



Brussels, 5.12.2013
SWD(2013) 497 final

PART 3/5

COMMISSION STAFF WORKING DOCUMENT

**Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT
Seventh Report on the Statistics on the Number of Animals used for Experimental and
other Scientific Purposes in the Member States of the European Union**

{ COM(2013) 859 final }

COMMISSION STAFF WORKING DOCUMENT

**Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT
Seventh Report on the Statistics on the Number of Animals used for Experimental and
other Scientific Purposes in the Member States of the European Union**

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

TABLE OF CONTENTS

ESTONIA.....	5
IRELAND	16
GREECE	27
SPAIN	37

ESTONIA

Statistical data submitted

The statistical data were submitted by the Animal Welfare and Zootechnics bureau of the Ministry of Agriculture.

Comments of Estonian authorities

Estonia has 10 approved experimental animal breeding and user establishments. Six of them are active at the University of Tartu.

Commission of the authorization of the animal testing permits first started in August 2004.

During the period 2009-2011 there have been issued 92 licenses for conducting animal experiments in Estonia. Most of the experiments have been conducted at the University of Tartu.

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

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

In the field of biological studies, the majority of experiments involved the investigation of human diseases (nervous and mental illnesses, various forms of cancer). The authorization and licensing animal testing and conducting animal experiments is regulated by national and EU legislation.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	26048	3379	21109	0	1560	
1.b. Rats (<i>Rattus norvegicus</i>)	2556	500	2056	0	0	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	72	0	72	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	120	0	120	0	0	
1.e. Other Rodents (other <i>Rodentia</i>)	0					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	3	3	0	0	0	0
1.g. Cats (<i>Felis catus</i>)	0	0	0	0	0	0
1.h. Dogs (<i>Canis familiaris</i>)	0	0	0	0	0	0
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	40					
1.l. Pigs (<i>Sus</i>)	325					
1.m. Goats (<i>Capra</i>)	0					
1.n. Sheep (<i>Ovis</i>)	0					
1.o. Cattle (<i>Bos</i>)	6750					
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>)	20					
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	701					
1.w. Reptiles (<i>Reptilia</i>)	0					
1.x. Amphibians (<i>Amphibia</i>)	0					
1.y. Fish (<i>Pisces</i>)	4400					
1.z. TOTAL	41035					

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	8631	17357	0	0	60	0	0	0	26048
2.b. Rats	1664	892	0	0	0	0	0	0	2556
2.c. Guinea-Pigs	72	0	0	0	0	0	0	0	72
2.d. Hamsters	0	120	0	0	0	0	0	0	120
2.e. Other Rodents	0	0	0	0	0	0	0	0	0
2.f. Rabbits	0	3	0	0	0	0	0	0	3
2.g. Cats	0	0	0	0	0	0	0	0	0
2.h. Dogs	0	0	0	0	0	0	0	0	0
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	40	0	0	0	0	0	0	0	40
2.l. Pigs	0	83	0	0	242	0	0	0	325
2.m. Goats	0	0	0	0	0	0	0	0	0
2.n. Sheep	0	0	0	0	0	0	0	0	0
2.o. Cattle	6710	0	0	0	24	16	0	0	6750
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	20	0	0	0	0	0	0	0	20
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	216	0	0	0	485	0	0	0	701
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	0	0	0	0	0	0	0	0	0
2.y. Fish	400	4000	0	0	0	0	0	0	4400
2.z. TOTAL	17753	22455	0	0	811	16	0	0	41035

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	60									60
3.b. Rats	0									0
3.c. Guinea-Pigs	0									0
3.d. Hamsters	0									0
3.e. Other Rodents	0									0
3.f. Rabbits	0									0
3.g. Cats	0									0
3.h. Dogs	0									0
3.i. Ferrets	0									0
3.j. Other Carnivores	0									0
3.k. Horses, donkeys and cross breeds	0									0
3.l. Pigs	242									242
3.m. Goats	0									0
3.n. Sheep	0									0
3.o. Cattle	24									24
3.p. Prosimians	0									0
3.q. New World Monkeys	0									0
3.r. Old World Monkeys	0									0
3.s. Apes	0									0
3.t. Other Mammals	0									0
3.u. Quail	0									0
3.v. Other birds	485									485
3.w. Reptiles	0									0
3.x. Amphibians	0									0
3.y. Fish	0									0
3.z. TOTAL	811	0	0	0	0	0	0	0	0	811

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	0	4450	7588	5719	0	17757
4.b. Rats	40	596	6	250	0	892
4.c. Guinea-Pigs	0	0	0	32	0	32
4.d. Hamsters	0	0	0	120	0	120
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	0	0	0	3	0	3
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	0	0	0	0	0	0
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	0	0
4.l. Pigs	0	0	0	83	0	83
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	0	0	0
4.o. Cattle	0	0	0	0	10	10
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	0	36	36
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	0	0	0	4000	4000
4.z. TOTAL	40	5046	7594	6207	4046	22933

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

Regulatory requirements versus species

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice					60		60
6.b. Rats					0		0
6.c. Guinea-Pigs					0		0
6.d. Hamsters					0		0
6.e. Other Rodents					0		0
6.f. Rabbits					0		0
6.g. Cats					0		0
6.h. Dogs					0		0
6.i. Ferrets					0		0
6.j. Other Carnivores					0		0
6.k. Horses, donkeys and cross breeds					0		0
6.l. Pigs					242		242
6.m. Goats					0		0
6.n. Sheep					0		0
6.o. Cattle					24		24
6.p. Prosimians					0		0
6.q. New World Monkeys					0		0
6.r. Old World Monkeys					0		0
6.s. Apes					0		0
6.t. Other Mammals					0		0
6.u. Quail					0		0
6.v. Other birds					485		485
6.w. Reptiles					0		0
6.x. Amphibians					0		0
6.y. Fish					0		0
6.z. TOTAL	0	0	0	0	811	0	811

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			60											60
7.b. Rats			0											0
7.c. Guinea-Pigs			0											0
7.d. Hamsters			0											0
7.e. Other Rodents			0											0
7.f. Rabbits			0											0
7.g. Cats			0											0
7.h. Dogs			0											0
7.i. Ferrets			0											0
7.j. Other Carnivores			0											0
7.k. Horses, donkeys and cross breeds			0											0
7.l. Pigs			242											242
7.m. Goats			0											0
7.n. Sheep			0											0
7.o. Cattle			24											24
7.p. Prosimians			0											0
7.q. New World Monkeys			0											0
7.r. Old World Monkeys			0											0
7.s. Apes			0											0
7.t. Other Mammals			0											0
7.u. Quail			0											0
7.v. Other birds			485											485
7.w. Reptiles			0											0
7.x. Amphibians			0											0
7.y. Fish			0											0
7.z. TOTAL	0	0	811	0	0	0	0	0	0	0	0	0	0	811

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			811											811
8.b. Products/substances used or intended to be used mainly in agriculture			0											0
8.c. Products/substances used or intended to be used mainly in industry			0											0
8.d. Products/substances used or intended to be used mainly in the household			0											0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries			0											0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption			0											0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption			0											0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns			0											0
8.i. Other toxicological or safety evaluations			0											0
8.j. TOTAL	0	0	811	0	0	0	0	0	0	0	0	0	0	811

IRELAND

Statistical data submitted

The statistical data for Ireland were provided by the Department of Health.

Comments of Irish authorities¹

General

- A total of 264,990 animals were used. This represents an increase of 135% compared to the 112,835 animals used in 2008.
- 131 new licences were issued in 2011. This is a reduction of 49% on the 259 licences issued in 2008. In this context, a change in procedures, whereby licences are issued to the project leader rather than each researcher working on the project, contributed to this reduction.
- Rodents accounted for 98% (259,879) of all animals used which compares to 74% (83,124) of all animals in 2008.
- No primates were used. This was in accordance with Ireland's policy not to licence for the use of primates.
- Of the animals used, 7% (17,739) were bred in registered breeding establishments in Ireland while 6% (16,955) came from other Member States in the EU and 86% (228,688) came from Non-EU Member States of the Council of Europe which are parties to Convention ETS 123. When rodents are excluded from this analysis, the % of animals bred in registered breeding establishments in Ireland rises to 72%.
- Regulatory requirements (195,649) and studies related to human and animal diseases (67,977) accounted for 99.5% of all animals used in scientific procedures.

Animals Used for Selected Purposes

- Of the 264,990 animals used, 67,977 (26%) were involved in studies on human and animal diseases.
- Of the 259,979 rodents used, 64,883 (25%) were involved in studies on human and animal diseases.
- Of the 473 dogs used, 361 (76%) were involved in studies specific to animal diseases.
- Of the 120 cats, 64 (53%) were involved in studies specific to animal diseases.
- Of the 238 horses, donkeys and crossbreeds used, 216 (91%) were involved in studies specific to animal diseases.
- Of the 348 sheep used, 317 (91%) were involved in studies specific to animal diseases.
- Of the 1,700 cattle used, 942 (55%) were involved in studies on human and animal diseases.
- All "other mammals" (480) were involved in studies specific to animal diseases.

¹ **N.B.** Two corrections were identified after the data submission: 1) The 39 goats should be corrected to 13 goats. The detailed information in Table 4 should be corrected from 26 goats in Column 4.5 and 13 goats in Column 4.6 to zero goats in Column 4.5 and 13 goats in Column 4.6; 2) 2 pigs listed in Column 4.6 should be moved to Column 4.5.

- Of the 503 “other birds” used, 463 (92%) were involved in studies specific to animal diseases.

Toxicological and other Safety Evaluations

- No animals were used in the testing of cosmetic products. This was in accordance with Ireland’s policy not to licence procedures involving the testing of cosmetics.
- Toxicological and other safety evaluations accounted for 74% (195,446) of animals used which compares with 52,065 (46%) in 2008.
- 195,309 (99.9%) of toxicological and other safety evaluations were done pursuant to regulatory requirements.
- 194,607 (99.6%) of the animals used in toxicological and other safety evaluations were rodents.

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>)	248958	11182	12986	223996	794	
1.b. Rats (<i>Rattus norvegicus</i>)	10476	2952	3781	3595	148	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	545		96	449		
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	715	30	47	638		177
1.g. Cats (<i>Felis catus</i>)	120	120				59
1.h. Dogs (<i>Canis familiaris</i>)	473	473				120
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>)	238					
1.l. Pigs (<i>Sus</i>)	286					
1.m. Goats (<i>Capra</i>)	39					
1.n. Sheep (<i>Ovis</i>)	348					
1.o. Cattle (<i>Bos</i>)	1700					
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>)	480					
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	503					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	21					
1.y. Fish (<i>Pisces</i>)	88					
1.z. TOTAL	264990					

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	20283	33835	184		194158	269	15	214	248958
2.b. Rats	5659	4624				117	4	72	10476
2.c. Guinea-Pigs		96			449				545
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	35	45			635				715
2.g. Cats		64			56				120
2.h. Dogs		361			112				473
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds	7			22		209			238
2.l. Pigs	5	54	7		36			184	286
2.m. Goats		39							39
2.n. Sheep	317						2	29	348
2.o. Cattle	904	24		134		14	550	74	1700
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals		480							480
2.u. Quail									0
2.v. Other birds						463		40	503
2.w. Reptiles									0
2.x. Amphibians	21								21
2.y. Fish	52							36	88
2.z. TOTAL	27283	39622	191	156	195446	1072	571	649	264990

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	105								194053	194158
3.b. Rats										0
3.c. Guinea-Pigs									449	449
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits									635	635
3.g. Cats	56									56
3.h. Dogs	112									112
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs							36			36
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	273	0	0	0	0	0	36	0	195137	195446

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	1387	9044	1927	41831	198	54387
4.b. Rats	746	4273		5381		10400
4.c. Guinea-Pigs		26		22	48	96
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	17			63		80
4.g. Cats					64	64
4.h. Dogs					361	361
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds					216	216
4.l. Pigs	52		5		2	59
4.m. Goats				26	13	39
4.n. Sheep					317	317
4.o. Cattle	193				749	942
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals					480	480
4.u. Quail						0
4.v. Other birds					463	463
4.w. Reptiles						0
4.x. Amphibians					21	21
4.y. Fish				40	12	52
4.z. TOTAL	2395	13343	1932	47363	2944	67977

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	54	130					184
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		22					22
5.l. Pigs						7	7
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle		134					134
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	54	286	0	0	0	7	347

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	624			193429	85	194158
6.b. Rats							0
6.c. Guinea-Pigs					449		449
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits					635		635
6.g. Cats	40					16	56
6.h. Dogs	80	32					112
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs						36	36
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	140	656	0	0	194513	137	195446

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	175812	624	20				85							17617	194158
7.b. Rats															0
7.c. Guinea-Pigs														449	449
7.d. Hamsters															0
7.e. Other Rodents															0
7.f. Rabbits														635	635
7.g. Cats														56	56
7.h. Dogs														112	112
7.i. Ferrets															0
7.j. Other Carnivores															0
7.k. Horses, donkeys and cross breeds															0
7.l. Pigs														36	36
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	175812	624	20	0	0	0	85	0	0	0	0	0	0	18905	195446

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			20				85							168	273
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														36	36
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	175812	624												18701	195137
8.j. TOTAL	175812	624	20	0	0	0	85	0	0	0	0	0	0	18905	195446

GREECE

Statistical data submitted

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

Comments of Greek authorities

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

- Presidential Decree No 160/91 (Government Gazette, Series I, No 64) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC, and
- Law No 2015/92 (Government Gazette, Series I, No 30) approving the European Convention on the protection of animals used for experimental and other scientific purposes.

For the collection of statistics relating to the year 2011, the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 of 24 June 1997 were used. The Directorate for Veterinary Care, Drugs and Practice (Directorate-General for Veterinary Affairs, Ministry of Rural Development and Food) sent them directly to the educational establishments (universities and colleges of technology), research centres, healthcare institutions and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. These documents were not sent to cosmetics manufacturers for the year in question, as our department was informed that no cosmetics company uses animals for experimental purposes in Greece.

The total number of animals used in experiments in Greece in 2011 was 28,001, of which:

95.21% (26,659 animals) were **rodents** (24,354 mice - 91.35%, 2,266 rats - 8.5%, 39 guinea pigs - 0.15%), of which 29.54% were used for basic biological research, 31.10% for research and development of medical, dental and veterinary products and appliances, 0.07% to control the production and quality of medical and dental products and appliances, 29.6% for toxicological and other safety studies, 7.77% for the diagnosis of disease, 0.76% for education and training purposes and, finally, 1.16% for other purposes.

2.5% (701 animals) were **rabbits**, of which 66.33% were used for basic biological research, 7.99% for the production and quality control of veterinary products and appliances, 14.27% for toxicological and other safety studies, 2.57% for the diagnosis of disease, 7.13% for education and training purposes and, finally, 1.71% for other purposes.

1.39% (390 animals) were **pigs**, of which 58.72% were used for basic biological research, 1.03% for research and development of medical, dental and veterinary products and appliances, 3.08% for toxicological and other safety studies, 1.03% for the diagnosis of disease, 34.62% for education and training purposes and 1.54% for other purposes.

- **0.79%** were **amphibians** (220 animals), which were used for education and training purposes.
- **0.07%** were **cats** (19 animals), which were used for basic biological studies.
- **0.03%** were **sheep** (8 animals), which were all used for the diagnosis of disease.
- **0.01%** were **dogs** (4 animals), which were all used for basic biological research.

The above data and the tables that have already been sent to you show that the three categories of experiment for which animals were most used in Greece in 2011 were biological research, followed by research and development of medical, dental and veterinary products and appliances and, lastly, toxicological and other safety studies.

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>)	24354	24284			70	
1.b. Rats (<i>Rattus norvegicus</i>)	2266	2251			15	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	39				39	
1.d. Hamsters (<i>Mesocricetus</i>)						
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	701	683			18	
1.g. Cats (<i>Felis catus</i>)	19	19				
1.h. Dogs (<i>Canis familiaris</i>)	4	4				
1.i. Ferrets (<i>Mustela putorius furo</i>)						
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)						
1.l. Pigs (<i>Sus</i>)	390					
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)	8					
1.o. Cattle (<i>Bos</i>)						
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>)						
1.u. Quail (<i>Coturnix coturnix</i>)						
1.v. Other birds (other <i>Aves</i>)						
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	220					
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	28001					

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	5965	8291			7822	2033	117	126	24354
2.b. Rats	1910		19		70		85	182	2266
2.c. Guinea-Pigs						39			39
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	465			56	100	18	50	12	701
2.g. Cats	19								19
2.h. Dogs	4								4
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs	229	4			12	4	135	6	390
2.m. Goats									0
2.n. Sheep						8			8
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians							220		220
2.y. Fish									0
2.z. TOTAL	8592	8295	19	56	8004	2102	607	326	28001

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									7822	7822
3.b. Rats	70									70
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	100									100
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	12									12
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	182	0	0	0	0	0	0	0	7822	8004

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		5638	2530	1516	20	9704
4.b. Rats	246	120	160	107		633
4.c. Guinea-Pigs					39	39
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	5			17	18	40
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	7			4	10	21
4.m. Goats						0
4.n. Sheep					8	8
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	258	5758	2690	1644	95	10445

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats		19					19
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		56					56
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	75	0	0	0	0	75

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					7822		7822
6.b. Rats	70						70
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	100						100
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	12						12
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	182	0	0	0	7822	0	8004

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		7822												7822
7.b. Rats													70	70
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits						40							60	100
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs													12	12
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	7822	0	0	0	40	0	0	0	0	0	0	142	8004

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						40								142	182
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		7822													7822
8.j. TOTAL	0	7822	0	0	0	40	0	0	0	0	0	0	142	8004	

SPAIN

Statistical data submitted

The Statistical data were provided by the Ministry for Agriculture, Food and the Environment, Directorate-General for Agriculture, Food and the Environment, Sub Directorate-General for Livestock Products.

Comments of Spanish authorities

The 2011 statistical report on the use of animals for experimental purposes was drawn up by the Ministry for Agriculture, Food and the Environment using data submitted by the Autonomous Communities which, in turn, received data from users registered in their respective territories.

In comparison with the previous report that was submitted in 2009, there was no significant variation in the total number of animals used. There were, however, a number of changes affecting the distribution of the data, reflecting current trends in the type of animals and their uses. There was:

- An increase in the use of mice but a drop in the use of rats;
- A drop in the use of primates with the focus on their use in safety tests (tests of chronic and sub-chronic toxicity);
- An increase in animals coming from 'other sources', which have tripled in number, the increase in mice being especially significant. Most of these come from the United States and – in much fewer numbers – from Japan, Canada and Australia. For the most part these are genetically modified animals;
- An increase in their use in studies of fundamental biology and of human and animal diseases, and for quality production and control; and
- A drop in their use in safety studies (essentially toxicology).

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>)	634912	519577	88532	798	26005	0
1.b. Rats (<i>Rattus norvegicus</i>)	126406	105889	18579	157	1781	0
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	13749	10116	3633	0	0	0
1.d. Hamsters (<i>Mesocricetus</i>)	1492	1255	225	0	12	0
1.e. Other Rodents (other <i>Rodentia</i>)	80	0	0	0	0	0
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	21302	19614	1181	0	507	0
1.g. Cats (<i>Felis catus</i>)	229	108	0	0	121	0
1.h. Dogs (<i>Canis familiaris</i>)	1252	1112	95	0	45	0
1.i. Ferrets (<i>Mustela putorius furo</i>)	87	87	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	245	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	346	0	0	0	0	0
1.l. Pigs (<i>Sus</i>)	11046	69	4	0	0	0
1.m. Goats (<i>Capra</i>)	455	0	0	0	0	0
1.n. Sheep (<i>Ovis</i>)	2790	10	0	0	0	0
1.o. Cattle (<i>Bos</i>)	1464	0	0	0	0	0
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	1	1	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	342	288	54	0	0	0
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	56	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	105	45	0	0	60	0
1.v. Other birds (other <i>Aves</i>)	21341	4	0	0	0	0
1.w. Reptiles (<i>Reptilia</i>)	0	0	0	0	0	0
1.x. Amphibians (<i>Amphibia</i>)	1097	0	0	0	0	0
1.y. Fish (<i>Pisces</i>)	61330	1535	0	0	0	0
1.z. TOTAL	900127	659710	112303	955	28531	0

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	370944	103633	24773	27598	49146	36806	5623	16389	634912
2.b. Rats	54843	34986	81	6597	5726	10841	6678	6654	126406
2.c. Guinea-Pigs	164	4213	4537	3376	1346	54	55	4	13749
2.d. Hamsters	606	348	0	0	128	408	2	0	1492
2.e. Other Rodents	15	0	0	0	0	0	25	40	80
2.f. Rabbits	1447	2612	6381	7613	1405	1235	267	342	21302
2.g. Cats	44	36	2	26	0	0	0	121	229
2.h. Dogs	50	691	0	192	157	4	88	70	1252
2.i. Ferrets	50	37	0	0	0	0	0	0	87
2.j. Other Carnivores	245	0	0	0	0	0	0	0	245
2.k. Horses, donkeys and cross breeds	10	36	27	4	60	202	7	0	346
2.l. Pigs	407	4145	43	628	251	521	2080	2971	11046
2.m. Goats	43	55	51	2	0	0	137	167	455
2.n. Sheep	413	427	0	614	387	144	713	92	2790
2.o. Cattle	72	366	0	36	322	185	3	480	1464
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	1	0	0	0	0	0	0	0	1
2.r. Old World Monkeys	7	73	0	0	252	0	10	0	342
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	56	0	0	0	0	56
2.u. Quail	0	0	0	0	45	0	0	60	105
2.v. Other birds	875	3930	321	11482	2835	1250	131	517	21341
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	1097	0	0	0	0	0	0	0	1097
2.y. Fish	36936	6291	0	0	7195	2365	146	8397	61330

2.z.	TOTAL	468269	161879	36216	58224	69255	54015	15965	36304	900127
------	-------	--------	--------	-------	-------	-------	-------	-------	-------	--------

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	12996	0	0	0	0	0	796	621	34733	49146
3.b. Rats	5420	18	115	0	0	0	16	0	157	5726
3.c. Guinea-Pigs	1346	0	0	0	0	0	0	0	0	1346
3.d. Hamsters	128	0	0	0	0	0	0	0	0	128
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1218	0	131	47	0	0	9	0	0	1405
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	157	0	0	0	0	0	0	0	0	157
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	60	0	0	0	0	0	0	0	0	60
3.l. Pigs	235	0	0	0	0	0	16	0	0	251
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	387	0	0	0	0	0	0	0	0	387
3.o. Cattle	322	0	0	0	0	0	0	0	0	322
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	252	0	0	0	0	0	0	0	0	252
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	45	0	0	0	0	0	0	0	45
3.v. Other birds	333	0	0	0	0	0	2502	0	0	2835
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	4000	0	0	0	0	276	0	456	2463	7195
3.z. TOTAL	26854	63	246	47	0	276	3339	1077	37353	69255

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	35673	85766	141240	121534	16315	400528
4.b. Rats	6520	27751	1430	47935	574	84210
4.c. Guinea-Pigs	0	12	0	4208	122	4342
4.d. Hamsters	20	241	400	270	286	1217
4.e. Other Rodents	0	285	0	14	0	299
4.f. Rabbits	125	69	6	2648	1798	4646
4.g. Cats	2	12	0	0	26	40
4.h. Dogs	0	0	3	287	284	574
4.i. Ferrets	0	36	0	51	0	87
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	60	60
4.l. Pigs	776	100	32	771	2452	4131
4.m. Goats	0	0	0	33	30	63
4.n. Sheep	22	0	0	147	365	534
4.o. Cattle	0	0	0	0	383	383
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	1	0	0	0	1
4.r. Old World Monkeys	4	40	2	281	0	327
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	56	56
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	0	5202	5202
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	46	100	409	0	555
4.y. Fish	2306	608	9603	10278	5979	28774
4.z. TOTAL	45448	114967	152816	188866	33932	536029

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	37024	0	0	8459	6888	52371
5.b. Rats	0	6678	0	0	0	0	6678
5.c. Guinea-Pigs	0	3524	0	984	3363	42	7913
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	8021	13	0	5901	59	13994
5.g. Cats	0	28	0	0	0	0	28
5.h. Dogs	0	192	0	0	0	0	192
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	31	0	0	0	0	31
5.l. Pigs	0	591	15	0	0	65	671
5.m. Goats	0	51	0	0	0	2	53
5.n. Sheep	30	532	0	0	0	52	614
5.o. Cattle	10	15	0	0	0	11	36
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	56	0	56
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	1144	10580	0	0	79	0	11803
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	1184	67267	28	984	17858	7119	94440

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	2040	18978	75	465	25054	2534	49146
6.b. Rats	931	1039	0	61	2771	924	5726
6.c. Guinea-Pigs	0	787	0	168	0	391	1346
6.d. Hamsters	128	0	0	0	0	0	128
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	1062	0	102	230	11	1405
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	157	0	157
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	60	0	0	0	0	0	60
6.l. Pigs	22	183	0	0	46	0	251
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	299	20	0	0	68	0	387
6.o. Cattle	230	38	0	0	54	0	322
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	252	0	252
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	45	0	0	0	0	0	45
6.v. Other birds	0	2735	0	0	100	0	2835
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	456	4000	0	0	2463	276	7195
6.z. TOTAL	4211	28842	75	796	31195	4136	69255

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	5380	25942	8962	0	0	0	5000	0	0	0	0	0	3862	49146
7.b. Rats	68	323	234	0	32	0	2724	0	390	0	294	0	1661	5726
7.c. Guinea-Pigs	0	389	0	0	562	0	0	0	0	0	0	0	395	1346
7.d. Hamsters	0	0	0	0	0	0	128	0	0	0	0	0	0	128
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	0	261	26	84	263	0	169	0	33	0	569	1405
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	157	0	0	0	0	0	0	157
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	60	0	0	0	0	60
7.l. Pigs	0	0	0	6	0	0	0	0	22	0	0	0	223	251
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	299	0	0	0	88	387
7.o. Cattle	0	0	0	0	0	0	0	0	230	0	0	0	92	322
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	252	0	0	0	0	0	0	252
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	45	0	0	0	0	0	0	45
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	2835	2835
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	0	0	0	0	0	0	732	0	3500	0	0	0	2963	7195
7.z. TOTAL	5448	26654	9196	267	620	84	9301	0	4670	0	327	0	12688	69255

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	1100	3659	394	167	620	6	8279	0	4670	0	327	0	7632	26854
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	63	0	0	0	0	0	0	63
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	53	0	78	115	0	0	0	0	0	0	246
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	47	0	0	0	0	0	0	0	0	0	47
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	276	0	0	0	0	0	0	276
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	53	768	0	0	0	0	0	0	0	0	0	0	2518	3339
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	546	0	0	0	0	0	456	0	0	0	0	0	75	1077
8.i. Other toxicological or safety evaluations	3749	22227	8802	0	0	0	112	0	0	0	0	0	2463	37353
8.j. TOTAL	5448	26654	9196	267	620	84	9301	0	4670	0	327	0	12688	69255

