and cross breeds	22	0	0	0	0	0	0	0	0	22
3.l. Pigs	600	62	0	0	0	0	0	0	66	728
3.m. Goats	0	10	0	0	0	0	0	0	0	10
3.n. Sheep	99	0	0	0	0	0	0	0	1	100
3.o. Cattle	195	0	0	0	0	0	0	0	0	195
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	53	0	0	0	0	0	0	0	70	123
3.r. Old World Monkeys	2.358	0	0	0	0	0	0	0	375	2733
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	706	1.041	30	0	0	0	0	0	6	1783
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	62.571	2.464	6.349	0	0	0	0	10.146	25.519	107049
3.z. TOTAL	190056	17121	23512	132	0	0	0	10229	43838	284888

**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	25.167	85.363	101.726	500.412	17.182	729850
4.b. Rats	16.152	95.146	2.713	189.881	75	303967
4.c. Guinea-Pigs	675	707	0	26.420	1.333	29135
4.d. Hamsters	67	762	0	1.438	584	2851
4.e. Other Rodents	162	766	155	625	27	1735
4.f. Rabbits	656	216	0	8.292	1.201	10365
4.g. Cats	10	43	0	8	123	184
4.h. Dogs	254	0	2	3.613	91	3960
4.i. Ferrets	20	125	0	815	6	966
4.j. Other Carnivores	45	0	0	462	326	833
4.k. Horses, donkeys and cross breeds	3	0	0	74	213	290
4.l. Pigs	161	143	0	2.523	4.289	7116
4.m. Goats	0	0	0	78	399	477
4.n. Sheep	77	455	0	6.608	2.342	9482
4.o. Cattle	226	15	0	2.571	1.379	4191
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	2	46	0	214	0	262
4.r. Old World Monkeys	75	158	0	2.519	0	2752
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	10	5	0	810	0	825
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	4.573	2.595	0	17.237	98.894	123299
4.w. Reptiles	0	30	0	0	0	30
4.x. Amphibians	96	33	351	8.513	0	8993
4.y. Fish	119	47.743	3	351.819	8.674	408358
4.z. TOTAL	48550	234351	104950	1124932	137138	1649921

**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	218	6161	0	158	116191	6783	129511
5.b. Rats	0	1440	0	0	5288	407	7135
5.c. Guinea-Pigs	321	1432	0	156	3347	20	5276
5.d. Hamsters	0	576	0	0	0	0	576
5.e. Other Rodents	0	0	0	0	30	0	30
5.f. Rabbits	9	132	0	0	516	0	657
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	137	2	139
5.i. Ferrets	0	0	0	0	514	48	562
5.j. Other Carnivores	27	0	0	0	0	0	27
5.k. Horses, donkeys and cross breeds	0	0	0	0	21	0	21
5.l. Pigs	0	337	0	0	635	0	972
5.m. Goats	0	0	0	0	5	0	5
5.n. Sheep	14	121	0	0	608	1	744
5.o. Cattle	0	726	0	0	55	23	804
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	33	0	33
5.r. Old World Monkeys	0	0	0	0	12	0	12
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	206	0	0	6282	0	6488
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	1390	0	0	58	21922	23370
5.z. TOTAL	589	12521	0	314	133732	29206	176362

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

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

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

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

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	37	9718	0	1714	42538	2944	56951
6.b. Rats	97	2510	0	617	92799	4754	100777
6.c. Guinea-Pigs	0	272	0	30	1504	105	1911
6.d. Hamsters	0	0	0	0	873	0	873
6.e. Other Rodents	0	0	0	0	191	0	191
6.f. Rabbits	18	1955	0	121	5191	146	7431
6.g. Cats	0	12	0	0	41	0	53
6.h. Dogs	0	0	0	40	3506	116	3662
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	296	0	0	0	0	0	296
6.k. Horses, donkeys and cross breeds	0	0	0	0	1	21	22
6.l. Pigs	0	123	0	32	509	64	728
6.m. Goats	0	0	0	0	10	0	10
6.n. Sheep	2	24	0	0	73	1	100
6.o. Cattle	10	70	0	0	115	0	195
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	99	24	123
6.r. Old World Monkeys	0	0	0	0	2643	90	2733
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	272	0	0	1505	6	1783
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	1311	9074	0	1451	9299	85914	107049
6.z. TOTAL	1771	24030	0	4005	160897	94185	284888

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

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

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

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS****Types of tests versus species**

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	917	8.832	5.962	12	1.074	0	3.344	5.659	544	2.923	0	0	27.684	56951
7.b. Rats	1.674	2.042	30.143	0	0	0	7.834	3.478	3.943	5.353	29.488	0	16.822	100777
7.c. Guinea-Pigs	0	0	2	0	0	0	0	0	0	0	0	0	1.909	1911
7.d. Hamsters	0	0	208	0	0	0	80	0	0	0	0	0	585	873
7.e. Other Rodents	27	0	0	0	0	0	0	0	0	0	0	0	164	191
7.f. Rabbits	0	0	490	740	0	479	0	0	3.635	0	86	0	2.001	7431
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	53	53
7.h. Dogs	0	0	2.020	0	0	0	1.167	0	0	0	2	0	473	3662
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	296	296
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	22	22
7.l. Pigs	0	0	293	0	0	0	68	0	0	0	0	0	367	728
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	10	10
7.n. Sheep	0	0	36	0	0	0	34	0	0	0	0	0	30	100
7.o. Cattle	0	0	44	0	0	0	0	0	0	0	0	0	151	195
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	29	0	0	0	24	0	0	0	0	0	70	123
7.r. Old World Monkeys	0	0	1.414	0	0	0	720	0	0	0	0	0	599	2733
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	180	135	651	0	0	0	0	0	0	0	108	0	709	1783
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	5.903	61.278	3.398	0	0	0	7.530	0	364	0	1.589	0	26.987	107049
7.z. TOTAL	8701	72287	44690	752	1074	479	20801	9137	8486	8276	31273	0	78932	284888

**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	72	59231	37822	51	556	9	12862	8229	7550	4867	19293	0	39514	190056
8.b. Products/substances used or intended to be used mainly in agriculture	846	1067	1440	57	16	56	2531	908	332	701	6446	0	2721	17121
8.c. Products/substances used or intended to be used mainly in industry	1331	1806	4127	641	314	411	5232	0	604	1403	3794	0	3849	23512
8.d. Products/substances used or intended to be used mainly in the household	0	0	18	0	0	0	0	0	0	114	0	0	0	132
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	4184	2633	942	0	0	0	0	0	0	0	1589	0	881	10229
8.i. Other toxicological or safety evaluations	2268	7550	341	3	188	3	176	0	0	1191	151	0	31967	43838
8.j. TOTAL	8701	72287	44690	752	1074	479	20801	9137	8486	8276	31273	0	78932	284888