

EN

EN

EN



EUROPEAN COMMISSION

Brussels, 8.12.2010
SEC(2010) 1107 final/2

CORRIGENDUM:

Annule et remplace le document SEC(2010) 1107 du 30.9.2010 final

Concerne : toutes les versions

COMMISSION STAFF WORKING DOCUMENT

**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**

TABLE OF CONTENTS

I.	INTRODUCTION	4
II.	DATA SUBMITTED AND GENERAL ASSESSMENT	6
II.1.	Data submitted by the Member States	6
II.2.	General assessment	6
II.3.	Structure of the Report	8
PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2008		9
III.1.	Results of EU Table 1: <i>Species and number of animals</i>	9
III.2.	Results of EU Table 1: <i>Origin of animals used</i>	16
III.3.	Results of EU Table 2: <i>Purposes of the experiments</i>	19
III.4.	Results of EU Table 3: <i>Toxicological and safety evaluation by type of product/endpoint</i>	23
III.5.	Results of EU Table 4: <i>Animals used for studies of diseases</i>	26
III.6.	Results of EU Table 5: <i>Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine</i>	31
III.7.	Results of EU harmonized Table 6: <i>Origin of regulatory requirements for animals used in toxicological and other safety evaluations</i>	34
III.8.	Results of EU Table 7: <i>Animals used in toxicity tests for toxicological and other safety evaluations</i>	37
III.9.	Results of EU Table 8: <i>Type of toxicity tests carried out for toxicological and other safety evaluations of products</i>	41
PART B: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES		
BELGIUM.....		46
BULGARIA		61
CZECH REPUBLIC		71
DENMARK.....		80
GERMANY.....		89
ESTONIA.....		99

IRELAND	108
GREECE	117
SPAIN	127
FRANCE	136
ITALY	145
CYPRUS	154
LATVIA	159
LITHUANIA	168
LUXEMBOURG	177
HUNGARY	181
MALTA	190
THE NETHERLANDS	199
AUSTRIA	210
POLAND	224
PORTUGAL	233
ROMANIA	247
SLOVENIA	256
SLOVAKIA	267
FINLAND	279
SWEDEN	288
UNITED KINGDOM	298

I. INTRODUCTION

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes¹, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The first two statistical reports drafted in accordance with the provisions of the above mentioned directive which were published in 1994² and 1999³, covering data on experimental animals collected in 1991 and 1996 respectively in the Member States, allowed only a limited amount of statistical analysis due to the absence of a consistent system of reporting the data. In 1997 an agreement was reached between the Commission and the competent authorities of the Member States to submit data for future reports using a format of eight harmonized tables. The third and fourth statistical reports published in 2003⁴ and 2005⁵ covering data collected in 1999 and 2002 were based on these agreed harmonized tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. In spite of the progress made in the content of these two statistical reports, it ought to be stressed that there were some inconsistencies in the data submitted by the Member States and also that in all cases except the report of 2003, one Member State collected data from another year. The Fifth Statistical Report, published in 2007⁶, contained for the first time data collected in the 10 Member States which joined the EU in 2004. In the Sixth Statistical Report the complete set of standardized tables provided by all 27 Member States were successfully evaluated, although comparison of the results with previous reports was essentially qualitative owing to the addition of data from the new Member States.

This Report includes data submitted by Romania and Bulgaria, which joined the EU in 2007. It gives an overview of the number of animals used in the Member States for experimental purposes for the year 2008 with the exception of one Member State which provided data from 2007.

The Commission Staff Working Document accompanies 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*. The report summarizes the data and conclusions presented in this Staff Working Document.

¹ OJ L 358, 18.12.1986, p.1.
² COM (94) 195 final
³ COM (1999) 191 final
⁴ COM (2003) 19 final
⁵ COM (2005) 7 final
⁶ COM (2007) 675 final

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

All 27 Member States submitted the data in the agreed EU format.

A quality control check on the set of data submitted for 2008 has been carried out and is essentially governed by four criteria based on certain relationships between the data in the different tables.

- The first of these relationships is the total number of animals used by species, column 1.2 of EU table 1, which is broken down into purposes of experiments in EU table 2. Thus, the totals of the Tables 1 and 2 should be identical.
- The second relationship concerns column 2.6 of EU table 2 'animals used for toxicological and other safety evaluation' which is broken down into types of products/endpoints in EU table 3; into Regulatory requirements in EU table 6; and into types of toxicological tests in EU table 7. Therefore, the total of column 2.6 must be equal to the totals of tables 3, 6, 7 and in addition table 8 'type of tests versus products' respectively.
- The third relationship is that the sum of column 2.4 and 2.5 of EU table 2 must be equal to the total of EU table 5.
- In the fourth relationship, the total of EU table 3 should be equal to the total of table 8.

The last criterion has shown obvious weaknesses when tested on the tables provided by the Member States and has led to include an additional 5th quality check criterion.

- Fifth: each individual total in the total line of table 3 must be equal to each individual total in the total column of table 8 as the column headings are identical.

For this Sixth report all the above quality criteria have been fulfilled by the Member States. It is therefore considered that the data provided by the Member States affords a consistent base for a sound statistical analysis of all eight EU tables.

II.2. General assessment

Each Member State is requested, pursuant to Articles 13 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. The data for this report covers the year 2008 with the exception of France which provided data from 2007.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes⁷ allows the use of animals in experiments for education and training, but where the purposes of such experiments are not covered by the Directive, Member States will according to the Resolution apply national provisions which are no less severe than those of the Directive.

⁷ OJ C 331, 23.12.86, p. 2.

Therefore, a number of Member States have also included animals covered by the Resolution in the report.

The first part of this report aims at providing a comprehensive overview on the numbers of animals used for various experimental purposes in the Community in 2008. The purposes of the use of animals have been analysed, and some of these purposes have been broken down further into more precise parameters. It also considers different legislative requirements regarding the use of experimental animals and the type of testing carried out on different species.

As the two newest Member States, Bulgaria and Romania, have submitted data for the first time, it is in principle not possible to draw accurate quantitative conclusions on the evolution of the use of animals for experimental purposes in the EU by comparing data with those of the previous reports. However, as their total use amounts to less than 1% of the total number of animals used in 2008, some comparisons in trends have been attempted, and significant changes in use have been highlighted in the report.

The second part of this report provides the individual data from the Member States together with their respective comments and interpretations.

In the EU, the total number of animals used for experimental and other scientific purposes in 2008 in the Member States amounts to just over 12 million (with data from France from 2007).

As in previous reports rodents together with rabbits represent more than 80% of the total number of animals used in the EU. Mice are by far the most commonly used species accounting for 59% of the total use, followed by rats with 17%.

The second most used group of animals was, as in previous years, cold-blooded animals which represent almost 10%. The third largest group of animals used was birds with a little over 6% of the total use.

As stated in the previous two statistical reports no Great Apes were used in experiments in the EU in 2008.

II.3. Structure of the Report

The report is divided into two parts:

A A global compilation and overview for the European Union of the statistical data of the Member States for 2008.

A consolidated table has been computed on the basis of the data submitted by the Member States for each EU table and is presented at the end of each chapter. Each table is illustrated by a graphical presentation to give a more readable overview of the EU situation.

Similarly to results of the Report of 2005, for which France submitted statistical data for 2004, the data analysed for this Report includes statistical data from the year 2007 from France. Therefore, the totals used in this report are a mixture of years. Comparisons were nevertheless made on this basis since no other data were available.

The reader is invited to take note that the numbering of tables and graphical presentation in Part A of the report are linked to the numbers of the EU tables and not to the numbering of the chapters of the report.

B The data submitted by each Member State with a summary of the Member State's comments.

PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2008

III.1. Results of EU Table 1: Species and number of animals

Two types of information can be drawn from the data submitted by the Member States in EU Table 1. The first relates to the total number of animals subdivided into 25 species used by the Member States. The second type of information relates to the place of origin of the animals used for experimental or other scientific purposes.

III.1.1. The data on the total number of animals used in the MS

Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by 27 Member States. Whereas in previous years Malta had not used animals for scientific purposes, in 2008 this country reported animal use for the first time.

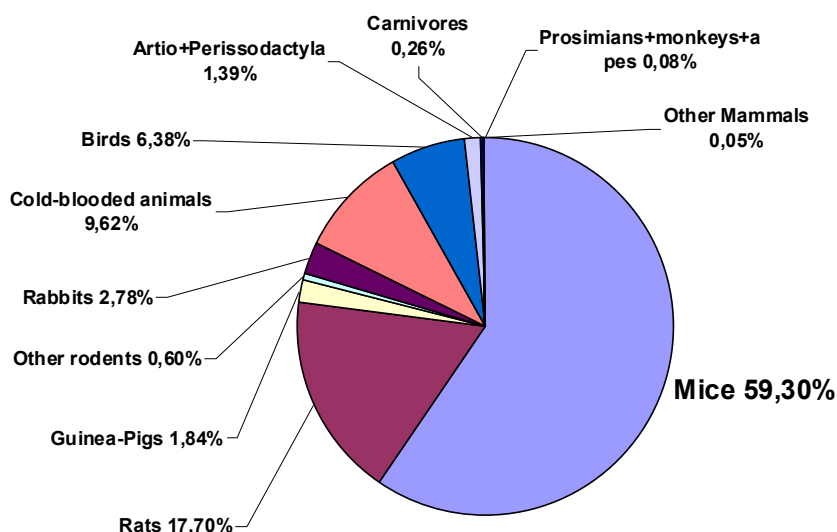
The total number of animals used in 2008 in the 27 Member States amounts to 12.0 million animals. It is important to note that the number of animals used in the new Member States who joined the EU in 2008 (Bulgaria and Romania) represents not even 1,0% of the total number of animals used in the EU 27.

III.1.2. Treatment and interpretation of the data of Table 1.1

In order to present an overall evaluation and subsequently a graphical analysis, animal species were grouped. The result of this exercise is presented in Table 1.2 at the end of this chapter. This grouping in Table 1.2 allows an overview of the species used and is illustrated in Figure 1.1.

It should also be pointed out that re-used animals are not included in the figures so that animals are not counted twice.

Figure 1.1
Percentages of animals used by classes in the Member States



Rodents together with rabbits represent more than 80% of the total number of animals used. Mice (59,3%) and rats (17,6%) are by far the most commonly used species.

The second most used group is represented by cold-blooded animals namely reptiles, amphibians and fish at 9,6%.

Birds is the next highest animal group used for experimental purposes at 6,3%.

The Artiodactyla and Perissodactyla group including horses, donkeys and crossbreeds (Perissodactyla), pigs, goats, sheep and cattle (Artiodactyla) represents 1,4% of the total number of animals used in the Member States.

Carnivores represent 0,3% of the total number of animals used and non-human primates represent 0,08% of the animals used in 2008.

III.1.3. Comparison with the data of the previous reports

In this chapter, and the following chapters where comparisons are addressed, the reader is invited to take note of the fact that in 1996, in 2002, in 2005 and for this report France has reported data respectively for 1997, 2001, 2004 and 2007 which does not allow a rigorous comparison between data reported for each year. Nevertheless, assuming that fluctuations in the annual numbers of animals used per species in a country are limited, it is possible to make semi-quantitative estimates of the observed trends by comparing changes in proportions of use, expressed as a percentage.

Comparison between proportions of classes of animals used in 1996, 1999, 2002, 2005 and 2008

Class of species	1996(*)	1999	2002(**)	2005(***)	2008(****)
% Rodents-rabbits	81,3	86,9	78,0	77,5	82,2
% Cold-blooded animals	12,9	6,6	15,4	15,	9,6
% Birds		4,7	5	5,4	6,4
% Artio and Perissodactyla		1,2	1,2	1,1	1,4

(*) 14 Member States reporting for 1996, one for 1997

(**) 14 Member States reporting for 2002, one for 2001

(***) 24 Member States reporting for 2005, one for 2004

(****) 27 Member States reporting for 2008, one for 2007

Overall, the percentage of rodents and rabbits shows some fluctuation, but remains close to 80%. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 12 to 15%. In 2008 the use of cold-blooded animals has dropped considerably to below 10%. However, in 1999 a much lower percentage of 6,6% was observed.

Birds representing the third largest percentage of animals used, seems to be in constant increase over the years from 4 to 6,4%. The group of horses, donkeys and cross-bred animals (artiodactyla) and pigs, goats, sheep and cattle (perissodactyla) fluctuates at around 1%.

Contrary to what would have been expected, the effect of the inclusion of the data of new Member States since 2005 i.e. Bulgaria and Romania, did not lead to an increase in the total number of animals, on the contrary, there is a decrease of more than 116,500 animals.

Table 1.0 contains a comparison of the change that has taken place since 2008 for each species, expressed in number of animals per species, between EU 27 (data from 2008) and EU 25 (data from 2005) (first three columns) and in percentage per species (fourth column). The second half is a comparison between EU 25 (data of 2008 without Romania and Bulgaria)

Table 1.0 : Changes in species number and proportion between 2005 and 2008

Species	Number of animals in EU 25 2005	Number of animals in EU 27 2008	Change since 2005	% change by species	Change since 2005	Number of animals EU 25 2008 excl. RO,BG	% change by species
1.a Mice (<i>Mus musculus</i>)	6430346	7122188	691842	10,76	630992	7061338	9,81
1.b Rats (<i>Rattus norvegicus</i>)	2336032	2121727	-214305	-9,17	-223989	2112043	-9,59
1.c Guinea-Pigs (<i>Cavia porcellus</i>)	257307	220985	-36322	-14,12	-46774	210533	-18,18
1.d Hamsters (<i>Mesocricetus</i>)	31535	32739	1204	3,82	759	32294	2,41
1.e Other Rodents (other Rodentia)	64474	39506	-24968	-38,73	-24968	39506	-38,73
1.f Rabbits (<i>Oryctolagus cuniculus</i>)	312681	333213	20532	6,57	17514	330195	5,60
1.g Cats (<i>Felis catus</i>)	3898	4088	190	4,87	179	4077	4,59
1.h Dogs (<i>Canis familiaris</i>)	24119	21315	-2804	-11,63	-2819	21300	-11,69
1.i Ferrets (<i>Mustela putorius furo</i>)	2690	3208	518	19,26	518	3208	19,26
1.j Other Carnivores	8711	2853	-5858	-67,25	-5858	2853	-67,25
1.k Horses, donkeys and cross breeds (<i>Equidae</i>)	5312	5976	664	12,50	633	5945	11,92
1.l Pigs (<i>Sus</i>)	66305	92813	26508	39,98	26369	92674	39,77
1.m Goats (<i>Capra</i>)	2146	3840	1694	78,94	1614	3760	75,21
1.n Sheep (<i>Ovis</i>)	30021	30190	169	0,56	-212	29809	-0,71
1.o Cattle (<i>Bos</i>)	36271	33952	-2319	-6,39	-2448	33823	-6,75
1.p Prosimians (<i>Prosimia</i>)	677	1261	584	86,26	584	1261	86,26
1.q New World Monkeys (<i>Ceboidae</i>)	1564	904	-660	-42,20	-660	904	-42,20
-1.r Old World Monkeys (<i>Cercopithecoidea</i>)	8208	7404	-804	-9,80	-804	7404	-9,80
1.s Apes (<i>Hominoidea</i>)	0	0	0	0,00	0	0	0,00
1.t Other Mammals (other Mammalia)	9950	5704	-4246	-42,67	-4246	5704	-42,67
1.u Quail (<i>Coturnix coturnix</i>)	9246	9626	380	4,11	371	9617	4,01
1.v Other birds (other Aves)	649813	754485	104672	16,11	101999	751812	15,70
1.w Reptiles (<i>Reptilia</i>)	2477	4101	1624	65,56	1624	4101	65,56
1.x Amphibians (<i>Amphibia</i>)	74620	61789	-12831	-17,20	-17631	56989	-23,63
1.y Fish (<i>Pisces</i>)	1749178	1087155	-662023	-37,85	-662073	1087105	-37,85
1.z TOTAL	12117581	12001022	-116559	-0,96	-209326	11908255	-1,73

There is an increase in the number of mice used since 2005 of 691,842 which is 10,7% of the total number of mice used in 2005 and a decrease for rats (9,2%) and fish (37,8%). The largest change in 2008, increase in the use of mice, is almost entirely compensated for by the decrease in the use of fish.

The total number of pigs, goats, prosimians, and reptiles has increased by between 40% – 86,3%.

The total number of rats, guinea-pigs, other rodents, dogs, cattle and other mammals as well as amphibians and fish used has decreased substantially since the last report. When expressed in percentages these decreases range from more than 40 to around 9%.

The largest percentile change has, however, been noted in the decrease of the use of other carnivores. However, these species are not used in great numbers (from 8,711 to 2,853). There is also a large decrease of 42,7% in the total number of 'other mammals'.

It is also worth noting the large decrease in the use of new world monkeys of 42,2% as well as a decrease of 9,8% of old world monkeys. Prosimian use overall, however, has increased by 86,3%.

For species used in greater numbers, significant increases occurred in 2008 for mice, rabbits, pigs and 'other birds' where percentage changes ranged from 6,6 to 40%.

The following animals which are normally used in fewer numbers show an increase in use: ferrets (19,3%), horses, donkeys and cross-breeds (12,5%), goats (78,9%) and reptiles (65,5%).

As in 2002 and 2005, no great apes were used for experimental or other scientific purposes in 2008.

Member States provided examples of the type of species covered by category 'other' as follows:

Other rodents: gerbils, old world jerboas (*Jaculus jaculus*); chinchillas, beavers, ground squirrels, hamsters, grey dwarf hamsters (*Cricetulus migratorius*) and different species of mice.

Other carnivores: wild-life species used for zoological and ecological studies e.g. foxes, badgers, seals, otters and fitchew.

Other mammals: boars, bats and shrews, llamas, moles, European bison and red deer.

Other birds: mainly Japanese Quail (*coturnix japonica*) and bob-white quail, poultry species, and zebra finches, canaries, parakeets, parrots and farmed avian species for example, chickens.

In the three columns in the second half of the table, the addition of data from Bulgaria, Romania has virtually no effect on the proportional changes between the species.

Romania has little effect on the proportional changes between the species ranging from no change to very marginal variations per species. However, there is a net decrease of guinea pigs – 4%, and 10% for amphibians, when data from Bulgaria and Romania are excluded.

**Table 1.1: Total number of animals used for experimental purposes in the EU Member States
Data of 2008 (*)**

Species	AT	BE	BG	CY	CZ	DK	ET	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SP	SK	SL	SE	UK	Totals
a. Mice	177544	480681	16265	2114	54776	168164	28754	78446	1561809	1314493	19786	158799	71224	553000	6912	3827	3280	50	237681	123897	39811	44585	543680	6942	10313	203112	1212243	7122188
b. Rats	9928	108580	4513	0	21531	75850	5268	26058	392773	390853	4367	89375	11741	230347	2407	1194	430	44	105780	45824	6571	5171	175325	9692	1675	53141	343289	2121727
c. Guinea-Pigs	3284	36554	3845	0	1902	5343	22	215	46030	35870	45	9743	91	13875	32	93	100	0	6062	6495	152	6607	12620	982	7	1766	29250	220985
d. Hamsters	693	2124	182	0	251	4	120	302	12063	7061	0	215	68	717	0	0	0	0	3358	312	29	263	1262	0	0	864	2851	32739
e. Other Rodents	47	1055			1233	1760	0	3142	3594	8392		356		1235			0		2439	11966			251	45	0	2033	1958	39506
f. Rabbits	18761	42025	813	0	6304	2931	630	814	96427	97938	1498	8134	204	9706	48	199	20	0	7418	3086	99	2205	19626	679	307	1332	12009	333213
g. Cats	2	78	11	0	45	154	0		1848	798	4	40	295	26	0	0	0	0	253	83		0	100	18	0	149	184	4088
h. Dogs	41	788	15	0	552	271	0	54	4131	4450	44	686	557	943	0	0	0	0	1244	230		0	1046	4	0	1982	4277	21315
i. Ferrets	14	324	0	0	122	117	0		800	55	0	0		0	0	0	0	0	472	0		0	287	0	0	39	978	3208
j. Other Carnivores	0	0			45	101	0	761	0	410		0		0			0		10	520			5	0	0	53	948	2853
k. horses, donkeys & cross-breeds	47	62	17		378	54	0	37	652	584	1	40	144	46			0		2562	529	6	14	90		0	423	290	5976
l. Pigs	5086	2969	137		2013	6863		819	8768	12361	624	1193	224	3607		80	0		11729	11742	222	2	15121	22	3	1973	7255	92813
m. Goats	39	195	80		174	107	0		1159	531	24	92		41			0		229	300			372	5	0	5	487	3840
n. Sheep	142	356	250		1148	88		571	3573	4638	68	200	456	469			0		3486	2217	28	131	2386	9	4	152	9818	30190
o. Cattle	574	657	126		799	939	0	300	3206	6252	72	93	4019	462			0		2236	7540	10	3	1091		0	1379	4194	33952
p. Prosimians	0	0	0	0	0	0	0		718	543	0	0		0	0	0	0	0	0	0		0	0	0	0	0	0	1261
q. N W Monkeys	0	0	0	0	0	0	0		233	305	0	5		18	0	0	0	0	73	0		0	8	0	0	0	262	904
r. O W Monkeys	0	41	0	0	80	0	0		1797	1415	0	1		344	0	0	0	0	82	0		0	517	0	0	35	3092	7404
s. Apes	0	0	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0		0	0	0	0	0	0	0
t. Other Mammals	0	151			1774	243		84	0	541		16	32	151			0		202	1246			28	21	0	263	952	5704
u. Quail	14	431	0	0	0	0	0		1548	1803	0	13		249	0	0	0	0	0	5100		9	138	120	0	201	0	9626
v. Other birds	1367	17151	1477		148722	2820		5568	156814	53986	88	32554	582	32241		40	0		90890	27391	160	1196	52104	696	129	3432	125077	754485
w. Reptiles	17	374			1012	221		317	758	192		108		454			0		121	248			704		0	170	109	4101
x. Amphibians	277	2388	4800		3016	293		34	9451	10815	200	1182		2432		149	0		870	1221			704		0	641	23316	61789
y. Fish	2579	28386	50		54836	31245		21078	20228	67496	1200	2077	23198	13955			0	600	23859	25941	3800		71098	25	0	211459	484045	1087155
z. TOTAL	220456	725370	32581	2114	300713	297568	34794	138600	2328380	2021782	28021	304922	112835	864318	9399	5582	3830	694	501056	275888	50888	60186	897859	19260	12438	484604	2266884	12001022

(*) France is reporting for 2007

**Table 1.2: Classes of animals used for experimental purposes in the EU Member States
Data of 2008 (*)**

Species	AT	BE	BG	CY	CZ	DK	ET	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SP	SK	SL	SE	UK	Totals
Mice	177544	480681	16265	2114	54776	168164	28754	78446	1561809	1314493	19786	158799	71224	553000	6912	3827	3280	50	237681	123897	39811	44585	543680	6942	10313	203112	1212243	7122188
Rats	9928	108580	4513	0	21531	75850	5268	26058	392773	390853	4367	89375	11741	230347	2407	1194	430	44	105780	45824	6571	5171	175325	9692	1675	53141	343289	2121727
Guinea-Pigs	3284	36554	3845	0	1902	5343	22	215	46030	35870	45	9743	91	13875	32	93	100	0	6062	6495	152	6607	12620	982	7	1766	29250	220985
Hamsters + other rodents	740	3179	182	0	1484	1764	120	3444	15657	15453	0	571	68	1952	0	0	0	0	5797	12278	29	263	1513	45	0	2897	4809	72245
Rabbits	18761	42025	813	0	6304	2931	630	814	96427	97938	1498	8134	204	9706	48	199	20	0	7418	3086	99	2205	19626	679	307	1332	12009	333213
Cold-blooded animals (1)	2873	31148	4850	0	58864	31759	0	21429	30437	78503	1400	3367	23198	16841	0	149	0	600	24850	27410	3800	0	71802	25	0	212270	507470	1153045
Birds (2)	1381	17582	1477	0	148722	2820	0	5568	158362	55789	88	32567	582	32490	0	40	0	0	90890	32491	160	1205	52242	816	129	3633	125077	764111
Artio+perisso dactyla (3)	5888	4239	610	0	4512	8051	0	1727	17358	24366	789	1618	4843	4625	0	80	0	0	20242	22328	266	150	19060	36	7	3932	22044	166771
Carnivores	57	1190	26	0	764	643	0	815	6779	5713	48	726	852	969	0	0	0	0	1979	833	0	0	1438	22	0	2223	6387	31464
Prosimians+ monkeys +apes	0	41	0	0	80	0	0	0	2748	2263	0	6	0	362	0	0	0	0	155	0	0	0	525	0	0	35	3354	9569
Other mammals	0	151			1774	243		84	0	541		16	32	151			0		202	1246			28	21	0	263	952	5704
TOTAL	220456	725370	32581	2114	300713	297568	34794	138600	2328380	2021782	28021	304922	112835	864318	9399	5582	3830	694	501056	275888	50888	60186	897859	19260	12438	484604	2266884	12001022

Species %	AT	BE	BG	CY	CZ	DK	ET	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SP	SK	SL	SE	UK	Totals
Mice	80,53	66,27	49,92	100,00	18,22	56,51	82,64	56,60	67,08	65,02	70,61	52,08	63,12	63,98	73,54	68,56	85,64	7,20	47,44	44,91	78,23	74,08	60,55	36,04	82,92	41,91	53,48	59,35
Rats	4,50	14,97	13,85	0,00	7,16	25,49	15,14	18,80	16,87	19,33	15,58	29,31	10,41	26,65	25,61	21,39	11,23	6,34	21,11	16,61	12,91	8,59	19,53	50,32	13,47	10,97	15,14	17,68
Guinea-Pigs	1,49	5,04	11,80	0,00	0,63	1,80	0,06	0,16	1,98	1,77	0,16	3,20	0,08	1,61	0,34	1,67	2,61	0,00	1,21	2,35	0,30	10,98	1,41	5,10	0,06	0,36	1,29	1,84
Hamsters + other rodents	0,34	0,44	0,56	0,00	0,49	0,59	0,34	2,48	0,67	0,76	0,00	0,19	0,06	0,23	0,00	0,00	0,00	0,00	1,16	4,45	0,06	0,44	0,17	0,23	0,00	0,60	0,21	0,60
Rabbits	8,51	5,79	2,50	0,00	2,10	0,98	1,81	0,59	4,14	4,84	5,35	2,67	0,18	1,12	0,51	3,57	0,52	0,00	1,48	1,12	0,19	3,66	2,19	3,53	2,47	0,27	0,53	2,78
Cold-blooded animals (1)	1,30	4,29	14,89	0,00	19,57	10,67	0,00	15,46	1,31	3,88	5,00	1,10	20,56	1,95	0,00	2,67	0,00	86,46	4,96	9,94	7,47	0,00	8,00	0,13	0,00	43,80	22,39	9,61
Birds (2)	0,63	2,42	4,53	0,00	49,46	0,95	0,00	4,02	6,80	2,76	0,31	10,68	0,52	3,76	0,00	0,72	0,00	0,00	18,14	11,78	0,31	2,00	5,82	4,24	1,04	0,75	5,52	6,37
Artio+perisso dactyla (3)	2,67	0,58	1,87	0,00	1,50	2,71	0,00	1,25	0,75	1,21	2,82	0,53	4,29	0,54	0,00	1,43	0,00	0,00	4,04	8,09	0,52	0,25	2,12	0,19	0,06	0,81	0,97	1,39
Carnivores	0,03	0,16	0,08	0,00	0,25	0,22	0,00	0,59	0,29	0,28	0,17	0,24	0,76	0,11	0,00	0,00	0,00	0,00	0,39	0,30	0,00	0,00	0,16	0,11	0,00	0,46	0,28	0,26
Prosimians+ monkeys+ apes	0,00	0,01	0,00	0,00	0,03	0,00	0,00	0,00	0,12	0,11	0,00	0,00	0,00	0,04	0,00	0,00	0,00	0,00	0,03	0,00	0,00	0,00	0,06	0,00	0,00	0,01	0,15	0,08
Other mammals	0,00	0,02	0,00	0,00	0,59	0,08	0,00	0,06	0,00	0,03	0,00	0,01	0,03	0,02	0,00	0,00	0,00	0,00	0,04	0,45	0,00	0,00	0,00	0,11	0,00	0,05	0,04	0,05
Mice																												
TOTAL	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

FR(*) France reporting for 2007

(1) reptiles + amphibians + fish

(2) Quails and other birds

(3) Horses, donkeys, and cross breeds + pigs + goats and sheep +cattle

(4) Cats + dogs + ferrets + other carnivores

III.2. Results of EU Table 1: Origin of animals used

III.2.1. The data on the origin of the species

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 27 Member States are reported in Table 1.3 at the end of this chapter. The consolidated table 1.3 only indicates species for which the origin must be reported.

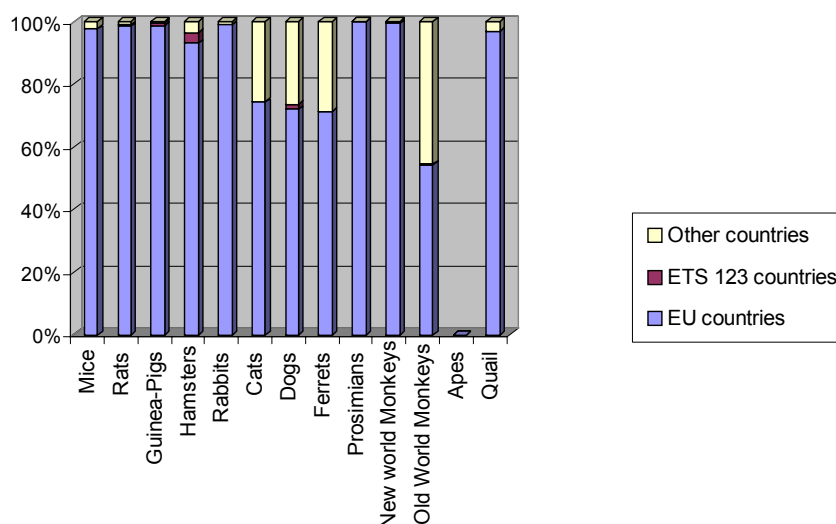
In addition, EU Table 1.3 contains information on the number of animals re-used in experiments.

III.2.2. Treatment and interpretation of the data

The data of column 1.3 and 1.4 of Table 1.3 of this report have been grouped to represent animals coming from the European Union.

Figure 1.2 represents the percentage of animals from the reported origin versus the species.

Figure 1.2: Origin of species



The chart shows clearly that the majority of the species originated from EU countries. However, certain species such as cats, dogs and ferrets and old world monkeys are also of non-European origin.

III.2.3. Comparison with data of the previous report

The general pattern on the origin of the species is quite similar to that observed in previous reports. It should be noted however, that for the first time in 2005 the prosimians were all of EU origin and remain so for this report. A similar trend can also be observed with the new world monkeys where almost all originate from either EU Member States or countries which are a party to the Council of Europe Convention ETS 123. Finally, also old world monkeys coming from the EU increased from about 26% in 2005 to more than 50% in 2008. On the other hand the number of cats of EU origin also increased whereas dogs and ferrets of non-European origin have remained unchanged since the last report.

**Table 1.3: Number of animals used in relation to their place of origin
Data of 2008 (*)**

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>)	7122188	6042205	900230	21382	158371	3768
1.b. Rats (<i>Rattus norvegicus</i>)	2121727	1761785	329385	9844	20713	3035
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	220985	161973	56167	2051	792	962
1.d. Hamsters (<i>Mesocricetus</i>)	32739	24999	5476	1074	1190	54
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	333213	315006	14753	364	3087	15958
1.g. Cats (<i>Felis catus</i>)	4088	2306	726	14	1042	1181
1.h. Dogs (<i>Canis familiaris</i>)	21315	12467	2885	309	5654	4178
1.i. Ferrets (<i>Mustela putorius furo</i>)	3208	1847	442	0	919	64
1.p. Prosimians (<i>Prosimia</i>)	1261	718	543	0	0	33
1.q. New World Monkeys (<i>Ceboidea</i>)	904	816	83	5	0	346
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	7404	3213	850	5	3336	1509
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	9626	7824	1500	0	302	0
1.z. TOTAL	9878658	8335159	1313040	35048	195406	

* France: data of 2007

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 this column

Note 2: Only species for which the origin has to be reported are included in this table

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

III.3. Results of EU Table 2: Purposes of the experiments

III.3.1. The data on purposes of the experiments

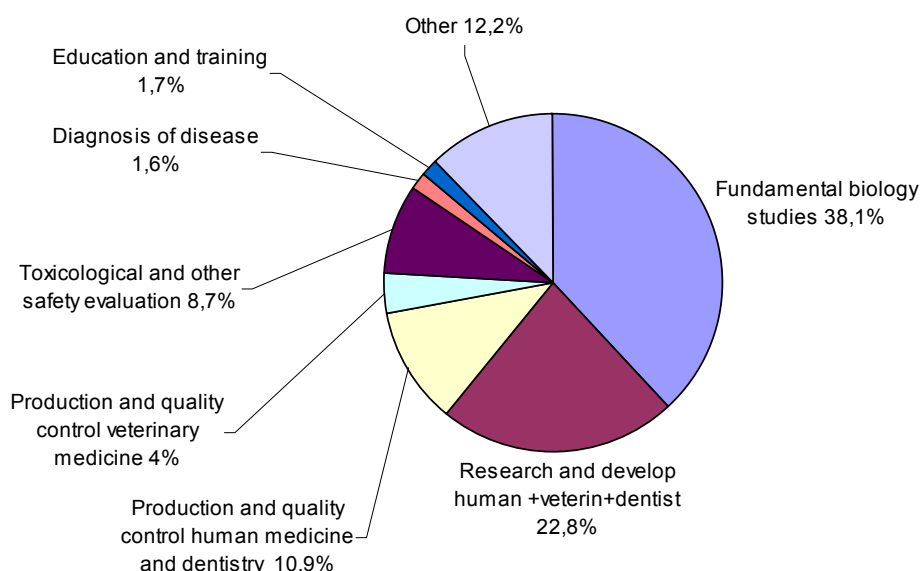
The consolidated data on purposes of the experiments of the 27 Member States are presented in Table 2.1 at the end of this chapter.

III.3.2. Treatment and interpretation of the data

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in the 27 Member States in 2008. In order to facilitate the presentation of results some species and some purposes were grouped in Table 2.2.

The percentage of the number of animals used for selected purposes is presented in Figure 2.1.

Figure 2.1
Purposes of experiments



More than 60% of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biological studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 14,9% of the total number of animals.

Toxicological and other safety evaluation represents 8,7% of the total number of animals used for experimental purposes.

Other purposes of procedures represents 12% of the total number of animals and covers a wide range of experiments such as virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgenesis,

oncological treatment, pharmaceutical research and development, combined drug testing and genetics.

III.3.3. Comparison with the data of the previous report

The comparison aims to detect changes in trends rather than draw formal conclusions. The most significant change that has taken place since 2005 is that the number of animals used for research and development for human medicine, dentistry and veterinary medicine has dropped sharply from 31% to 22,8% (in terms of animal numbers the decrease is from 3,746,028 to 2,733,706). To be noted in particular is the significant reduction of more than 800,000 cold-blooded animals since the last report of 2005. On the other hand, the percentage of animals used for fundamental biological research has increased from 33% to 38% (that is, from 4,035,470 to 4,575,054) as well as for 'other purposes', from 8% to 12%. It should be underlined that both fundamental biology and research and development in human and veterinary medicine are the areas using by far the highest number of animals for experimental purposes in the EU.

The number of animals used for toxicological and other safety evaluation has remained virtually unchanged since the last report and amounts to 8,7% of the total number of animals used for experimental purposes in the EU. This represents 1,042,153 animals.

In general the number of animals used for production and quality control of devices for medicine, veterinary medicine and dentistry has also remained unchanged since 2005. However, regarding the use by species, the use of mice and rabbits has increased substantially for production and quality control of products and devices for human medicine and dentistry. One Member State indicated that funding had been made available for pre-clinical trials for human medicine, which lead to an increase in use of experimental animals.

Another Member State using a large number of rabbits for production and quality control of veterinary medicine indicated that the laboratory responsible for that increase had reported the data in the wrong column, that is, they should have been reported under production and quality control of human medicine and dentistry rather than for products and devices for veterinary medicine. The increase was due to the production of polyclonal antibodies to improve transplant in human medicine. However, it was no longer possible to correct the error in the consolidated report.

Regarding increases in other purposes of use, there is a substantial increase in the use of mice, pigs and birds for 'fundamental biological research' and in 'other experiments'.

Several Member States confirmed that the increase in the use of mice for fundamental biological research is attributed to the new research possibilities offered by the transgenic species. These animal models are being used both for human and animal health studies. An increase was also reported for the purpose of experiments in anatomy and developmental biology, physiology, genetics and cancer research, and for immunology and microbiology.

There are several reasons for the increase in the use of pigs in 'fundamental biological' and also in 'other studies'. One Member State using a large number of pigs for fundamental biological studies and for other procedures indicated that in recent years funding for projects relating to cardiovascular research has increased significantly. The same applies in the case of experimental surgery which is taking place in many hospitals in the same Member State. Another area using an increased number of pigs relates to pig disease studies, including for

example the observation of vaccine effectiveness. It was reported that the increase was also due to fundamental research on pigs' enzymes and digestive functions, and because the tissues and organs of transgenic pigs are used for transplants in humans.

The large number of birds used for fundamental biological research in one Member State was due to a campaign of bird ringing. The increase of the number of birds used for 'other experiments' was reported to be due to parasitology/immunology studies and to the development of genetically modified birds.

Table 2.2: Number of animals used for selected purposes versus species

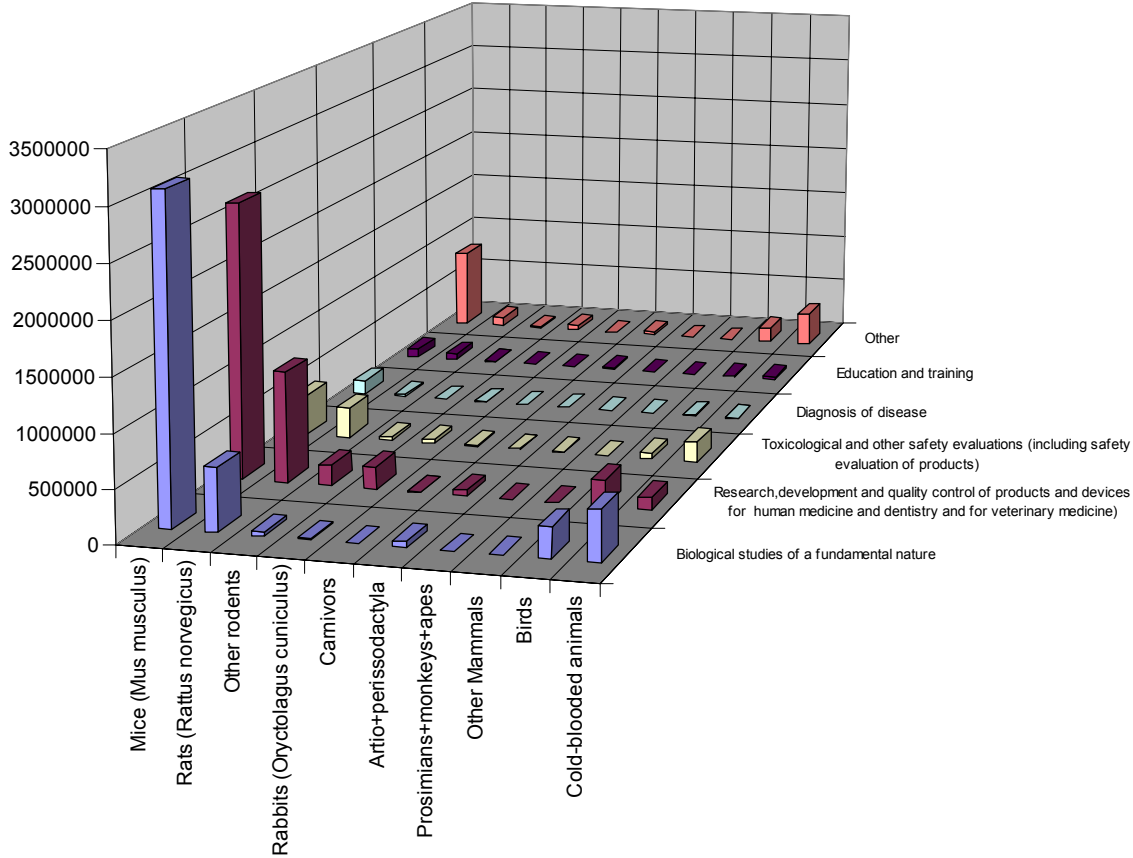
Species	Biological studies of a fundamental nature	Research, development and quality control of products and devices for human medicine and dentistry and for veterinary medicine	Toxicological and other safety evaluations (including safety evaluation of products)	Diagnoses of disease	Education and training	Other	Total
Mice	3080775	2624856	398199	137578	82606	798174	7122188
Rats	595542	1060290	294683	22997	59412	88803	2121727
Other rodents	44240	195427	33858	3145	7826	8734	293230
Rabbits	17813	212618	39987	3376	3326	56093	333213
Carnivores	4804	11378	11964	1360	515	1443	31464
Artio+perissodactyla	55080	56359	8996	4620	13134	28582	166771
Prosimians+monkeys+apes	1213	1260	6507	153	10	426	9569
Other mammals	5279	177	0	12	25	211	5704
Birds	292895	247618	53477	8415	11444	150262	764111
Cold-blooded animals	477413	113766	194482	3651	29159	334574	1153045
TOTAL	4575054	4523749	1042153	185307	207457	1467302	12001022

Figure 2.2 presents the number of animals used for selected purposes by classes of species.

The highest number of mice and rats is attributed to fundamental biological studies and research, development and quality control of products and devices for medicine, dentistry and veterinary medicine. It is noteworthy that a high number of cold-blooded animals have been used for 'other purposes' as well as for 'biological studies of a fundamental nature'.

One can observe a significant reduction in the use of cold-blooded animals for research and development of devices for human and veterinary medicine and for dentistry since the last report of 2005.

Figure 2.2
Species and experimental purposes



**Table 2.1: Number of animals used in experiments for selected purposes
Purposes versus species
data of 2008***

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
1.a. Mice (<i>Mus musculus</i>)	3080775	1597381	856048	171427	398199	137578	82606	798174	7122188
1.b. Rats (<i>Rattus norvegicus</i>)	595542	840909	181140	38241	294683	22997	59412	88803	2121727
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	10632	44344	103852	17265	31883	1940	5804	5265	220985
1.d. Hamsters (<i>Mesocricetus</i>)	6994	8041	376	12513	1580	278	520	2437	32739
1.e. Other Rodents (other Rodentia)	26614	9006	30	0	395	927	1502	1032	39506
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	17813	29764	131031	51823	39987	3376	3326	56093	333213
1.g. Cats (<i>Felis catus</i>)	560	1738	57	679	322	124	97	514	4091
1.h. Dogs (<i>Canis familiaris</i>)	1814	4405	157	2070	11077	1111	362	316	21312
1.i. Ferrets (<i>Mustela putorius furo</i>)	551	1287	564	8	269	45	56	428	3208
1.j. Other Carnivores (other Carnivora)	1879	75	0	338	296	80	0	185	2853
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	1402	728	224	2559	22	239	489	313	5976
1.l. Pigs (<i>Sus</i>)	23531	22799	423	9001	8065	1452	8134	19408	92813
1.m. Goats (<i>Capra</i>)	1098	721	93	26	43	90	422	1347	3840
1.n. Sheep (<i>Ovis</i>)	9727	4098	6020	2149	409	1616	1243	4928	30190
1.o. Cattle (<i>Bos</i>)	19322	3990	214	3314	457	1223	2846	2586	33952
1.p. Prosimians (<i>Prosimia</i>)	568	0	0	0	543	150	0	0	1261
1.q. New World Monkeys (<i>Ceboidea</i>)	235	235	33	0	270	0	0	131	904
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	410	761	231	0	5694	3	10	295	7404
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	5279	86	28	63	0	12	25	211	5704
1.u. Quail (<i>Coturnix coturnix</i>)	5520	57	0	0	2170	9	1575	295	9626
1.v. Other birds (other <i>Aves</i>)	287375	77748	10593	159220	51307	8406	9869	149967	754485
1.w. Reptiles (<i>Reptilia</i>)	3781	94	0	0	0	0	147	79	4101
1.x. Amphibians (<i>Amphibia</i>)	32780	1914	0	0	291	202	12213	14389	61789
1.y. Fish (<i>Pisces</i>)	440852	83525	20418	7815	194191	3449	16799	320106	1087155
1.z. TOTAL	4575054	2733706	1311532	478511	1042153	185307	207457	1467302	12001022

(*) France is reporting for 2007

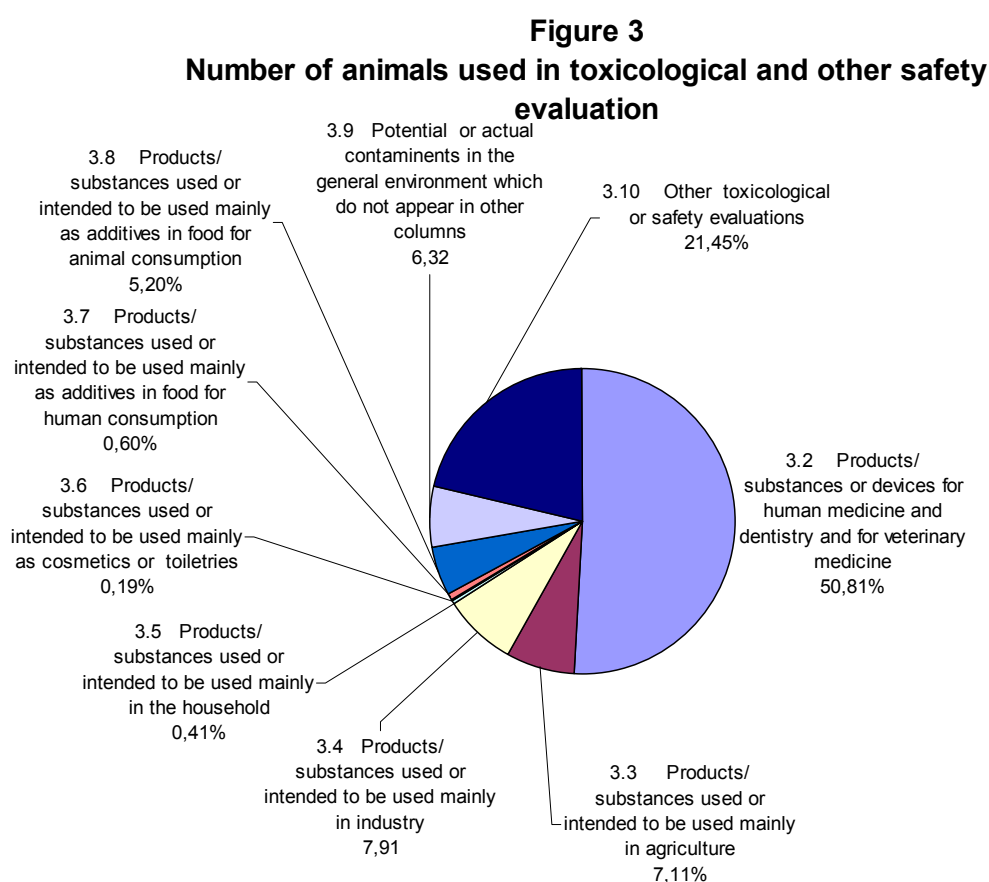
III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoint

III.4.1. The data on toxicological and safety evaluation by type of product/endpoint

The consolidated table giving the number of animals used for toxicological and other safety evaluation of products (EU Table 3) in 27 Member States in 2008 is presented in Table 3.1 at the end of this chapter. In table 3.1 the number of animals used for toxicological or other safety evaluation is broken down into types of products for which testing was required.

The percentage of the number of animals used for different types of product is presented in Figure 3.

III.4.2. Treatment and interpretation of the data



The number of animals used for toxicological and other safety evaluation for different products or environmental test schemes amounts to 1,042,153, which represents 8,7% of the total number of animals used for experimental purposes in 2008 (see Table 2.1, column 2.6).

Toxicological or other safety evaluations are split up according to the type of sector for which they are intended. The percentage of animals used for toxicological evaluation of three groups of products/substances, i.e. additives in food for human consumption, cosmetics and household products, is very small (1,18%) when compared to the other product groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents 50,8% of the animals used for toxicological or other safety evaluations.

The group of products/substances falling under the scrutiny of Member States authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used 15% of the animals for toxicological and other safety evaluations.

There is a clear decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture and for potential contaminants of the environment. The decrease ranges respectively from above 96,000 to about 82,000; from below 98,000 to about 74,000 and from above 84,000 to about 65,000 in comparison to the data submitted in the 2005 statistical report.

There is also a significant decrease in the number of animals used for testing of products for cosmetics and toiletries ranging from 5,500 to just below 2,000 (a 65% drop). This change has to be seen in light of the legal requirement to phase out animal testing for cosmetics in the EU where a ban on testing has been applicable since 2009 for all human health effects with the exception of three toxicological end-points: repeated-dose toxicity, reproductive toxicity and toxicokinetics. The year 2013 is the deadline for a marketing ban for cosmetics tested for these remaining specific health effects.

There is however also a significant increase since 2005 in the number of animals used for tests for additives in food for animal consumption (from 34,225 to 54,164). This may reflect the animal feed sanitary concerns expressed in the EU after the discovery of harmful contaminants in such products over the last 10 years.

It should also be noted that in comparison to the 2005 report, there is a significant increase in the number of animals used for 'other' toxicological or safety evaluation (ranging from around 180,000 to about 220,000). Member States reported that this particular use of animals concerned new methods and tests, such as tests on transmission of microcystins on embryonic membrane, bioassays, toxicity evaluation for humans via the environment, and control of safety of toys.

**Table 3.1: Number of animals used in toxicological and other safety evaluation
Products versus species**

Data of 2008*

3.1.Species	3.2. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3. Products/ substance s used or intended to be used mainly in agriculture	3.4.Products / substances used or intended to be used mainly in industry	3.5.Products / substances used or intended to be used mainly in the household	3.6.Products / substances used or intended to be used mainly as cosmetics or toiletries	3.7.Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8.Products / substances used or intended to be used mainly as additives in food for animal consumption	3.9.Potential or actual contaminants in the general environment which do not appear in other columns	3.10.Other toxicological or safety evaluations	3.11.Total
1.a. Mice (<i>Mus musculus</i>)	188227	10129	20249	1922	880	2818	1680	9433	162919	398257
1.b. Rats (<i>Rattus norvegicus</i>)	187283	31421	41562	1709	174	2764	303	2932	26496	294644
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	23152	2830	3679	0	38	24	7	0	2192	31922
1.d. Hamsters (<i>Mesocricetus</i>)	1559	0	21	0	0	0	0	0	0	1580
1.e. Other Rodents (other Rodentia)	0	164	0	0	0	0	0	204	27	395
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	30516	2696	4453	50	153	11	7	12	2127	40025
1.g. Cats (<i>Felis catus</i>)	312	0	0	0	0	0	0	0	10	322
1.h. Dogs (<i>Canis familiaris</i>)	9888	340	16	0	0	0	0	0	833	11077
1.i. Ferrets (<i>Mustela putorius furo</i>)	269	0	0	0	0	0	0	0	0	269
1.j. Other Carnivores (other Carnivore)	296	0	0	0	0	0	0	0	0	296
1.k. Horses, donkeys and cross breeds (Equidae)	22	0	0	0	0	0	0	0	0	22
1.l. Pigs (<i>Sus</i>)	3169	90	0	0	0	100	4584	64	66	8073
1.m. Goats (<i>Capra</i>)	21	14	0	0	0	0	0	8	0	43
1.n. Sheep (<i>Ovis</i>)	408	0	0	0	0	0	0	0	1	409
1.o. Cattle (<i>Bos</i>)	409	4	0	0	0	0	0	0	44	457
1.p. Prosimians (Prosimia)	543	0	0	0	0	0	0	0	0	543
1.q. New World Monkeys (Ceboidea)	200	0	0	0	0	0	0	0	70	270
1.r. Old World Monkeys (Cercopithecoidea)	5121	0	0	0	0	0	0	0	573	5694
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	210	0	0	0	0	0	0	0	210
1.u. Quail (<i>Coturnix coturnix</i>)	64	2110	0	0	0	0	0	0	0	2174
1.v. Other birds (other Aves)	8838	2116	30	0	0	0	39553	97	320	50954
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	179	108	0	0	0	0	0	0	4	291
1.y. Fish (Pisces)	69021	21915	12416	601	722	523	8030	53062	27936	194226
1.z. TOTAL	529497	74147	82426	4282	1967	6240	54164	65812	223618	1042153

(*) France reporting for 2007

III.5. Results of EU Table 4: Animals used for studies of diseases

III.5.1. The data on animals used for studies of diseases

The consolidated table of results on animals used for studies of diseases (EU Table 4) in the 27 Member States is presented in Table 4.1 at the end of this chapter.

III.5.2. Treatment and interpretation of the data

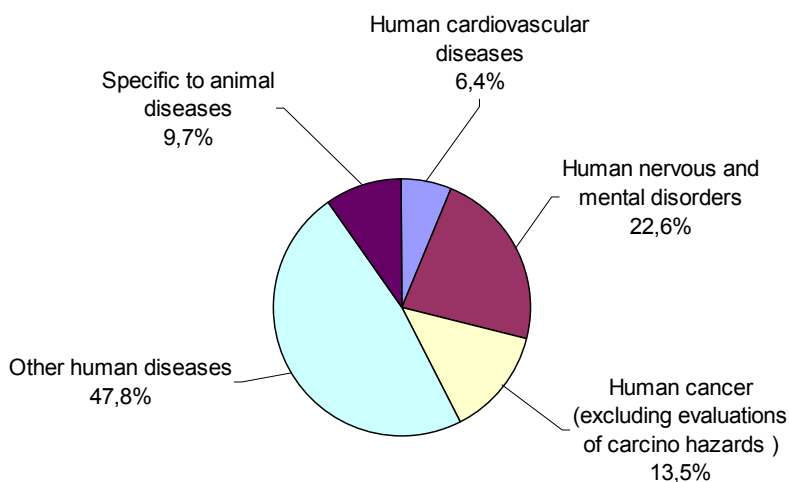
Table 4.1 gives the number of animals used per type of studies on diseases.

In 2008 the number of animals used for the study of both animal and human diseases represented about 6,322,000 animals which is more than half (52%) the total number of animals used for experimental purposes in the EU.

Figure 4.1 presents the percentage of animals used in studies per type of diseases.

The proportion of animals used for studies of human diseases represents more than 90% of the total number of animals used for all disease studies.

Figure 4.1
Proportion of animals used for the studies of diseases



Overall in 2008 there is a 50% decrease in the number of animals used for studies on specific animal diseases - from 1,329,000 to 614,000. In particular, a significant change occurred in the use of cold-blooded species where figures decreased from around 954,000 animals in 2005 to 43,914 in 2008.

Interesting to note is that despite the overall decrease, the use of mice increased substantially in 2008. Around 30% of the increase (about 681,000) can be attributed to different studies of diseases (see also observations under chapter III.3.3).

Some Member States confirmed that the increase of the use of animals in general, or mice in particular in table 4, is also reported under several headings of table 2, such as fundamental biological research and research and development of products for human and veterinary medicine and even production and control process for human and veterinary medicine. For the 2008 data one Member States indicated, however, that the increase of use of mice was primarily attributed to fundamental biological research.

It should be remembered that the studies on specific animal diseases are important in light of epidemic diseases affecting animals such as in the case of foot and mouth disease, swine fever and more recently avian flu. However, animals have also been used in studies on genetic diseases. According to 2008 data there has been more than a 50% reduction in animals used for studies on animal diseases. This could be because there have been no new significant animal disease epidemics in 2008 or in the preceding years.

The above observation is not necessarily reflected in the use of all species in particular for the use of mice and other birds by some Member States.

Regarding the specific animal diseases studies linked to the increase in the number of birds, Member States reported studies on bird flu, Gumboro disease and bronchitis including studies on quality and safety of vaccines.

Table 4.1: Number of animals used in experiments for studies on human and animal diseases
Main category of diseases versus species
Data of 2008 *

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
1.a. Mice (<i>Mus musculus</i>)	249486	858612	803038	1883499	292772	4087407
1.b. Rats (<i>Rattus norvegicus</i>)	125904	489630	43336	600979	16909	1276758
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	2856	5004	262	47326	3252	58700
1.d. Hamsters (<i>Mesocricetus</i>)	1940	2986	791	6751	3104	15572
1.e. Other Rodents (other Rodentia)	673	6737	239	5093	4617	17359
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	5373	1386	1781	28138	6983	43661
1.g. Cats (<i>Felis catus</i>)	14	169	0	126	1930	2239
1.h. Dogs (<i>Canis familiaris</i>)	1233	207	144	4544	3810	9938
1.i. Ferrets (<i>Mustela putorius furo</i>)	20	184	0	2153	105	2462
1.j. Other Carnivores (other Carnivore)	72	0	0	468	411	951
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	3	0	0	154	1614	1771
1.l. Pigs (<i>Sus</i>)	4638	417	100	9589	17299	32043
1.m. Goats (<i>Capra</i>)	170	39	87	478	1014	1788
1.n. Sheep (<i>Ovis</i>)	597	601	24	8065	6833	16120
1.o. Cattle (<i>Bos</i>)	243	36	0	2860	13756	16895
1.p. Prosimians (<i>Prosimia</i>)	0	40	0	311	370	721
1.q. New World Monkeys (<i>Ceboidea</i>)	7	101	0	419	21	548
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	111	261	6	3173	8	3559
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	29	55	5	887	449	1425
1.u. Quail (<i>Coturnix coturnix</i>)	0	400	0	177	413	990
1.v. Other birds (other <i>Aves</i>)	4769	4563	47	21365	194727	225471
1.w. Reptiles (<i>Reptilia</i>)	0	90	0	0	934	1024
1.x. Amphibians (<i>Amphibia</i>)	362	603	2886	10852	2022	16725
1.y. Fish (<i>Pisces</i>)	5841	57964	2458	381109	40958	488330
1.z. TOTAL	404341	1430085	855204	3018516	614311	6322457

France reporting for 2007

Table 4.2: Number of animals used in studies of diseases by classes of animals

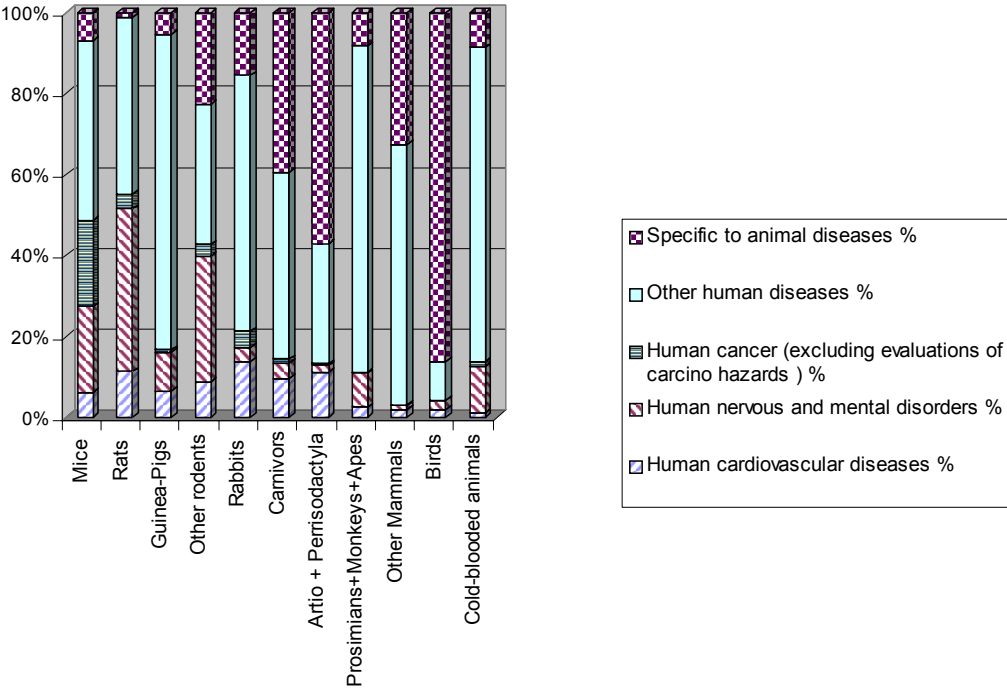
Classes of animals	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino. hazards)	Other human diseases	Specific animal diseases	Total
Mice	249486	858612	803038	1883499	292772	4087407
Rats	125904	489630	43336	600979	16909	1276758
Guinea-Pigs	2856	5004	262	47326	3252	58700
Other rodents	2613	9723	1030	11844	7721	32931
Rabbits	5373	1386	1781	28138	6983	43661
Carnivores	1339	560	144	7291	6256	15590
Artio + Perrisodactyla	5651	1093	211	21146	40516	68617
Prosimians+Monkeys+Apes	118	402	6	3903	399	4828
Other Mammals	29	55	5	887	449	1425
Birds	4769	4963	47	21542	195140	226461
Cold-blooded animals	6203	58657	5344	391961	43914	506079
TOTAL	404341	1430085	855204	3018516	614311	6322457

Classes of animals%	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino. hazards)	Other human diseases	Specific animal diseases	Total
Mice	6,10	21,01	19,65	46,08	7,16	100,00
Rats	9,86	38,35	3,39	47,07	1,32	100,00
Guinea-Pigs	4,87	8,52	0,45	80,62	5,54	100,00
Other rodents	7,93	29,53	3,13	35,97	23,45	100,00
Rabbits	12,31	3,17	4,08	64,45	15,99	100,00
Carnivores	8,59	3,59	0,92	46,77	40,13	100,00
Artio + Perrisodactyla	8,24	1,59	0,31	30,82	59,05	100,00
Prosimians+Monkeys+Apes	2,44	8,33	0,12	80,84	8,26	100,00
Other Mammals	2,04	3,86	0,35	62,25	31,51	100,00
Birds	2,11	2,19	0,02	9,51	86,17	100,00
Cold-blooded animals	1,23	11,59	1,06	77,45	8,68	100,00

Species of Table 4.1 were grouped into classes of animals and presented in Table 4.2. The relative percentage of animals per class of species used in studies by type of disease has been calculated and is also presented in the lower part of Table 4.2.

Figure 4.2 presents the proportion of animals used by classes per type of studies of diseases.

Figure 4.2
Proportion of animals used by classes per type of studies of diseases



The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Significant numbers of both *artiodactyla* and *perissodactyla* and birds are used for this purpose. Member States reported that it is still current practice to test vaccines on these species. However, in some Member States only birds are used if the infection concerns bird species.

The data on the use of most species for all types of studies on both human and animal diseases show a great similarity to the data of 2005. However, there is a substantial decrease in the use of ‘other mammals’ for studies of human diseases in particular ‘other human diseases’, whereas the opposite is observed for cold-blooded animals which have been more widely used in studies on human diseases rather than animal diseases.

III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

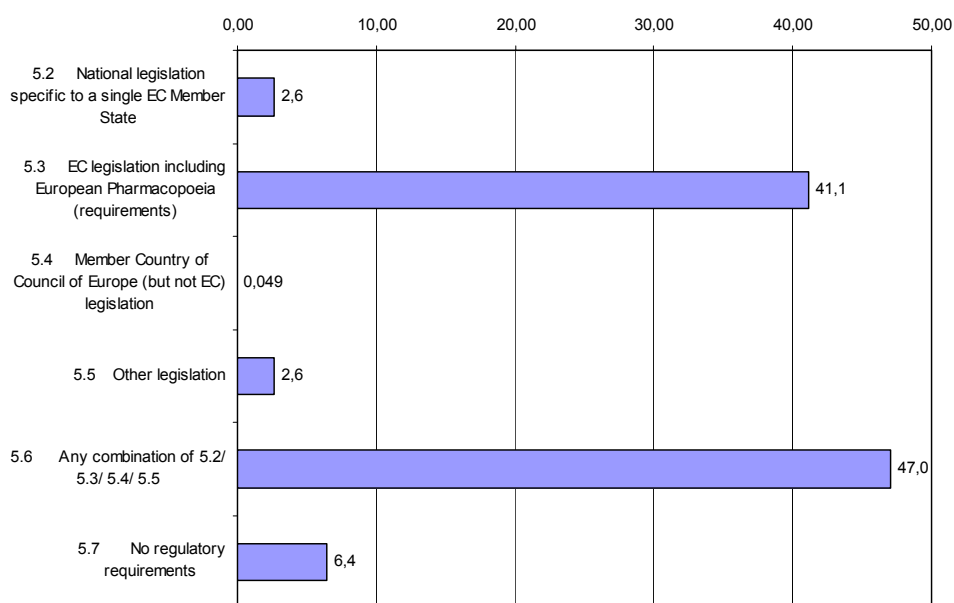
III.6.1. The data on animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The consolidated table for the 27 Member States reporting the origin of the regulatory requirements in relation to animals used for the production and quality control of products for human medicine and dentistry and for veterinary medicine (EU Table 5) is presented in Table 5.1 at the end of this chapter.

III.6.2. Treatment and interpretation of the data

The number of animals used in tests for the production and quality control of products for human medicine and dentistry and for veterinary medicine represents 14,9% of the total number of animals used for experimental purposes. Figure 5 gives the percentages of the animals used to satisfy the different regional regulatory requirements in this area.

Figure 5
Percentages of animals used for regulatory requirements for the production and quality control of products and devices for human medicine, dentistry and for veterinary medicine



The largest proportion of animals in this area (47%) was used to satisfy requirements from several pieces of legislation (from national, the EU, the Council of Europe member country legislation, and from legislation outside of the EU (Fig 5)). The testing carried out to satisfy EU legislation including the European Pharmacopoeia covered 41,1% of the animals used in this area.

In comparison to the report of 2005 there is a net decrease in the number of animals used to satisfy simultaneously several pieces of legislation. On the other hand there is a net increase of tests carried out for the European legislation (including the European Pharmacopoeia).

Consequently, there is a net decrease in the number of animals used to satisfy national legislation, which is an encouraging trend showing an attempt to move towards EU harmonisation of regulatory requirements.

Table 5.1: Number of animals used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine
Regulatory requirements versus species
Data of 2008 *

5.1. Species	5.2. National legislation specific to a single EC Member State1	5.3. EC legislation including European Pharmacopoeia (requirements)	5.4. Member Country of Council of Europe (but not EC) legislation2)	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
1.a. Mice (<i>Mus musculus</i>)	33233	359722	371	21567	569279	43303	1027475
1.b. Rats (<i>Rattus norvegicus</i>)	5107	86403	405	16406	105741	5319	219381
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	2519	43916	0	6494	62550	5615	121094
1.d. Hamsters (<i>Mesocricetus</i>)	0	8916	0	358	3613	2	12889
1.e. Other Rodents (other Rodentia)	0	0	0	0	30	0	30
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	851	107271	0	1077	53039	20539	182777
1.g. Cats (<i>Felis catus</i>)	43	614	0	8	58	10	733
1.h. Dogs (<i>Canis familiaris</i>)	208	985	0	0	982	55	2230
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	2	0	0	522	48	572
1.j. Other Carnivores (other Carnivore)	27	311	0	0	0	0	338
1.k. Horses, donkeys and cross breeds (Equidae)	307	225	0	0	164	2087	2783
1.l. Pigs (<i>Sus</i>)	518	5436	0	91	2385	994	9424
1.m. Goats (<i>Capra</i>)	68	27	0	3	10	11	119
1.n. Sheep (<i>Ovis</i>)	805	1523	54	5	703	5079	8169
1.o. Cattle (<i>Bos</i>)	139	2500	0	6	414	469	3528
1.p. Prosimians (Prosimia)	0	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	0	0	0	0	33	0	33
1.r. Old World Monkeys (Cercopithecoidea)	0	0	0	0	231	0	231
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	13	50	0	0	0	28	91
1.u. Quail (<i>Coturnix coturnix</i>)	0	0	0	0	0	0	0
1.v. Other birds (other Aves)	1887	117540	60	1676	41194	7556	169913
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	0	0	0	0	0
1.y. Fish (Pisces)	2260	1430	0	0	406	24137	28233
1.z. TOTAL	47985	736871	890	47691	841354	115252	1790043

(*) France reporting for 2007

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, Croatia, Iceland, Liechtenstein, Moldova, Norway, Russia, San Marino, Switzerland, 'the former Yugoslav Rep. of Macedonia' Turkey, Ukraine

III.7. Results of EU harmonized Table 6: Origin of regulatory requirements for animals used in toxicological and other safety evaluations

III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

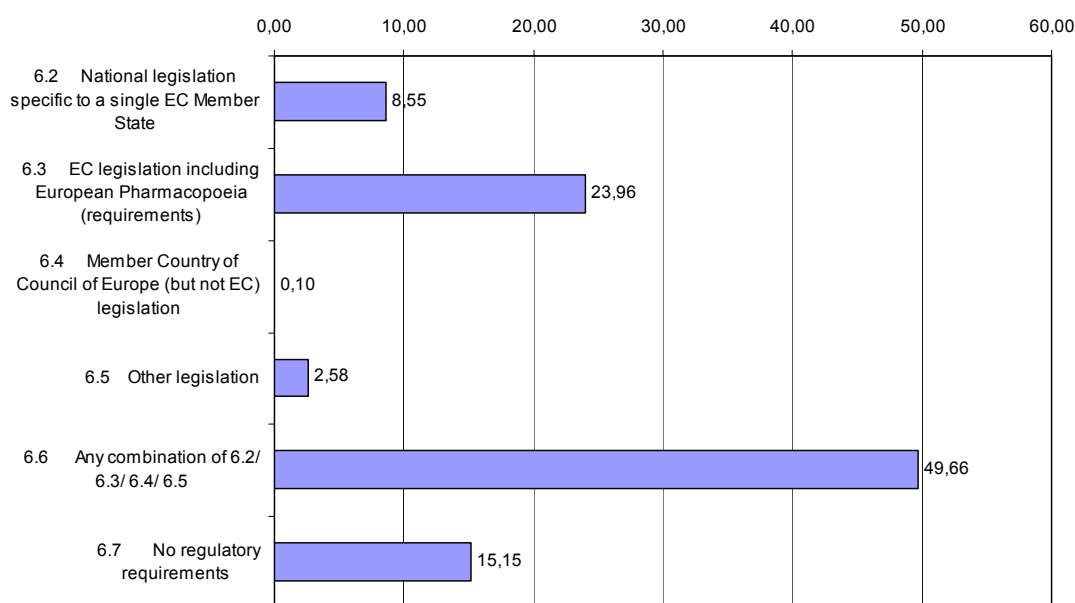
The consolidated table for the 27 Member States reporting data on animals used in toxicological and other safety evaluations in relation to the origin of regulatory requirements (EU Table 6) is presented in Table 6.1 at the end of this chapter.

III.7.2. Treatment and interpretation of the data

The use of animals for the regulatory requirements of different regions in the area of toxicological or other safety evaluation presented in Figure 6 follows a similar pattern to that of the use of animals used for regulatory purposes in human medicine, dentistry and in veterinary medicine in different regions, presented in the Figure 5 in the previous chapter.

As pointed out earlier, the number of animals used in toxicological or other safety evaluation represents 8,7% of the total number of animals used for experimental purposes in the EU.

Figure 6
Percentages of animals used for regulatory requirements for toxicological and other safety evaluation



Animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered almost half of the animals used in this area (50%). The testing required under EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area, namely 24%.

The increase of the numbers of animals used for toxicological and other safety evaluations since the last report is relatively low and represents about 15,800 animals.

In comparison to the last report there is a net slight decrease in the proportion of animals used to simultaneously satisfy several pieces of regional legislation from 54% to nearly 50%.

However, there is a substantial increase in the proportion of animals used for no regulatory requirements. In order to explain what is meant by the term 'no regulatory requirements', some Member States gave as an example projects using in-house methods to verify the safety and efficacy of veterinary biologicals and medicinal products using animals, and carried out according to a company's standards. The results may be accepted by that Member State national authority, although not required by legislation.

The testing carried out in 2008 to satisfy national legislation specific to a single Member State showed a decrease of about 7,500 animals which represents roughly a 1% decrease compared to the last report.

**Table 6.1: Number of animals used in toxicological and other safety evaluations
Regulatory requirements versus species**

Data of 2008*

6.1. Species	6.2. National legislation specific to a single EC Member State1)	6.3. EC legislation including European Pharmacopoeia (requirements)	6.4. Member Country of Council of Europe (but not EC) legislation2)	6.5. Other legislation	6.6. Any combination of 5.2/ 5.3/ 5.4/ 5.5	6.7. No regulatory requirements	6.8.Total
1.a. Mice (<i>Mus musculus</i>)	35721	129353	752	5034	198942	28397	398199
1.b. Rats (<i>Rattus norvegicus</i>)	17191	51343	89	11496	194371	20093	294583
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	660	14723	84	390	15166	960	31983
1.d. Hamsters (<i>Mesocricetus</i>)	101	238	0	0	1106	135	1580
1.e. Other Rodents (other Rodentia)	204	0	0	0	191	0	395
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	1179	12694	2	1744	23426	942	39987
1.g. Cats (<i>Felis catus</i>)	97	126	4	0	85	10	322
1.h. Dogs (<i>Canis familiaris</i>)	626	1421	58	769	8023	180	11077
1.i. Ferrets (<i>Mustela putorius furo</i>)	211	32	0	26	0	0	269
1.j. Other Carnivores (other Carnivore)	296	0	0	0	0	0	296
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0	0	0	0	1	21	22
1.l. Pigs (<i>Sus</i>)	172	1177	8	181	6102	425	8065
1.m. Goats (<i>Capra</i>)	29	0	0	0	14	0	43
1.n. Sheep (<i>Ovis</i>)	2	75	0	0	322	10	409
1.o. Cattle (<i>Bos</i>)	10	226	0	44	173	0	453
1.p. Prosimians (<i>Prosimia</i>)	0	543	0	0	0	0	543
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	246	24	270
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	265	0	732	4599	98	5694
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	24	680	0	0	1466	0	2170
1.v. Other birds (other <i>Aves</i>)	10	7406	0	5000	36017	2798	51231
1.w. Reptiles (<i>Reptilia</i>)	0	0	0	0	0	0	0
1.x. Amphibians (<i>Amphibia</i>)	0	0	0	0	179	112	291
1.y. Fish (<i>Pisces</i>)	32582	29413	0	1517	27071	103688	194271
1.z. TOTAL	89115	249715	997	26933	517500	157893	1042153

(*France is reporting for 2007

- 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, Croatia, Iceland, Liechtenstein, Moldova, Norway, Russia, San Marino, Switzerland, 'the former Yugoslav Rep. of Macedonia' Turkey, Ukraine

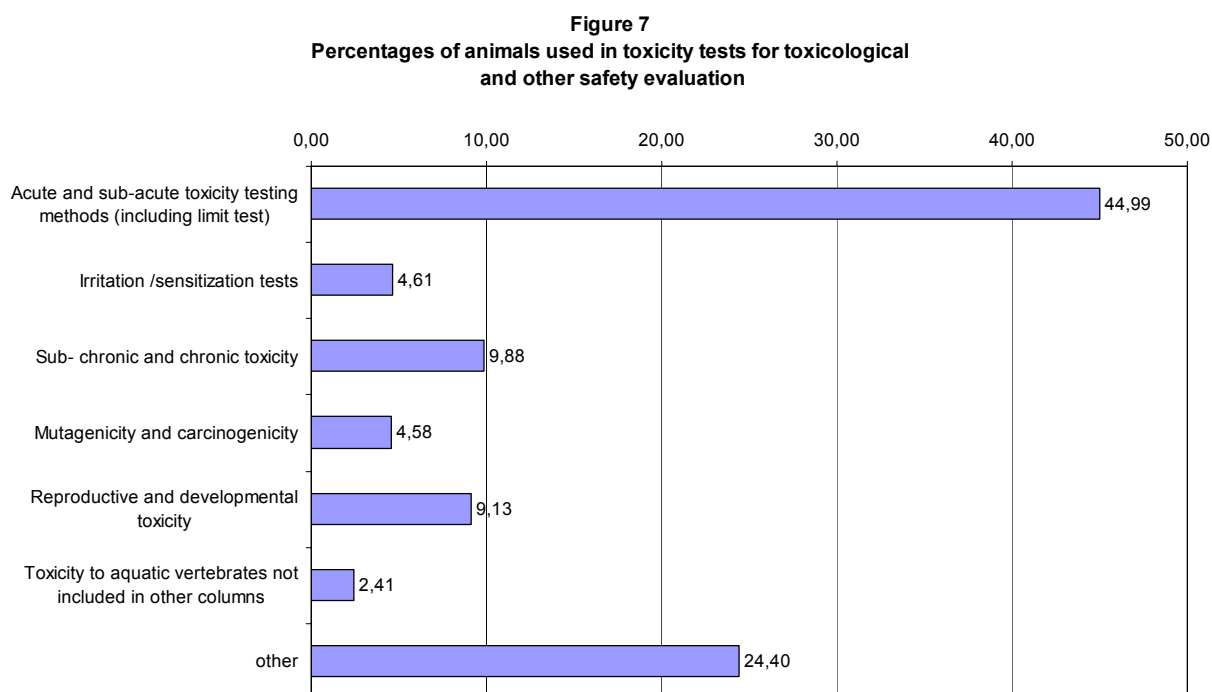
III.8. Results of EU Table 7: Animals used in toxicity tests for toxicological and other safety evaluations

III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

The consolidated table for the 27 Member States reporting on animals used in toxicity tests for the purpose of toxicological and other safety evaluations of products (EU Table 7) is presented in Table 7.1 at the end of this chapter.

III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of Table 7.1 have been grouped according to systemic and local toxicity and CMR (carcinogenicity, mutagenicity and toxicity to reproduction) effects in Table 7.2. A graph showing the percentage of animals used per toxicity test groups in 2008 is presented in Figure 7.



As pointed out in the previous chapter, the number of animals used in toxicological and other safety evaluations represents 8,7% of the total number of animals used for experimental purposes.

In Figure 7 the largest percentage (almost 45%) of use of animals in toxicological and other safety evaluations is due to acute and sub-acute toxicity tests. Also taking into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for 55% in this area.

13,7% of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction. Another important category of use of animals in 2008 is for 'other tests' with 24%. Breaking down further the category 'other', Member States reported testing in areas such as biological screening for pharmaceutical, healthcare and veterinary products. This includes neurotoxicity, toxicokinetics, testing of biological evaluation of medical devices: Intracutaneous testing of reactivity in rabbits, studies into the penetration of nanoparticles through tissue and

their biocompatibility, studies into the evaluation of sensitization potential of dyestuffs used in the textile industry and pharmacological studies included in safety tests.

By looking both in numbers and relative percentages of use of animals in comparison to the previous reports there are two noticeable changes:

There is a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests, ranging from 36% - 42% to almost 45% respectively. This represents in animal numbers an increase of more than 37,000 animals since the last report. Member States attributed the increase in part to several phases in new product development and new legislation, for example requiring that all generic substances should be tested.

On the other hand one can observe a steady decrease over the last three reports of the animals used for reproductive toxicity testing from: 12% to 10% and to 9% respectively. This demonstrates a saving since the 2005 report of 8,650 animals.

A general decrease in the number of animals used for regulatory toxicological evaluation could be attributed to the use of alternative methods according to some Member States. However, others have suggested that replacement methods have a much greater impact on research and development than on regulatory requirements.

**Table 7.1: Number of animals used in toxicological and other safety evaluations
Type of tests versus species**

Data of 2008*

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. Carcinogenicity	7.8. Develop-mental toxicity	7.9. Muta-genicity	7.10. Repro-ductive toxicity	7.11. Toxicity to aquatic vertebrates 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											
1.a. Mice (<i>Mus musculus</i>)	87440	87455	46654	926	16742	30	27173	10375	3744	12858	2759	200	101843	398199
1.b. Rats (<i>Rattus norvegicus</i>)	7060	12651	74924	768	1465	78	54915	10219	20263	14043	51314	26	46957	294683
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	1000	303	3363	140	20198	6	618	0	120	0	101	7	6027	31883
1.d. Hamsters (<i>Mesocricetus</i>)	16	0	343	22	0	0	310	0	0	21	0	0	868	1580
1.e. Other Rodents (other Rodentia)	27	0	0	0	0	0	204	0	0	0	0	0	164	395
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	110	38	5875	4200	32	2105	1240	0	6047	0	5349	7	14984	39987
1.g. Cats (<i>Felis catus</i>)	0	0	24	0	0	0	62	0	0	0	0	0	236	322
1.h. Dogs (<i>Canis familiaris</i>)	15	339	4637	0	0	0	4582	0	0	0	20	0	1484	11077
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	211	0	0	0	0	0	0	0	0	0	58	269
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0	0	296	296
1.k. Horses, donkeys and cross breeds (Equidae)	0	0	0	0	0	0	0	0	0	0	0	0	22	22
1.l. Pigs (<i>Sus</i>)	0	11	535	115	0	0	937	0	0	0	112	0	6355	8065
1.m. Goats (<i>Capra</i>)	0	0	0	0	0	0	0	0	0	0	0	0	43	43
1.n. Sheep (<i>Ovis</i>)	0	0	36	0	0	0	34	0	0	0	0	0	339	409
1.o. Cattle (<i>Bos</i>)	0	0	60	0	0	0	12	0	0	0	22	0	359	453
1.p. Prosimians (Prosimia)	0	0	261	0	0	0	143	0	0	0	0	0	139	543
1.q. New World Monkeys (Ceboidea)	0	0	65	0	0	0	71	0	64	0	0	0	70	270
1.r. Old World Monkeys (Cercopithecoidea)	18	0	1735	0	0	0	2861	0	176	0	58	0	846	5694
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	819	241	0	0	0	0	0	0	0	0	176	0	934	2170
1.v. Other birds (other Aves)	456	135	5937	1020	0	65	0	0	0	0	108	0	43510	51231
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	0	0	0	0	108	0	4	0	0	0	179	291
1.y. Fish (Pisces)	50983	70000	5110	119	0	0	9735	213	868	0	3796	24857	28590	194271
1.z. TOTAL	147944	171173	149770	7310	38437	2284	103005	20807	31286	26922	63815	25097	254303	1042153

(*) France reporting for 2007

Table 7.2: Grouping of certain type of tests on animals of table 7.1

7.1. Species	Acute and sub-acute toxicity testing methods (including limit test)	Irritation /sensitization tests	Sub- chronic and chronic toxicity	Mutagenicity and carcinogenicity	Reproductive and developmental toxicity	Toxicity to aquatic vertebrates not included in other columns	other	Total
1.a. Mice (<i>Mus musculus</i>)	221549	17698	27173	23233	6503	200	101843	398199
1.b. Rats (<i>Rattus norvegicus</i>)	94635	2311	54915	24262	71577	26	46957	294683
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	4666	20344	618	0	221	7	6027	31883
1.d. Hamsters (<i>Mesocricetus</i>)	359	22	310	21	0	0	868	1580
1.e. Other Rodents (other Rodentia)	27	0	204	0	0	0	164	395
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	6023	6337	1240	0	11396	7	14984	39987
1.g. Cats (<i>Felis catus</i>)	24	0	62	0	0	0	236	322
1.h. Dogs (<i>Canis familiaris</i>)	4991	0	4582	0	20	0	1484	11077
1.i. Ferrets (<i>Mustela putorius furo</i>)	211	0	0	0	0	0	58	269
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	296	296
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0	0	0	0	0	0	22	22
1.l. Pigs (<i>Sus</i>)	546	115	937	0	112	0	6355	8065
1.m. Goats (<i>Capra</i>)	0	0	0	0	0	0	43	43
1.n. Sheep (<i>Ovis</i>)	36	0	34	0	0	0	339	409
1.o. Cattle (<i>Bos</i>)	60	0	12	0	22	0	359	453
1.p. Prosimians (Prosimia)	261	0	143	0	0	0	139	543
1.q. New World Monkeys (Ceboidea)	65	0	71	0	64	0	70	270
1.r. Old World Monkeys (Cercopithecoidea)	1753	0	2861	0	234	0	846	5694
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	1060	0	0	0	176	0	934	2170
1.v. Other birds (other Aves)	6528	1085	0	0	108	0	43510	51231
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	108	0	4	0	179	291
1.y. Fish (<i>Pisces</i>)	126093	119	9735	213	4664	24857	28590	194271
1.z. TOTAL	468887	48031	103005	47729	95101	25097	254303	1042153

III.9. Results of EU Table 8: Type of toxicity tests carried out for toxicological and other safety evaluations of products

III.9.1. The data on type of toxicity tests carried out for toxicological and other safety evaluations of products

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products for the 27 Member States reporting (EU table 8) is presented in table 8.1 of this report. The data in table 8 have been subjected to a further quality criteria check developed by the Commission. The data provided by all Member States for this report were coherent.

III.9.2. Treatment and interpretation of the data

As pointed out earlier, animals used in toxicological and other safety evaluation represent 8,7% of the total number of animals used for experimental purposes.

In order to facilitate the interpretation of the results some types of toxicity testing have been grouped and the results can be found in consolidated table 8.2 at the end of this chapter. Figure 8 gives the proportion of animals used for toxicity and other safety evaluation by types of products.

The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products was done for the first time in the Fifth Statistical Report. However, because the graph in that report represented more the relative importance of tests within a type of product rather than the proportion of animals used per type of test for the different products, the graph was modified accordingly for this report.

Figure 8
Proportion of animals used for toxicity tests for toxicological and other safety evaluation by types of products

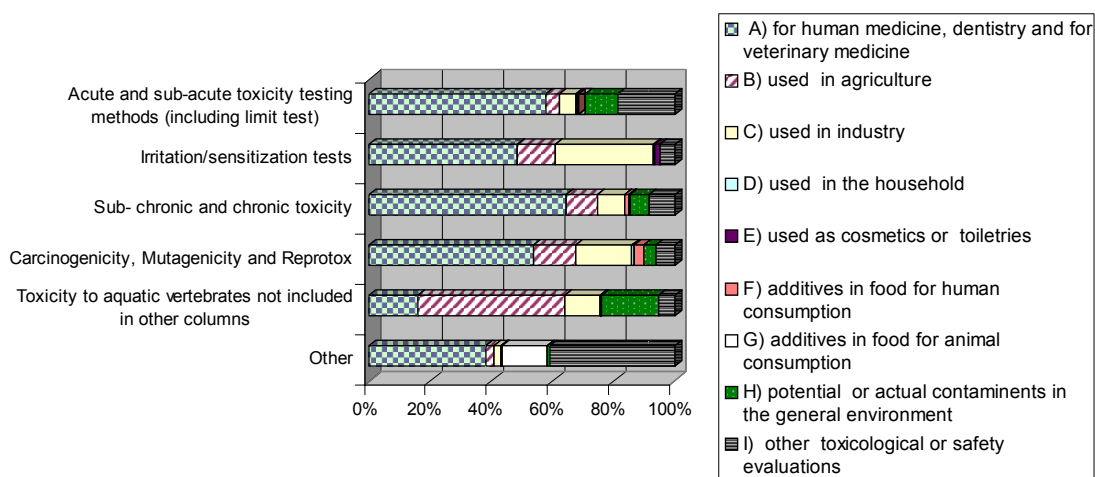


Figure 8 shows that the majority of animals tested in acute/sub-acute toxicity are intended for the purpose of human medicine, dentistry and veterinary medicine. This is followed by tests carried out for other toxicological or safety evaluation and then for agriculture and industrial products.

Products intended for medicine, dentistry and veterinary medicine require the highest proportion of animals for the different types of tests i.e. approximately 50%. The next highest proportion is for 'other' toxicological evaluations, above 20%, followed by animals used in tests for products for agriculture and industry each above 7%.

**Table 8.1: Number of animals used in toxicological and other safety evaluations
Type of tests versus products**

Data of 2008*

8.1. Products	8.2. Acute and sub-acute toxicity testing methods (including limit test)			8.3. Skin irritation	8.4. Skin sensitisation	8.5. Eye irritation	8.6. Sub-chronic and chronic toxicity	8.7. Carcinogenicity	8.8. Developmental toxicity	8.9. Mutagenicity	8.10. Reproductive toxicity	8.11. Toxicity to aquatic vertebrates not included in other columns	8.12. Other	8.13. Total
	8.2.1. LD50, LC50	8.2.2. Other lethal methods	8.2.3. Non lethal clinical signs methods											
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	43643	85795	116481	3732	17719	506	62442	15063	12314	14286	37079	3917	116640	529617
8.b. Products/ substances used or intended to be used mainly in agriculture	9066	4192	4987	724	4252	581	10089	3590	3120	2224	11578	11884	7860	74147
8.c. Products/ substances used or intended to be used mainly in industry	5263	4832	12483	2368	11129	1001	8324	306	11475	6490	8863	2870	7022	82426
8.d. Products/ substances used or intended to be used mainly in the household	617	1636	50	143	0	27	159	0	0	114	1016	0	520	4282
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	822	207	98	87	699	54	0	0	0	0	0	0	0	1967
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	64	112	213	3	0	6	1421	649	3157	320	167	0	128	6240
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	0	9142	177	0	0	0	100	0	0	0	0	80	44665	54164
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	37714	6243	2206	119	0	0	6294	213	85	1502	4111	4713	3410	66610
8.i. Other toxicological or safety evaluations	10080	60404	7909	173	1797	94	8004	2625	319	2937	3176	1234	123948	222700
8.j. TOTAL	107269	172563	144604	7349	35596	2269	96833	22446	30470	27873	65990	24698	304193	1042153

(*) France reporting for 2007

Table 8.2: Number of animals used in toxicological and other safety evaluation per types of products

8.1. Products	Acute and sub-acute toxicity testing methods (including limit test)	Irritation/sensitization tests	Sub-chronic and chronic toxicity	carcinogenicity, Mutagenicity and Reprotox.	Toxicity to aquatic vertebrates not included in other columns	Other	Total
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	245919	21957	62442	78742	3917	116640	529617
8.b. Products/ substances used or intended to be used mainly in agriculture	18245	5557	10089	20512	11884	7860	74147
8.c. Products/ substances used or intended to be used mainly in industry	22578	14498	8324	27134	2870	7022	82426
8.d. Products/ substances used or intended to be used mainly in the household	2303	170	159	1130	0	520	4282
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	1127	840	0	0	0	0	1967
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	389	9	1421	4293	0	128	6240
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	9319	0	100	0	80	44665	54164
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	46163	119	6294	5911	4713	3410	66610
8.i. Other toxicological or safety evaluations	78393	2064	8004	9057	1234	123948	222700
8.j. TOTAL	424436	45214	96833	146779	24698	304193	1042153

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

BELGIUM

Statistical data submitted

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

Comments of the Belgian authorities

1. LABORATORIES

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

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

2. NUMBER OF ANIMALS USED IN EXPERIMENTS

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

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

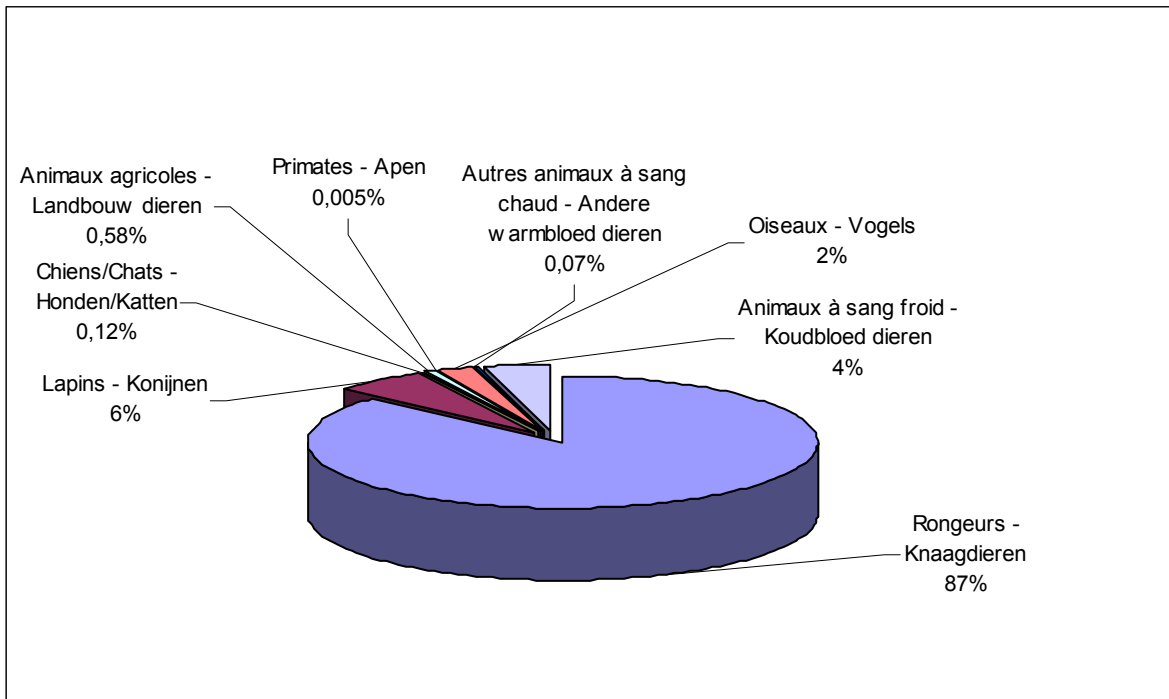


Figure 1: Breakdown of species used in experiments

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

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

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

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

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

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

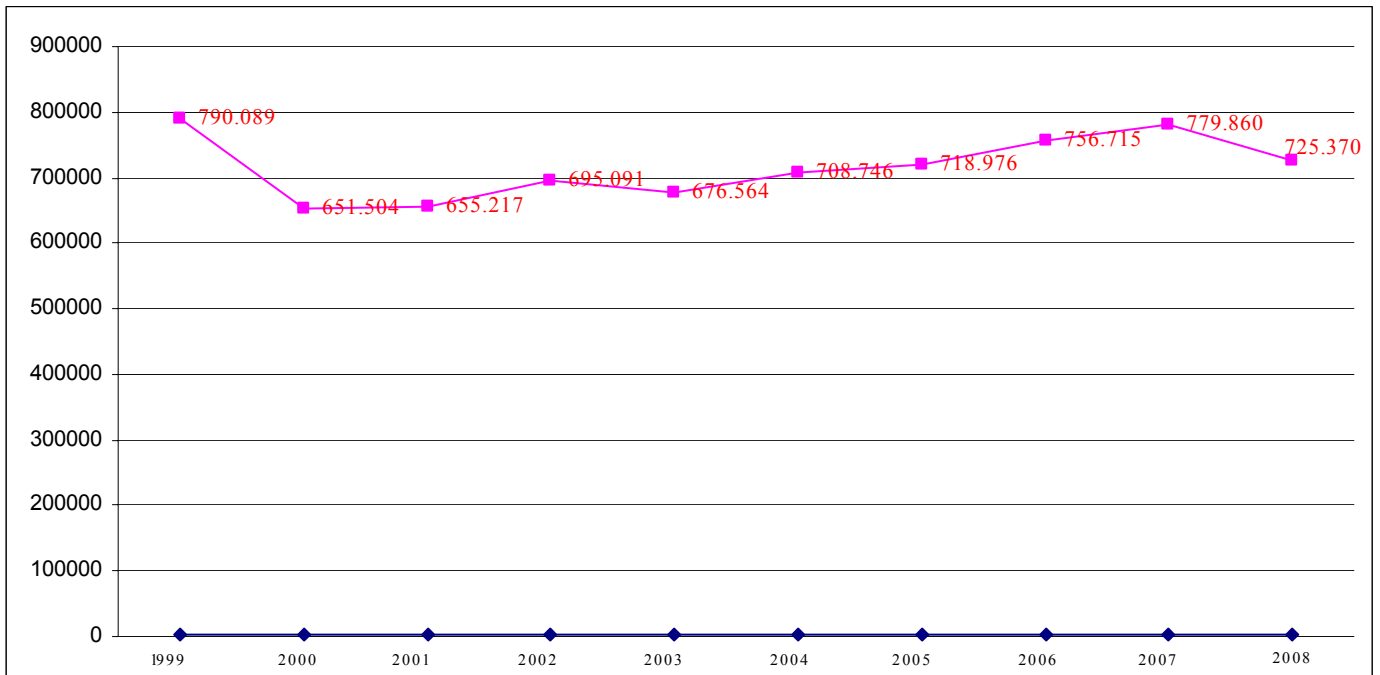


Figure 2: Trend in the number of animals used since 1999

3. EXPERIMENTS CARRIED OUT

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

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

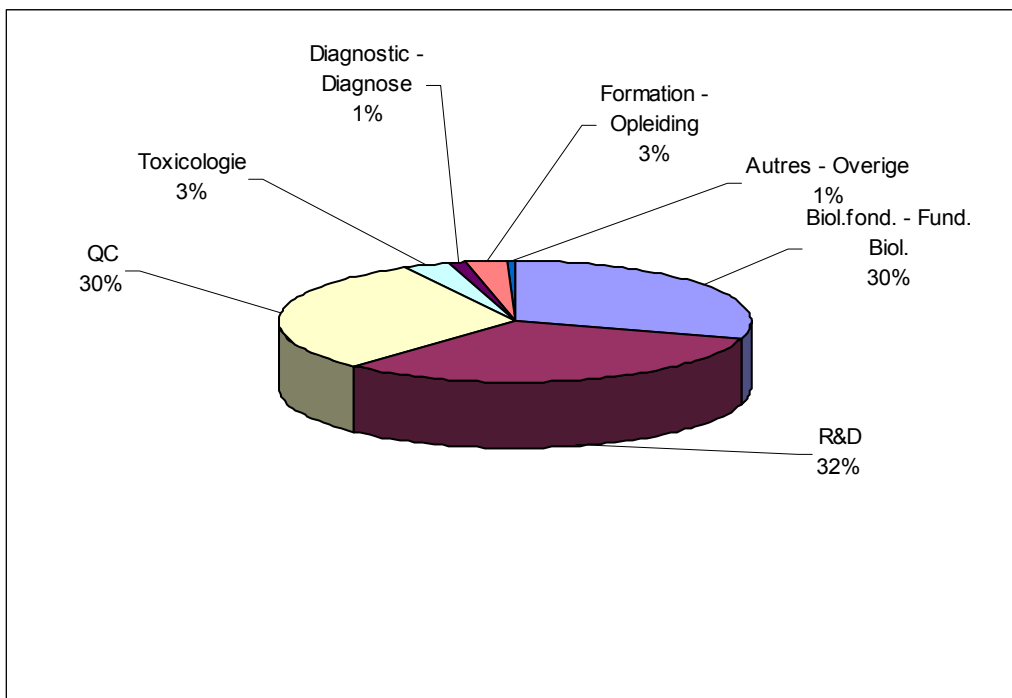


Figure 3: Breakdown of the experimental fields

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

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

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

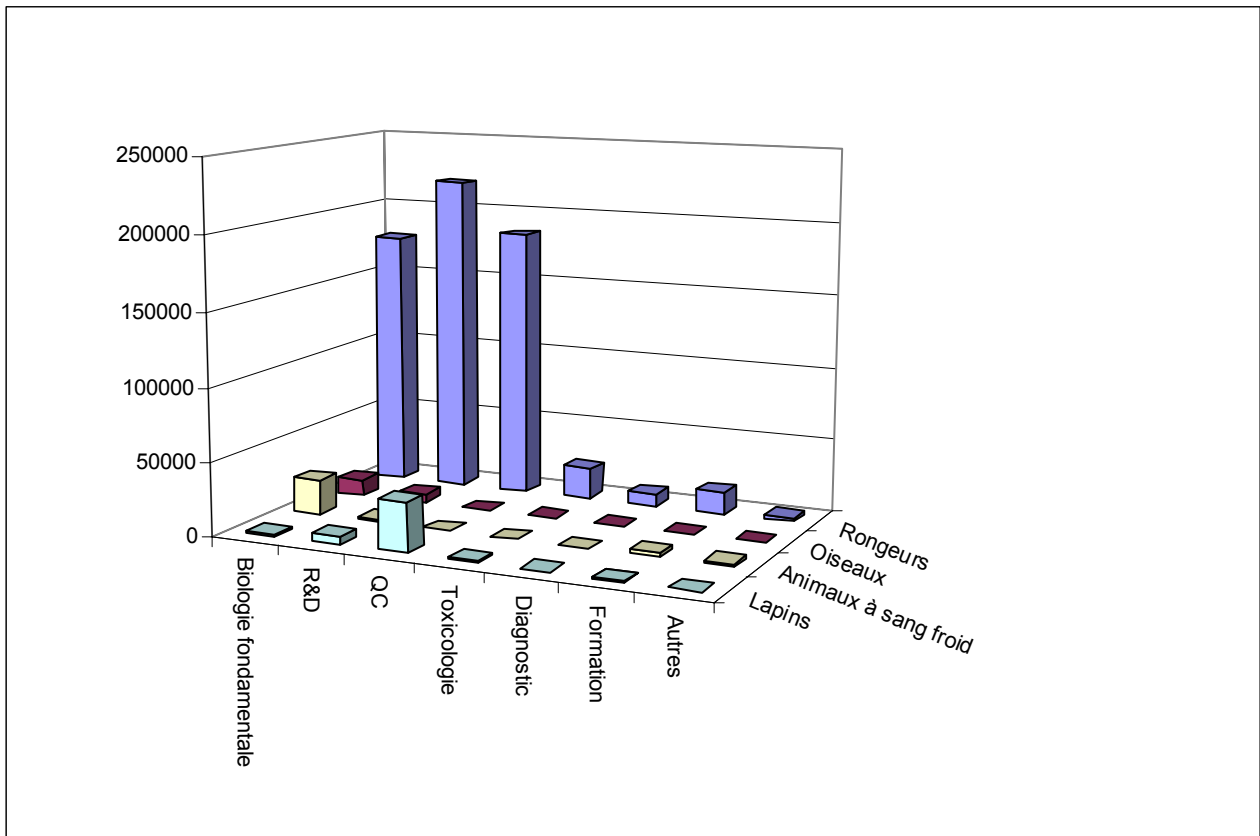


Figure 4: Breakdown of experimental fields by the animals most used

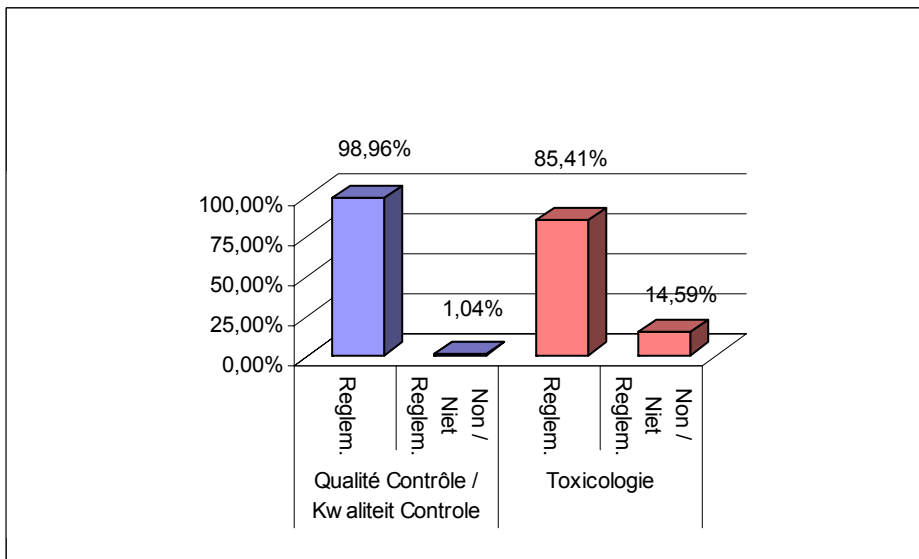


Figure 5: Proportion of quality control and toxicology tests imposed by law

Provenance of animals used in experiments

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	480681	141865	317570	2367	18879	
1.b. Rats (<i>Rattus norvegicus</i>)	108580	19139	88029	116	1296	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	36554	4648	29865	2041	0	
1.d. Hamsters (<i>Mesocricetus</i>)	2124	724	289	1074	37	
1.e. Other Rodents (other <i>Rodentia</i>)	1055					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	42025	38836	3189	0	0	589
1.g. Cats (<i>Felis catus</i>)	78	31	47	0	0	48
1.h. Dogs (<i>Canis familiaris</i>)	788	47	289	0	452	483
1.i. Ferrets (<i>Mustela putorius furo</i>)	324	0	185	0	139	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	62					
1.l. Pigs (<i>Sus</i>)	2969					
1.m. Goats (<i>Capra</i>)	195					
1.n. Sheep (<i>Ovis</i>)	356					
1.o. Cattle (<i>Bos</i>)	657					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	5
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	41	0	12	0	29	28
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	151					
1.u. Quail (<i>Coturnix coturnix</i>)	431	431	0	0	0	
1.v. Other birds (other <i>Aves</i>)	17151					
1.w. Reptiles (<i>Reptilia</i>)	374					
1.x. Amphibians (<i>Amphibia</i>)	2388					
1.y. Fish (<i>Pisces</i>)	28386					
1.z. TOTAL	725370					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	155149	155327	138227	2445	8950	8282	10086	2215	480681
2.b. Rats	20692	59947	11668	697	12705	246	2266	359	108580
2.c. Guinea-Pigs	388	3531	29243	647	153	0	2583	9	36554
2.d. Hamsters	377	0	2	1653	30	0	62	0	2124
2.e. Other Rodents	391	660	0	0	0	0	4	0	1055
2.f. Rabbits	1441	5293	3389	30388	1213	4	251	46	42025
2.g. Cats	27	33	0	18	0	0	0	0	78
2.h. Dogs	49	38	0	18	682	1	0	0	788
2.i. Ferrets	12	312	0	0	0	0	0	0	324
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	25	2	0	0	0	0	35	0	62
2.l. Pigs	1309	486	0	1097	0	2	11	64	2969
2.m. Goats	53	142	0	0	0	0	0	0	195
2.n. Sheep	183	161	0	4	0	0	8	0	356
2.o. Cattle	130	85	0	374	44	0	19	5	657
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	11	0	29	0	0	1	0	0	41
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	95	32	24	0	0	0	0	0	151
2.u. Quail	431	0	0	0	0	0	0	0	431
2.v. Other birds	10729	5855	0	87	0	0	0	480	17151
2.w. Reptiles	374	0	0	0	0	0	0	0	374
2.x. Amphibians	553	1500	0	0	108	0	227	0	2388
2.y. Fish	23406	265	0	0	66	0	3116	1533	28386
2.z. TOTAL	215825	233669	182582	37428	23951	8536	18668	4711	725370

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	6754	0	0	0	0	0	0	0	2196	8950
3.b. Rats	11310	0	45	0	0	0	0	0	1350	12705
3.c. Guinea-Pigs	153	0	0	0	0	0	0	0	0	153
3.d. Hamsters	30	0	0	0	0	0	0	0	0	30
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1213	0	0	0	0	0	0	0	0	1213
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	682	0	0	0	0	0	0	0	0	682
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	0	0	0	0	0	0	0	0	0
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	44	44
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	108	0	0	0	0	0	0	0	108
3.y. Fish	0	0	66	0	0	0	0	0	0	66
3.z. TOTAL	20142	108	111	0	0	0	0	0	3590	23951

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	6291	65749	42230	136336	3178	253784
4.b. Rats	1652	37145	1426	33261	106	73590
4.c. Guinea-Pigs	428	95	0	1805	67	2395
4.d. Hamsters	15	0	18	322	0	355
4.e. Other Rodents	0	640	0	320	76	1036
4.f. Rabbits	152	9	3	322	181	667
4.g. Cats	0	0	0	31	3	34
4.h. Dogs	202	0	0	56	0	258
4.i. Ferrets	0	0	0	312	12	324
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	36	36
4.l. Pigs	271	8	0	245	440	964
4.m. Goats	42	0	0	101	28	171
4.n. Sheep	145	0	0	0	3	148
4.o. Cattle	0	0	0	0	66	66
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	12	0	12
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	3	6	5	4	61	79
4.u. Quail	0	400	0	0	0	400
4.v. Other birds	0	0	0	0	7881	7881
4.w. Reptiles	0	0	0	0	43	43
4.x. Amphibians	20	0	0	0	0	20
4.y. Fish	0	0	0	0	2111	2111
4.z. TOTAL	9221	104052	43682	173127	14292	344374

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	13396	0	17081	109778	417	140672
5.b. Rats	0	752	0	2135	7635	1843	12365
5.c. Guinea-Pigs	0	1609	0	4708	23573	0	29890
5.d. Hamsters	0	579	0	0	1074	2	1655
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	1960	0	1049	30766	2	33777
5.g. Cats	0	18	0	0	0	0	18
5.h. Dogs	0	18	0	0	0	0	18
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	1097	0	0	0	0	1097
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	4	0	0	0	0	4
5.o. Cattle	13	361	0	0	0	0	374
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	29	0	29
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	24	24
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	87	0	0	0	0	87
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	13	19881	0	24973	172855	2288	220010

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	626	1113	0	0	5268	1943	8950
6.b. Rats	61	76	0	1350	9775	1443	12705
6.c. Guinea-Pigs	0	104	0	0	49	0	153
6.d. Hamsters	0	0	0	0	30	0	30
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	183	0	0	1030	0	1213
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	682	0	682
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	0	0
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	44	0	0	44
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	108	108
6.y. Fish	0	0	0	66	0	0	66
6.z. TOTAL	687	1476	0	1460	16834	3494	23951

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	471	9	2068	0	0	0	553	821	0	202	1611	0	3215	8950
7.b. Rats	0	301	4533	0	0	0	1611	1428	0	1236	2151	0	1445	12705
7.c. Guinea-Pigs	0	0	27	0	104	0	0	0	0	0	0	0	22	153
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	30	30
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	306	156	9	0	0	0	0	0	610	0	132	1213
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	409	0	0	0	82	0	0	0	0	0	191	682
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	12	0	0	0	22	0	10	44
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	108	0	0	0	0	0	0	108
7.y. Fish	66	0	0	0	0	0	0	0	0	0	0	0	0	66
7.z. TOTAL	537	310	7343	156	113	0	2366	2249	0	1438	4394	0	5045	23951

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	471	283	7020	156	113	0	1786	2228	0	853	4372	0	2860	20142
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	108	0	0	0	0	0	0	108
8.c. Products/substances used or intended to be used mainly in industry	66	27	18	0	0	0	0	0	0	0	0	0	0	111
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i. Other toxicological or safety evaluations	0	0	305	0	0	0	472	21	0	585	22	0	2185	3590
8.j. TOTAL	537	310	7343	156	113	0	2366	2249	0	1438	4394	0	5045	23951

BULGARIA

Statistical data submitted

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

Comments of the Bulgaria authorities

The National Veterinary Service (NVS) is the competent authority on animal welfare matters (AW) in Bulgaria. An organizational and implementation principle is that the AW requirements on the matters concerning animals used for experimental purposes must be performed by the 28 regional veterinary services (RVS) within the NVS. The requirements of Directive 86/609/EEC have been transposed into the national legislation, namely in Ordinance № 15 on the minimum requirements for protection and welfare of laboratory animals and the requirements to the establishments using, breeding and/or supplying such animals (in force since 01.05.2006; published in SG No. 17 of 24 February 2006) and in the Law for Veterinary Activities.

In Bulgaria, experiments involving usage of live animals are carried out only where it is not possible to apply any alternative method(s) of the same purpose and result.

The use of experimental animals is permitted only in establishments, that are authorized as being in compliance with the requirements laid down in Article 153 (1) of the Law on Veterinary Activity and which have official permit signed by the NVS Director-General. The NVS Director-General would issue the above mentioned permit on the basis of an ethical assessment and a positive opinion from the Animal Ethics Commission with NVS. The Animal Ethics Commission has been established as a permanently operating consultative body with the NVS Director-General. This Commission includes the following staff:

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

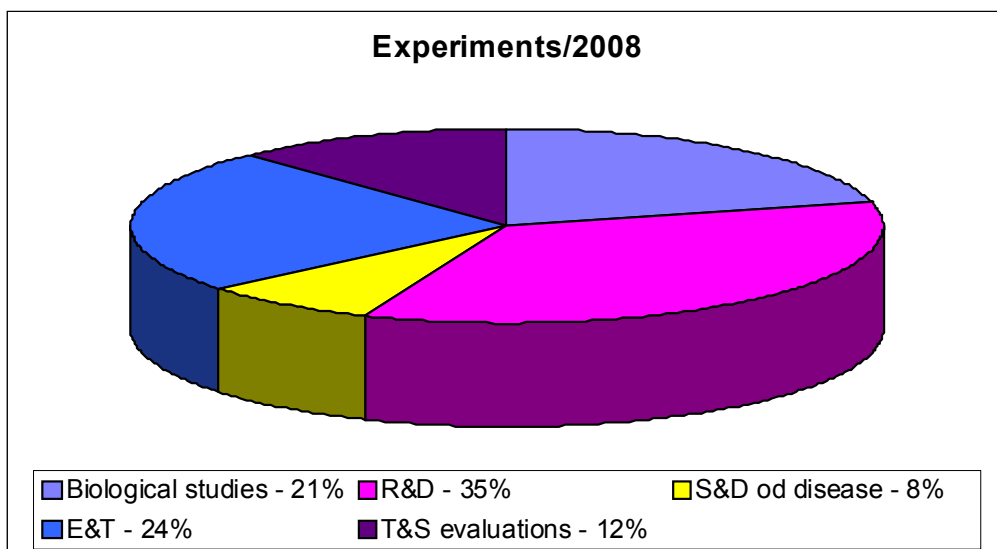
The following experiments have been carried out in 2008 :

-Biological studies of a fundamental nature

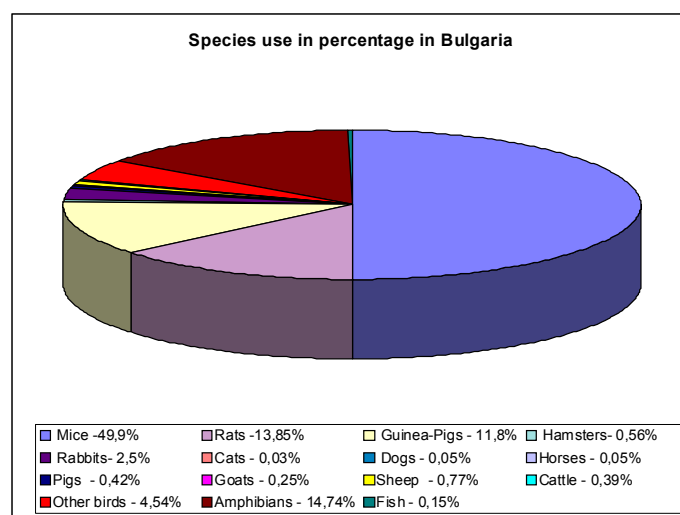
-Research and development of products and devices for human medicine and dentistry and for veterinary medicine (R&D)

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

- Studies and Diagnosis of Human and Animal disease (S&D of disease)
- Education and training (E&T)



Species use in percentage in Bulgaria



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

Experiments not permitted in Bulgaria:

1. for educational purposes, which cause death of animals; in educational establishments animal experiments shall be replaced by other methods for visualizing the subject taught in all cases where the use of animals might be replaced by other methods and if the aim is not to provide the students with specific practical skills.
2. if the result can be achieved with any method not involving the use of live animal(s);
3. if they use stray and/or domestic dogs or cats as experimental animals.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	16265	15820			445	
1.b. Rats (<i>Rattus norvegicus</i>)	4513	3124			1389	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	3845	3807			38	
1.d. Hamsters (<i>Mesocricetus</i>)	182	112			70	
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	813	807			6	
1.g. Cats (<i>Felis catus</i>)	11	11				
1.h. Dogs (<i>Canis familiaris</i>)	15	13			2	
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>)	17					
1.l. Pigs (<i>Sus</i>)	137					
1.m. Goats (<i>Capra</i>)	80					
1.n. Sheep (<i>Ovis</i>)	250					
1.o. Cattle (<i>Bos</i>)	126					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	1477					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	4800					
1.y. Fish (<i>Pisces</i>)	50					
1.z. TOTAL	32581					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	6197	108	7050	264	1964		682		16265
2.b. Rats	237	684	529	30	1080		1953		4513
2.c. Guinea-Pigs	4	634	2057	54	1000		96		3845
2.d. Hamsters	178						4		182
2.e. Other Rodents									0
2.f. Rabbits	37	24	393	60	62	13	216	8	813
2.g. Cats			5	3	4		2		14
2.h. Dogs	2						10		12
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds							17		17
2.l. Pigs		24	10	10			93		137
2.m. Goats	20	60							80
2.n. Sheep	16	46				15	173		250
2.o. Cattle						16	110		126
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds	239	16	30	920		224	48		1477
2.w. Reptiles									0
2.x. Amphibians	200						4600		4800
2.y. Fish							50		50
2.z. TOTAL	7130	1596	10074	1341	4110	268	8054	8	32581

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	1900					64				1964
3.b. Rats	1080									1080
3.c. Guinea-Pigs	1000									1000
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	62									62
3.g. Cats	4									4
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross 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	4046	0	0	0	0	64	0	0	0	4110

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice			480	1800		2280
4.b. Rats	40		50	85		175
4.c. Guinea-Pigs	4					4
4.d. Hamsters			100	8		108
4.e. Other Rodents						0
4.f. Rabbits	4			2	13	19
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep					15	15
4.o. Cattle					16	16
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds				9	254	263
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	48	0	630	1904	298	2880

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice		7314					7314
5.b. Rats		30				529	559
5.c. Guinea-Pigs		2054				57	2111
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	10	443					453
5.g. Cats		5					5
5.h. Dogs	3						3
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs		10				10	20
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds	30	920					950
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	43	10776	0	0	0	596	11415

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	150	1700	64			50	1964
6.b. Rats		200				780	980
6.c. Guinea-Pigs	100	1000					1100
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		60	2				62
6.g. Cats			4				4
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross 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	250	2960	70	0	0	830	4110

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1864		100											1964
7.b. Rats	900	130	50											1080
7.c. Guinea-Pigs	1000													1000
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits	60			2										62
7.g. Cats													4	4
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	3824	130	150	2	0	0	0	0	0	0	0	0	4	4110

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	3760	130	150	2									4	4046
8.b. Products/substances used or intended to be used mainly in agriculture														0
8.c. Products/substances used or intended to be used mainly in industry														0
8.d. Products/substances used or intended to be used mainly in the household														0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	64													64
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	3824	130	150	2	0	0	0	0	0	0	0	0	4	4110

CZECH REPUBLIC

Statistical data submitted

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

Comments of the Czech authorities

Protection of animals and animal welfare in the Czech Republic (CR) is the responsibility of the Ministry of Agriculture (*Ministerstvo zemědělství*). The Central Commission for Animal Welfare (*Ústřední komise pro ochranu zvířat*) has changed to the technical advisory board of the Minister of Agriculture. The animal welfare activities are implemented pursuant to Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended. The supervision of these matters has been the responsibility of the Regional Veterinary Administrations’ inspectors in 13 regions of the CR and the Municipal Veterinary Administration in Prague.

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

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

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

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

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

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

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

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	54776	51832	2888		56	
1.b. Rats (<i>Rattus norvegicus</i>)	21531	20600	931			
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	1902	1902				
1.d. Hamsters (<i>Mesocricetus</i>)	251	251				
1.e. Other Rodents (other <i>Rodentia</i>)	1233					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	6304	6263	14		27	47
1.g. Cats (<i>Felis catus</i>)	45	15	30			
1.h. Dogs (<i>Canis familiaris</i>)	552	478	30		44	18
1.i. Ferrets (<i>Mustela putorius furo</i>)	122	122				
1.j. Other Carnivores (other <i>Carnivora</i>)	45					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	378					
1.l. Pigs (<i>Sus</i>)	2013					
1.m. Goats (<i>Capra</i>)	174					
1.n. Sheep (<i>Ovis</i>)	1148					
1.o. Cattle (<i>Bos</i>)	799					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	80	80				59
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)	1774					
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	148722					
1.w. Reptiles (<i>Reptilia</i>)	1012					
1.x. Amphibians (<i>Amphibia</i>)	3016					
1.y. Fish (<i>Pisces</i>)	54836					
1.z. TOTAL	300713					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	14326	9138	2019	15795	703	6172	550	6073	54776
2.b. Rats	9878	4523	133	1260	3270	3	2359	105	21531
2.c. Guinea-Pigs	169	545	39	905	132	35	77		1902
2.d. Hamsters	14	180					57		251
2.e. Other Rodents	1125						83	25	1233
2.f. Rabbits	918	467	122	3533	202	217	780	65	6304
2.g. Cats		30		15					45
2.h. Dogs	44	335		18	151	2	2		552
2.i. Ferrets		118				4			122
2.j. Other Carnivores	9	36							45
2.k. Horses, donkeys and cross breeds	19	30		306			13	10	378
2.l. Pigs	1146	208		468	100	8	83		2013
2.m. Goats	32	23					119		174
2.n. Sheep	108			100		250	65	625	1148
2.o. Cattle	54	29		332	4	162	184	34	799
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys		80							80
2.s. Apes									0
2.t. Other Mammals	1774								1774
2.u. Quail									0
2.v. Other birds	146422	594		506	746	54	371	29	148722
2.w. Reptiles	958						54		1012
2.x. Amphibians	2915						101		3016
2.y. Fish	16894			90	37402	300	150		54836
2.z. TOTAL	196805	16336	2313	23328	42710	7207	5048	6966	300713

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	553	8	155					45		761
3.b. Rats	947	405	1825					54		3231
3.c. Guinea-Pigs	71		100							171
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	142	24	60			2		12		240
3.g. Cats										0
3.h. Dogs	151									151
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs		8				100				108
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle		4								4
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals		210								210
3.u. Quail										0
3.v. Other birds	349	48								397
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish	305	677	1945	549	422	523		32066	950	37437
3.z. TOTAL	2518	1384	4085	549	422	625	0	32177	950	42710

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	185	181	6411	10073	2945	19795
4.b. Rats	2629	1865	1996	1901	2803	11194
4.c. Guinea-Pigs			12	135		147
4.d. Hamsters				52		52
4.e. Other Rodents					35	35
4.f. Rabbits	134		60	118	281	593
4.g. Cats						0
4.h. Dogs	39	2		2	42	85
4.i. Ferrets				122		122
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds					7	7
4.l. Pigs	102			3	537	642
4.m. Goats					147	147
4.n. Sheep	18			250	37	305
4.o. Cattle					114	114
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys	31			49		80
4.s. Apes						0
4.t. Other Mammals				10		10
4.u. Quail						0
4.v. Other birds				212	1641	1853
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					1925	1925
4.z. TOTAL	3138	2048	8479	12927	10514	37106

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	5884	11930					17814
5.b. Rats	67	1260		66			1393
5.c. Guinea-Pigs	180	741					921
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	88	3490					3578
5.g. Cats		15					15
5.h. Dogs		18					18
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds	292	14					306
5.l. Pigs	46	422					468
5.m. Goats							0
5.n. Sheep	3	97					100
5.o. Cattle		332					332
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds	48	458				100	606
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish	90						90
5.z. TOTAL	6698	18777	0	66	0	100	25641

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	511					192	703
6.b. Rats	2755	41				474	3270
6.c. Guinea-Pigs	100	32					132
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	171	12				19	202
6.g. Cats							0
6.h. Dogs	151						151
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs						100	100
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds						670	670
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	24468	9179				3835	37482
6.z. TOTAL	28156	9264	0	0	0	5290	42710

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		506			155								42	703
7.b. Rats	337		718		12		679		387	115	532		490	3270
7.c. Guinea-Pigs				10	116	6								132
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				97	19	26							60	202
7.g. Cats														0
7.h. Dogs	15						80						56	151
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs													100	100
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds													670	670
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish	33782											3700		37482
7.z. TOTAL	34134	506	718	107	302	32	759	0	387	115	532	3700	1418	42710

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	255	506		68	35	11	477					138	1028	2518
8.b. Products/substances used or intended to be used mainly in agriculture	750		400		12		12						210	1384
8.c. Products/substances used or intended to be used mainly in industry	1067		318	39	255	21	270		387	95	532	975	126	4085
8.d. Products/substances used or intended to be used mainly in the household	549													549
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	422													422
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption								625						625
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	30421									20	45	1637	54	32177
8.i. Other toxicological or safety evaluations												950		950
8.j. TOTAL	33464	506	718	107	302	32	759	625	387	115	577	3700	1418	42710

DENMARK

Statistical data submitted

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

Comments of Danish authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	53293	82439	11900	155	4923	2932	1096	11426	168164
2.b. Rats	15346	45628	3244	0	7269	833	2628	902	75850
2.c. Guinea-Pigs	207	2017	1695	25	1311	76	12	0	5343
2.d. Hamsters	4	0	0	0	0	0	0	0	4
2.e. Other Rodents	62	1698	0	0	0	0	0	0	1760
2.f. Rabbits	357	1808	447	4	218	2	42	53	2931
2.g. Cats	123	0	0	0	0	10	0	21	154
2.h. Dogs	1	119	0	0	130	21	0	0	271
2.i. Ferrets	97	20	0	0	0	0	0	0	117
2.j. Other Carnivores	62	39	0	0	0	0	0	0	101
2.k. Horses, donkeys and cross breeds	15	13	7	0	0	0	19	0	54
2.l. Pigs	2245	1862	0	43	648	102	1029	934	6863
2.m. Goats	0	93	0	0	0	0	0	14	107
2.n. Sheep	5	38	26	6	0	0	13	0	88
2.o. Cattle	616	124	0	18	0	131	50	0	939
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	233	0	0	0	0	0	10	0	243
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	2604	111	2	84	6	13	0	0	2820
2.w. Reptiles	198	23	0	0	0	0	0	0	221
2.x. Amphibians	92	65	0	0	0	136	0	0	293
2.y. Fish	5939	16602	0	0	8443	0	261	0	31245
2.z. TOTAL	81499	152699	17321	335	22948	4256	5160	13350	297568

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	2845	0	537	0	0	62	0	439	1040	4923
3.b. Rats	4515	74	0	1346	0	120	0	127	1087	7269
3.c. Guinea-Pigs	1260	0	0	0	0	24	0	0	27	1311
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	215	0	0	0	0	3	0	0	0	218
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	130	0	0	0	0	0	0	0	0	130
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	648	0	0	0	0	0	0	0	0	648
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	6	6
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	493	0	0	0	7950	0	0	8443
3.z. TOTAL	9613	74	1030	1346	0	209	7950	566	2160	22948

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	2802	59758	13426	35581	1150	112717
4.b. Rats	2075	34100	823	19699	40	56737
4.c. Guinea-Pigs	269	1700	0	194	0	2163
4.d. Hamsters	0	0	0	0	0	0
4.e. Other Rodents	0	1416	0	282	24	1722
4.f. Rabbits	199	0	1129	757	21	2106
4.g. Cats	0	0	0	0	85	85
4.h. Dogs	21	39	0	80	0	140
4.i. Ferrets	0	20	0	97	0	117
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	15	15
4.l. Pigs	471	179	0	1869	111	2630
4.m. Goats	0	0	87	6	0	93
4.n. Sheep	0	0	0	0	0	0
4.o. Cattle	0	0	0	79	36	115
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	130	130
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	64	0	0	0	240	304
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	151	0	0	0	151
4.y. Fish	0	8165	0	0	1180	9345
4.z. TOTAL	5901	105528	15465	58644	3032	188570

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	155	14	0	0	11870	16	12055
5.b. Rats	0	2408	0	0	836	0	3244
5.c. Guinea-Pigs	25	0	0	0	1310	385	1720
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	4	0	0	28	22	397	451
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	7	7
5.l. Pigs	43	0	0	0	0	0	43
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	6	0	0	0	0	26	32
5.o. Cattle	18	0	0	0	0	0	18
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	84	0	0	0	0	2	86
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	335	2422	0	28	14038	833	17656

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	667	0	0	0	2366	1890	4923
6.b. Rats	98	0	0	50	4502	2619	7269
6.c. Guinea-Pigs	0	0	0	72	1188	51	1311
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	216	2	218
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	130	0	130
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	648	0	648
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	6	0	0	0	0	0	6
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	493	0	0	0	0	7950	8443
6.z. TOTAL	1264	0	0	122	9050	12512	22948

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	0	1955	0	931	0	382	0	0	658	45	0	952	4923
7.b. Rats	0	0	1146	0	0	0	3146	0	0	174	2372	0	431	7269
7.c. Guinea-Pigs	0	0	1223	0	0	0	0	0	0	0	0	0	88	1311
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	46	19	0	3	39	0	0	0	109	0	2	218
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	126	0	0	0	0	0	4	130
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	8	12	0	0	600	0	0	0	28	0	0	648
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	6	0	0	0	0	0	0	0	0	0	0	6
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	199	7950	0	0	0	0	0	0	0	0	0	294	0	8443
7.z. TOTAL	199	7950	4384	31	931	3	4293	0	0	832	2554	294	1477	22948

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	125	0	4027	31	407	0	4366	0	0	148	401	0	108	9613
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	18	0	0	0	56	0	0	74
8.c. Products/substances used or intended to be used mainly in industry	199	0	0	0	188	0	294	0	0	0	45	0	304	1030
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	1016	0	330	1346
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	3	120	0	0	0	0	0	86	209
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	7950	0	0	0	0	0	0	0	0	0	0	0	7950
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	566	0	0	0	566
8.i. Other toxicological or safety evaluations	0	0	21	0	336	0	0	0	0	118	1041	0	644	2160
8.j. TOTAL	324	7950	4048	31	931	3	4798	0	0	832	2559	0	1472	22948

GERMANY

Statistical data submitted

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

Comments of German authorities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	1.314.493	1.167.335	129.636	10.760	6.762	
1.b. Rats (<i>Rattus norvegicus</i>)	390.853	305.309	79.003	5.395	1.146	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	35.870	35.624	246	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	7.061	6.782	149	0	130	
1.e. Other Rodents (other <i>Rodentia</i>)	8.392					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	97.938	97.313	621	4	0	9.076
1.g. Cats (<i>Felis catus</i>)	798	246	294	0	258	303
1.h. Dogs (<i>Canis familiaris</i>)	4.450	1.911	1.536	0	1.003	1.081
1.i. Ferrets (<i>Mustela putorius furo</i>)	55	11	44	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	410					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	584					
1.l. Pigs (<i>Sus</i>)	12.361					
1.m. Goats (<i>Capra</i>)	531					
1.n. Sheep (<i>Ovis</i>)	4.638					
1.o. Cattle (<i>Bos</i>)	6.252					
1.p. Prosimians (<i>Prosimia</i>)	543	0	543	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	305	252	48	5	0	63
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	1.415	102	205	0	1.108	396
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	541					
1.u. Quail (<i>Coturnix coturnix</i>)	1.803	1.803	0	0	0	
1.v. Other birds (other <i>Aves</i>)	53.986					
1.w. Reptiles (<i>Reptilia</i>)	192					
1.x. Amphibians (<i>Amphibia</i>)	10.815					
1.y. Fish (<i>Pisces</i>)	67.496					
1.z. TOTAL	2.021.782					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	723.037	273.935	148.754	41.668	75.985	7.855	26.200	17.059	1.314.493
2.b. Rats	74.880	180.418	51.412	10.468	53.312	1.609	16.248	2.506	390.853
2.c. Guinea-Pigs	936	6.002	16.870	3.700	6.623	18	616	1.105	35.870
2.d. Hamsters	2.036	2.822	16	1.331	40	52	295	469	7.061
2.e. Other Rodents	3.497	3.934	0	0	0	17	391	553	8.392
2.f. Rabbits	2.453	5.387	50.713	1.809	4.483	791	196	32.106	97.938
2.g. Cats	79	547	39	10	98	0	13	12	798
2.h. Dogs	193	1.003	0	939	1.935	189	161	30	4.450
2.i. Ferrets	42	0	0	2	0	0	1	10	55
2.j. Other Carnivores	15	0	0	311	0	80	0	4	410
2.k. Horses, donkeys and cross breeds	346	121	0	2	0	75	39	1	584
2.l. Pigs	2.633	5.918	29	447	352	693	2.079	210	12.361
2.m. Goats	225	271	11	2	4	10	2	6	531
2.n. Sheep	692	1.150	2.151	116	3	167	216	143	4.638
2.o. Cattle	4.295	528	22	436	33	622	282	34	6.252
2.p. Prosimians	0	0	0	0	543	0	0	0	543
2.q. New World Monkeys	49	91	0	0	147	0	0	18	305
2.r. Old World Monkeys	43	91	0	0	1.168	2	10	101	1.415
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	495	6	4	0	0	0	7	29	541
2.u. Quail	0	0	0	0	1.786	0	17	0	1.803
2.v. Other birds	7.095	29.863	307	11.714	885	2.245	462	1.415	53.986
2.w. Reptiles	151	21	0	0	0	0	20	0	192
2.x. Amphibians	9.477	234	0	0	4	0	1.064	36	10.815
2.y. Fish	34.405	2.730	0	40	23.853	2.421	3.571	476	67.496
2.z. TOTAL	867.074	515.072	270.328	72.995	171.254	16.846	51.890	56.323	2.021.782

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	61.040	4.146	10.375	0	0	0	0	217	207	75.985
3.b. Rats	33.080	8.284	11.425	16	0	0	0	239	268	53.312
3.c. Guinea-Pigs	3.613	1.449	1.482	0	0	0	0	0	79	6.623
3.d. Hamsters	40	0	0	0	0	0	0	0	0	40
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	2.861	952	633	0	0	0	0	0	37	4.483
3.g. Cats	88	0	0	0	0	0	0	0	10	98
3.h. Dogs	1.902	20	8	0	0	0	0	0	5	1.935
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	352	0	0	0	0	0	0	0	0	352
3.m. Goats	0	4	0	0	0	0	0	0	0	4
3.n. Sheep	3	0	0	0	0	0	0	0	0	3
3.o. Cattle	33	0	0	0	0	0	0	0	0	33
3.p. Prosimians	543	0	0	0	0	0	0	0	0	543
3.q. New World Monkeys	147	0	0	0	0	0	0	0	0	147
3.r. Old World Monkeys	1.168	0	0	0	0	0	0	0	0	1.168
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	1.786	0	0	0	0	0	0	0	1.786
3.v. Other birds	182	577	0	0	0	0	44	0	82	885
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	4	4
3.y. Fish	3.855	14.681	2.367	0	0	0	80	2.870	0	23.853
3.z. TOTAL	108.907	31.899	26.290	16	0	0	124	3.326	692	171.254

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	60.950	105.707	107.646	388.614	5.404	668.321
4.b. Rats	16.279	26.241	4.369	87.061	1.014	134.964
4.c. Guinea-Pigs	130	47	0	4.271	239	4.687
4.d. Hamsters	387	825	98	2.531	45	3.886
4.e. Other Rodents	0	814	0	2.623	1.439	4.876
4.f. Rabbits	758	106	304	2.413	194	3.775
4.g. Cats	0	40	0	0	527	567
4.h. Dogs	3	0	75	84	765	927
4.i. Ferrets	0	0	0	35	0	35
4.j. Other Carnivores	0	0	0	2	80	82
4.k. Horses, donkeys and cross breeds	0	0	0	43	294	337
4.l. Pigs	447	7	10	2.170	2.359	4.993
4.m. Goats	0	29	0	203	10	242
4.n. Sheep	59	48	0	528	919	1.554
4.o. Cattle	9	21	0	79	4.603	4.712
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	21	0	26	0	47
4.r. Old World Monkeys	4	16	0	80	0	100
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	44	0	42	0	86
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	118	48	0	2.239	7.706	10.111
4.w. Reptiles	0	10	0	0	47	57
4.x. Amphibians	224	56	0	468	0	748
4.y. Fish	1.768	958	131	3.913	5.368	12.138
4.z. TOTAL	81.136	135.038	112.633	497.425	31.013	857.245

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	174.107	0	850	11.320	4.145	190.422
5.b. Rats	0	61.747	0	0	0	133	61.880
5.c. Guinea-Pigs	0	19.743	0	512	0	315	20.570
5.d. Hamsters	0	1.347	0	0	0	0	1.347
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	42.765	0	0	8.697	1.060	52.522
5.g. Cats	0	39	0	0	0	10	49
5.h. Dogs	0	217	0	0	680	42	939
5.i. Ferrets	0	2	0	0	0	0	2
5.j. Other Carnivores	0	311	0	0	0	0	311
5.k. Horses, donkeys and cross breeds	0	2	0	0	0	0	2
5.l. Pigs	0	436	0	0	0	40	476
5.m. Goats	0	0	0	0	2	11	13
5.n. Sheep	0	0	0	0	58	2.209	2.267
5.o. Cattle	0	412	0	0	0	46	458
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	4	4
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	1.005	0	0	10.158	858	12.021
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	40	0	0	0	0	40
5.z. TOTAL	0	302.173	0	1.362	30.915	8.873	343.323

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	153	55.706	0	537	16.213	3.376	75.985
6.b. Rats	110	27.852	10	16	21.608	3.716	53.312
6.c. Guinea-Pigs	0	4.117	0	0	2.503	3	6.623
6.d. Hamsters	0	40	0	0	0	0	40
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	3.515	0	0	891	77	4.483
6.g. Cats	14	74	0	0	0	10	98
6.h. Dogs	36	777	0	0	1.093	29	1.935
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	205	0	0	135	12	352
6.m. Goats	0	0	0	0	4	0	4
6.n. Sheep	0	0	0	0	0	3	3
6.o. Cattle	0	33	0	0	0	0	33
6.p. Prosimians	0	543	0	0	0	0	543
6.q. New World Monkeys	0	0	0	0	147	0	147
6.r. Old World Monkeys	0	0	0	0	1.168	0	1.168
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	320	0	0	1.466	0	1.786
6.v. Other birds	0	320	0	0	483	82	885
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	4	4
6.y. Fish	1.270	8.128	0	0	12.847	1.608	23.853
6.z. TOTAL	1.583	101.630	10	553	58.558	8.920	171.254

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	28.611	8.594	12.390	70	9.944	0	1.804	1.068	0	6.227	0	0	7.277	75.985
7.b. Rats	2.510	5.884	18.972	25	0	0	5.704	0	3.393	3.974	5.647	0	7.203	53.312
7.c. Guinea-Pigs	0	0	843	0	5.653	0	0	0	0	0	15	0	112	6.623
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	40	40
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	28	18	171	925	0	479	0	0	925	0	1.426	0	511	4.483
7.g. Cats	0	0	24	0	0	0	62	0	0	0	0	0	12	98
7.h. Dogs	0	339	747	0	0	0	639	0	0	0	0	0	210	1.935
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	11	88	0	0	0	34	0	0	0	0	0	219	352
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	4	4
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	3	3
7.o. Cattle	0	0	16	0	0	0	0	0	0	0	0	0	17	33
7.p. Prosimians	0	0	261	0	0	0	143	0	0	0	0	0	139	543
7.q. New World Monkeys	0	0	36	0	0	0	47	0	64	0	0	0	0	147
7.r. Old World Monkeys	0	0	184	0	0	0	750	0	176	0	58	0	0	1.168
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	459	217	0	0	0	0	0	0	0	0	176	0	934	1.786
7.v. Other birds	204	0	205	0	0	0	0	0	0	0	0	0	476	885
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	4	0	0	0	0	4
7.y. Fish	2.446	326	0	0	0	0	294	0	0	0	129	19.443	1.215	23.853
7.z. TOTAL	34.258	15.389	33.937	1.020	15.597	479	9.477	1.068	4.562	10.201	7.451	19.443	18.372	171.254

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	28.654	12.043	26.171	497	5.551	3	7.274	1.008	1.551	4.218	4.786	3.412	13.739	108.907
8.b. Products/substances used or intended to be used mainly in agriculture	3.244	2.572	2.680	367	2.793	372	974	0	1.072	1.271	725	11.884	3.945	31.899
8.c. Products/substances used or intended to be used mainly in industry	2.046	566	4.671	156	7.177	91	1.209	60	1.935	4.322	1.928	1.895	234	26.290
8.d. Products/substances used or intended to be used mainly in the household	16	0	0	0	0	0	0	0	0	0	0	0	0	16
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	80	44	124
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	289	208	239	0	0	0	20	0	0	0	12	2.172	386	3.326
8.i. Other toxicological or safety evaluations	9	0	176	0	76	13	0	0	4	390	0	0	24	692
8.j. TOTAL	34.258	15.389	33.937	1.020	15.597	479	9.477	1.068	4.562	10.201	7.451	19.443	18.372	171.254

ESTONIA

Statistical data submitted

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

Comments of Estonian authorities

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

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

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

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

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

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	28754	11779	13137		3838	
1.b. Rats (<i>Rattus norvegicus</i>)	5268	2058	3210	0	0	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	22		22			
1.d. Hamsters (<i>Mesocricetus</i>)	120		120			
1.e. Other Rodents (other <i>Rodentia</i>)	0					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	630	0	630	0	0	0
1.g. Cats (<i>Felis catus</i>)	0					
1.h. Dogs (<i>Canis familiaris</i>)	0					
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0					
1.l. Pigs (<i>Sus</i>)						
1.m. Goats (<i>Capra</i>)	0					
1.n. Sheep (<i>Ovis</i>)						
1.o. Cattle (<i>Bos</i>)	0					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)						
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	34794					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	24323	4291	100		40				28754
2.b. Rats	2870	2398							5268
2.c. Guinea-Pigs						22			22
2.d. Hamsters	15	105							120
2.e. Other Rodents									0
2.f. Rabbits	510	120							630
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	27718	6914	100	0	40	22	0	0	34794

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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						40				40
3.b. Rats										0
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits										0
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs										0
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail										0
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	0	0	0	0	0	40	0	0	0	40

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	621	11357	10124	6512		28614
4.b. Rats	510	3412		1346		5268
4.c. Guinea-Pigs					22	22
4.d. Hamsters				120		120
4.e. Other Rodents						0
4.f. Rabbits				630		630
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross 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	1131	14769	10124	8608	22	34654

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice					100		100
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	100	0	100

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice					40		40
6.b. Rats							0
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits							0
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	0	0	0	0	40	0	40

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice			40											40
7.b. Rats														0
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits														0
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	0	40	0	0	0	0	0	0	0	0	0	0	40

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine															0
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption		40													40
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations															0
8.j. TOTAL	0	40	0	0	0	0	0	0	0	0	0	0	0	0	40

IRELAND

Statistical data submitted

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

Comments of Irish authorities

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

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

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

Fish accounted for 20% of all animals.

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

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

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

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

Animals Used for Selected Purposes

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

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

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

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

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

Toxicological and other Safety Evaluations

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

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

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	71.224	12.271	57.264	1.009	680	
1.b. Rats (<i>Rattus norvegicus</i>)	11.741	4.396	4.423	2.880	42	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	91	59	32	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	68	4	64	0	0	
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	204	6	198	0	0	0
1.g. Cats (<i>Felis catus</i>)	295	295	0	0	0	16
1.h. Dogs (<i>Canis familiaris</i>)	557	547	10	0	0	198
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>)	144					
1.l. Pigs (<i>Sus</i>)	224					
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)	456					
1.o. Cattle (<i>Bos</i>)	4.019					
1.p. Prosimians (<i>Prosimia</i>)						
1.q. New World Monkeys (<i>Ceboidea</i>)						
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)						
1.s. Apes (<i>Hominoidea</i>)						
1.t. Other Mammals (other <i>Mammalia</i>)	32					
1.u. Quail (<i>Coturnix coturnix</i>)						
1.v. Other birds (other <i>Aves</i>)	582					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)	23.198					
1.z. TOTAL	112.835					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	15.813	2.487	0	0	51.456	426	14	1.028	71.224
2.b. Rats	6.750	4.506	0	0	243	57	12	173	11.741
2.c. Guinea-Pigs	32	0	0	0	59	0	0	0	91
2.d. Hamsters	4	64	0	0	0	0	0	0	68
2.e. Other Rodents									0
2.f. Rabbits	6	114	0	0	84	0	0	0	204
2.g. Cats	0	197	0	0	98	0	0	0	295
2.h. Dogs	0	442	0	0	105	0	0	10	557
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds	21	0	0	99	0	3	13	8	144
2.l. Pigs	175	21	0	12	16	0	0	0	224
2.m. Goats									0
2.n. Sheep	282	2	0	10	0	120	42	0	456
2.o. Cattle	3.563	29	0	139	0	90	12	186	4.019
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	0	32	0	0	0	0	0	0	32
2.u. Quail									0
2.v. Other birds	201	287	0	0	4	90	0	0	582
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish	3.019	1.400	0	0	0	0	0	18.779	23.198
2.z. TOTAL	29.866	9.581	0	260	52.065	786	93	20.184	112.835

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	12	0		0		0		0	51.444	51.456
3.b. Rats									243	243
3.c. Guinea-Pigs	0	0		0		0		0	59	59
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits									84	84
3.g. Cats	98	0		0		0		0	0	98
3.h. Dogs	105	0		0		0		0	0	105
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breeds										0
3.l. Pigs	16	0		0		0		0	0	16
3.m. Goats										0
3.n. Sheep										0
3.o. Cattle										0
3.p. Prosimians										0
3.q. New World Monkeys										0
3.r. Old World Monkeys										0
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail	4	0		0		0		0	0	4
3.v. Other birds										0
3.w. Reptiles										0
3.x. Amphibians										0
3.y. Fish										0
3.z. TOTAL	235	0	0	0	0	0	0	0	51.830	52.065

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	770	5.534	2.374	9.030	1.018	18.726
4.b. Rats	1.525	7.778	42	1.840	128	11.313
4.c. Guinea-Pigs	0	0	0	32	0	32
4.d. Hamsters	0	0	0	64	4	68
4.e. Other Rodents						0
4.f. Rabbits	49	0	0	69	2	120
4.g. Cats	0	0	0	0	197	197
4.h. Dogs	0	0	0	4	438	442
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds					24	24
4.l. Pigs	94		43	0	59	196
4.m. Goats						0
4.n. Sheep	2	0	0	0	402	404
4.o. Cattle	0	0	0	0	3.682	3.682
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals					32	32
4.u. Quail						0
4.v. Other birds	12		2	1	563	578
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish	60	0	0	0	4.359	4.419
4.z. TOTAL	2.512	13.312	2.461	11.040	10.908	40.233

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds	0	99	0	0	0	0	99
5.l. Pigs	12	0	0	0	0	0	12
5.m. Goats							0
5.n. Sheep	0	10	0	0	0	0	10
5.o. Cattle	0	91	0	0	0	48	139
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	12	200	0	0	0	48	260

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	5.106	0	0	46.328	22	51.456
6.b. Rats	15	0	0	0	228	0	243
6.c. Guinea-Pigs	0	0	0	0	59	0	59
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	0	0	0	0	84	0	84
6.g. Cats	83	15	0	0	0	0	98
6.h. Dogs	57	48	0	0	0	0	105
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs	16	0	0	0	0	0	16
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds	4	0	0	0	0	0	4
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	175	5.169	0	0	46.699	22	52.065

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	42.721	1.866	0	0	0	0	0	0	0	0	0	0	6.869	51.456
7.b. Rats	0	0	0	0	0	0	0	0	15	0	0	0	228	243
7.c. Guinea-Pigs	0	0	0	0	0	0	0	0	0	0	0	0	59	59
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits	0	0	0	0	0	0	0	0	0		0	0	84	84
7.g. Cats	0	0	0	0	0	0	0	0	0		0	0	98	98
7.h. Dogs	0	0	0	0	0	0	0	0	0		0	0	105	105
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	16	16
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	4	4
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	42.721	1.866	0	0	0	0	0	0	15	0	0	0	7.463	52.065

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	12	0	0	0	0	0	0	0	0	0	0	0	223	235
8.b. Products/substances used or intended to be used mainly in agriculture														
8.c. Products/substances used or intended to be used mainly in industry														
8.d. Products/substances used or intended to be used mainly in the household														
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														
8.i. Other toxicological or safety evaluations	1.866	0	0	0	0	0	0	0	15	0	0	0	49.949	51.830
8.j. TOTAL	1.878	0	0	0	0	0	0	0	15	0	0	0	50.172	52.065

GREECE

Statistical data submitted

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

Comments of Greek authorities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	19786	19493	206		87	
1.b. Rats (<i>Rattus norvegicus</i>)	4367	4332	20		15	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	45	21			24	
1.d. Hamsters (<i>Mesocricetus</i>)	0					
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	1498	1467			31	
1.g. Cats (<i>Felis catus</i>)	4	4				
1.h. Dogs (<i>Canis familiaris</i>)	44	34	10			
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					
1.l. Pigs (<i>Sus</i>)	624					
1.m. Goats (<i>Capra</i>)	24					
1.n. Sheep (<i>Ovis</i>)	68					
1.o. Cattle (<i>Bos</i>)	72					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	88					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	200					
1.y. Fish (<i>Pisces</i>)	1200					
1.z. TOTAL	28021					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	6274	2271			7197	3574	172	298	19786
2.b. Rats	1670	1408	60		468	264	427	70	4367
2.c. Guinea-Pigs						40	5		45
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	542	732		55	40	40	88	1	1498
2.g. Cats		4							4
2.h. Dogs		39					5		44
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds							1		1
2.l. Pigs	91	295	14				224		624
2.m. Goats						18	6		24
2.n. Sheep						35	32	1	68
2.o. Cattle							72		72
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds	51					30	6	1	88
2.w. Reptiles									0
2.x. Amphibians							200		200
2.y. Fish	1200								1200
2.z. TOTAL	9828	4749	74	55	7705	4001	1238	371	28021

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	120								7077	7197
3.b. Rats	430	12						26		468
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	40									40
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross 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	590	12	0	0	0	0	0	26	7077	7705

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	1838	1756	1196	2512	207	7509
4.b. Rats	570	447	40	1138	11	2206
4.c. Guinea-Pigs					40	40
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	489	18		625	31	1163
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	237			122		359
4.m. Goats					18	18
4.n. Sheep					35	35
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds					30	30
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish	1000	200				1200
4.z. TOTAL	4134	2421	1236	4397	372	12560

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

Regulatory requirements versus species

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

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		120			7077		7197
6.b. Rats	38	430					468
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		40					40
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross 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	38	590	0	0	7077	0	7705

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		7077											120	7197
7.b. Rats			12							26			430	468
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits													40	40
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	7077	12	0	0	0	0	0	0	26	0	0	590	7705

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine													590	590
8.b. Products/substances used or intended to be used mainly in agriculture			12											12
8.c. Products/substances used or intended to be used mainly in industry														0
8.d. Products/substances used or intended to be used mainly in the household														0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns										26				26
8.i. Other toxicological or safety evaluations		7077												7077
8.j. TOTAL	0	7077	12	0	0	0	0	0	0	26	0	0	590	7705

SPAIN

Statistical data submitted

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

Comments of Spanish authorities

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

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

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

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

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

Finally, there has been a fall in the number of animals used for training purposes.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	543680	467820	67595	41	8224	
1.b. Rats (<i>Rattus norvegicus</i>)	175325	147505	27397	0	423	275
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	12620	9601	3019	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	1262	1138	113	0	11	
1.e. Other Rodents (other <i>Rodentia</i>)	251					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	19626	18651	873	0	102	396
1.g. Cats (<i>Felis catus</i>)	100	73	0	0	27	0
1.h. Dogs (<i>Canis familiaris</i>)	1046	990	43	0	13	1
1.i. Ferrets (<i>Mustela putorius furo</i>)	287	14	0	0	273	0
1.j. Other Carnivores (other <i>Carnivora</i>)	5					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	90					
1.l. Pigs (<i>Sus</i>)	15121					902
1.m. Goats (<i>Capra</i>)	372					20
1.n. Sheep (<i>Ovis</i>)	2386					3
1.o. Cattle (<i>Bos</i>)	1091					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	
1.q. New World Monkeys (<i>Ceboidea</i>)	8	0	8	0	0	
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	517	362	152	3	0	
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	
1.t. Other Mammals (other <i>Mammalia</i>)	28					
1.u. Quail (<i>Coturnix coturnix</i>)	138	81	0	0	57	
1.v. Other birds (other <i>Aves</i>)	52104					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)	704					
1.y. Fish (<i>Pisces</i>)	71098					
1.z. TOTAL	897859					

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	268703	136072	16012	19904	63052	20338	6665	12934	543680
2.b. Rats	63513	65305	2311	9750	8810	11256	8305	6075	175325
2.c. Guinea-Pigs	149	4537	868	3370	3566	102	28	0	12620
2.d. Hamsters	564	409	0	0	156	119	14	0	1262
2.e. Other Rodents	206	10	0	0	0	0	0	35	251
2.f. Rabbits	1247	3658	879	5318	6765	488	232	1039	19626
2.g. Cats	48	17	0	4	0	0	0	31	100
2.h. Dogs	65	389	0	176	349	6	44	17	1046
2.i. Ferrets	14	241	0	0	32	0	0	0	287
2.j. Other Carnivores	5	0	0	0	0	0	0	0	5
2.k. Horses, donkeys and cross breeds	0	0	0	90	0	0	0	0	90
2.l. Pigs	841	2428	0	903	4925	329	2013	3682	15121
2.m. Goats	52	37	27	0	0	0	125	131	372
2.n. Sheep	186	1070	50	812	78	44	124	22	2386
2.o. Cattle	154	472	0	304	58	0	103	0	1091
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	8	0	0	0	0	0	0	0	8
2.r. Old World Monkeys	16	74	0	0	427	0	0	0	517
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	16	0	12	0	0	28
2.u. Quail	57	57	0	0	24	0	0	0	138
2.v. Other birds	664	4113	344	4991	35297	30	42	6623	52104
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	661	0	0	0	0	0	13	30	704
2.y. Fish	52521	5780	0	0	940	400	152	11305	71098
2.z. TOTAL	389674	224669	20491	45638	124479	33124	17860	41924	897859

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	19644	0	0	0	126	0	1023	557	41702	63052
3.b. Rats	6570	170	296	120	124	0	0	0	1530	8810
3.c. Guinea-Pigs	3530	0	32	0	0	0	0	0	4	3566
3.d. Hamsters	156	0	0	0	0	0	0	0	0	156
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	6298	43	272	42	110	0	0	0	0	6765
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	254	52	0	0	0	0	0	0	43	349
3.i. Ferrets	32	0	0	0	0	0	0	0	0	32
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	791	0	0	0	0	0	4134	0	0	4925
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	78	0	0	0	0	0	0	0	0	78
3.o. Cattle	58	0	0	0	0	0	0	0	0	58
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	427	0	0	0	0	0	0	0	0	427
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	24	0	0	0	0	0	0	0	24
3.v. Other birds	1268	0	0	0	0	0	34029	0	0	35297
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	504	0	0	0	0	286	150	940
3.z. TOTAL	39106	289	1104	162	360	0	39186	843	43429	124479

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**Main categories versus species**

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	15692	36425	85628	48186	7331	193262
4.b. Rats	11159	33110	2520	58447	586	105822
4.c. Guinea-Pigs	0	234	60	4687	298	5279
4.d. Hamsters	51	103	349	68	175	746
4.e. Other Rodents	0	231	0	10	0	241
4.f. Rabbits	6	6	0	1989	2541	4542
4.g. Cats	4	9	0	3	0	16
4.h. Dogs	47	0	45	88	94	274
4.i. Ferrets	0	0	0	241	0	241
4.j. Other Carnivores	27	0	0	4	5	36
4.k. Horses, donkeys and cross breeds	0	0	0	0	86	86
4.l. Pigs	352	5	3	906	2592	3858
4.m. Goats	20	0	0	8	0	28
4.n. Sheep	26	36	24	170	873	1129
4.o. Cattle	0	0	0	0	606	606
4.p. Prosimians	0	0	0	3	0	3
4.q. New World Monkeys	0	3	0	0	0	3
4.r. Old World Monkeys	0	59	0	15	8	82
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	12	12
4.u. Quail	0	0	0	57	0	57
4.v. Other birds	0	0	0	20	7325	7345
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	5	130	382	0	517
4.y. Fish	200	500	485	23378	4866	29429
4.z. TOTAL	27584	70726	89244	138662	27398	353614

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	33234	0	403	0	2279	35916
5.b. Rats	0	11278	0	655	128	0	12061
5.c. Guinea-Pigs	0	3344	0	731	0	163	4238
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	5337	0	0	16	844	6197
5.g. Cats	4	0	0	0	0	0	4
5.h. Dogs	176	0	0	0	0	0	176
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	90	0	0	0	0	90
5.l. Pigs	0	507	0	0	130	266	903
5.m. Goats	0	27	0	0	0	0	27
5.n. Sheep	0	749	54	0	0	59	862
5.o. Cattle	26	278	0	0	0	0	304
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	16	0	0	0	0	16
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	0	3496	0	1321	0	518	5335
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	206	58356	54	3110	274	4129	66129

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	1147	18053	30	0	40120	3702	63052
6.b. Rats	290	2934	0	244	4286	1056	8810
6.c. Guinea-Pigs	0	434	84	288	2752	8	3566
6.d. Hamsters	80	76	0	0	0	0	156
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	100	764	0	218	5547	136	6765
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	30	0	0	284	35	349
6.i. Ferrets	0	32	0	0	0	0	32
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	329	0	0	4585	11	4925
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	28	0	0	44	6	78
6.o. Cattle	0	0	0	0	58	0	58
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	75	0	0	352	0	427
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	24	0	0	0	0	0	24
6.v. Other birds	0	1	0	0	34029	1267	35297
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	504	150	0	0	286	0	940
6.z. TOTAL	2145	22906	114	750	92343	6221	124479

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	6991	39161	908	56	298	0	840	0	0	0	0	0	14798	63052
7.b. Rats	246	398	949	290	76	0	2593	0	0	0	437	0	3821	8810
7.c. Guinea-Pigs	0	303	24	0	326	0	0	0	0	0	0	0	2913	3566
7.d. Hamsters	16	0	0	0	0	0	80	0	0	0	0	0	60	156
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	22	0	143	397	0	248	0	0	94	0	69	0	5792	6765
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	0	0	0	276	0	0	0	0	0	73	349
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	32	32
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	40	0	0	119	0	0	0	0	0	4766	4925
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	78	78
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	58	58
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	18	0	0	0	0	0	405	0	0	0	0	0	4	427
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	24	0	0	0	0	0	0	0	0	0	0	0	24
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	35297	35297
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	0	0	0	0	0	0	0	213	504	0	0	0	223	940
7.z. TOTAL	7293	39886	2024	783	700	248	4313	213	598	0	506	0	67915	124479

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 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	2082	2797	1788	416	602	62	3942		94		506		26817	39106
8.b. Products/substances used or intended to be used mainly in agriculture		39		105			141						4	289
8.c. Products/substances used or intended to be used mainly in industry		28	236	75	98	113	50		504					1104
8.d. Products/substances used or intended to be used mainly in the household				139		23								162
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	60	202		48		50								360
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption		1023											38163	39186
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	557							213					73	843
8.i. Other toxicological or safety evaluations	4594	35797					180						2858	43429
8.j. TOTAL	7293	39886	2024	783	700	248	4313	213	598	0	506	0	67915	124479

FRANCE

Statistical data submitted

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

Comments of the French authorities

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

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

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

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

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

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

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

Origin versus species

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

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

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

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

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

Purpose versus species

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

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- 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	23.187	3.441	2.074	0	704	0	0	3.776	17.684	50.866
3.b. Rats	26.440	6.006	3.375	159	0	0	0	1.499	9.968	47.447
3.c. Guinea-Pigs	4.468	608	1.755	0	38	0	0	0	448	7.317
3.d. Hamsters	0	0	21	0	0	0	0	0	0	21
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	5.247	563	481	0	43	0	0	0	1.403	7.737
3.g. Cats	24	0	0	0	0	0	0	0	0	24
3.h. Dogs	1.160	104	0	0	0	0	0	0	570	1.834
3.i. Ferrets	237	0	0	0	0	0	0	0	0	237
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	404	0	0	0	0	0	0	30	0	434
3.m. Goats	21	0	0	0	0	0	0	8	0	29
3.n. Sheep	205	0	0	0	0	0	0	0	0	205
3.o. Cattle	84	0	0	0	0	0	0	0	0	84
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	930	0	0	0	0	0	0	0	198	1.128
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	25	0	0	0	0	0	5.000	0	226	5.251
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	179	0	0	0	0	0	0	0	0	179
3.y. Fish	0	1.457	0	0	300	0	0	1.047	150	2.954
3.z. TOTAL	62.611	12.179	7.706	159	1.085	0	5.000	6.360	30.647	125.747

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	60.574	232.877	180.979	333.623	218.942	1.026.995
4.b. Rats	45.947	84.717	15.812	106.175	10.800	263.451
4.c. Guinea-Pigs	479	312	190	2.639	826	4.446
4.d. Hamsters	434	708	0	1.042	2.034	4.218
4.e. Other Rodents	300	1.774	60	191	306	2.631
4.f. Rabbits	1.197	2	123	6.710	1.643	9.675
4.g. Cats	0	31	0	60	837	928
4.h. Dogs	114	133	13	499	667	1.426
4.i. Ferrets	0	0	0	162	0	162
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	335	335
4.l. Pigs	736	0	0	547	2.070	3.353
4.m. Goats	0	10	0	6	355	371
4.n. Sheep	140	62	0	97	1.670	1.969
4.o. Cattle	0	0	0	0	991	991
4.p. Prosimians	0	40	0	308	370	718
4.q. New World Monkeys	0	4	0	115	21	140
4.r. Old World Monkeys	0	20	0	362	0	382
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	120	0	0	11.592	11.712
4.w. Reptiles	0	0	0	0	758	758
4.x. Amphibians	0	52	2.399	658	1.956	5.065
4.y. Fish	900	250	0	930	3.956	6.036
4.z. TOTAL	110.821	321.112	199.576	454.124	260.129	1.345.762

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

Regulatory requirements versus species

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

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

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

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

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

Regulatory requirements versus species

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1.455	7.107	9.877	648	1.733	0	12.298	2.524	730	139	0	0	14.355	50.866
7.b. Rats	36	1.169	5.128	12	1.290	78	16.839	5.287	2.075	1.547	4.489	0	9.497	47.447
7.c. Guinea-Pigs	0	0	36	0	6.584	0	0	0	0	0	86	0	611	7.317
7.d. Hamsters	0	0	0	0	0	0	0	0	0	21	0	0	0	21
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	349	1.059	0	377	568	0	669	0	965	0	3.750	7.737
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.h. Dogs	0	0	461	0	0	0	1.106	0	0	0	18	0	249	1.834
7.i. Ferrets	0	0	211	0	0	0	0	0	0	0	0	0	26	237
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	56	0	0	0	84	0	294	434
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	29	29
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	205	205
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	84	84
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	80	0	0	0	864	0	0	0	0	0	184	1.128
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	5.251	5.251
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	179	179
7.y. Fish	1.907	0	0	0	0	0	890	0	0	0	0	82	75	2.954
7.z. TOTAL	3.398	8.276	16.142	1.719	9.607	455	32.621	7.811	3.474	1.707	5.642	82	34.813	125.747

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	1.965	5.233	9.654	638	4.460	170	14.646	3.293	1.141	1.480	5.211	0	14.720	62.611
8.b. Products/substances used or intended to be used mainly in agriculture	1.430	310	0	100	608	88	5.944	2.682	867	0	150	0	0	12.179
8.c. Products/substances used or intended to be used mainly in industry	0	1.378	665	942	1.673	182	230	246	626	101	60	0	1.603	7.706
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	159	0	0	0	0	0	0	159
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	300	0	43	39	699	4	0	0	0	0	0	0	0	1.085
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	5.000	5.000
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	2.600	0	0	0	0	2.014	0	0	890	327	82	447	6.360
8.i. Other toxicological or safety evaluations	221	3.397	589	0	0	6	3.792	2.604	300	0	1.902	0	17.836	30.647
8.j. TOTAL	3.916	12.918	10.951	1.719	7.440	450	26.785	8.825	2.934	2.471	7.650	82	39.606	125.747

ITALY

Statistical data submitted

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

Comments of the Italian authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	311807	143156	26423	2300	34150	21911	10	13243	553000
2.b. Rats	86363	55681	67788	205	17730	1340	159	1081	230347
2.c. Guinea-Pigs	2710	2170	3521	397	4751	30	0	296	13875
2.d. Hamsters	227	258	0	0	145	87	0	0	717
2.e. Other Rodents	160	215	0	0	0	860	0	0	1235
2.f. Rabbits	1628	1140	4538	305	2009	6	0	80	9706
2.g. Cats	26	0	0	0	0	0	0	0	26
2.h. Dogs	20	46	0	0	877	0	0	0	943
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	31	0	15	0	0	0	0	0	46
2.l. Pigs	1350	1174	15	84	435	0	344	205	3607
2.m. Goats	37	3	0	1	0	0	0	0	41
2.n. Sheep	171	190	62	12	23	0	0	11	469
2.o. Cattle	270	134	0	6	9	2	0	41	462
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	18	0	0	0	0	0	0	18
2.r. Old World Monkeys	12	41	51	0	238	0	0	2	344
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	104	0	0	47	0	0	0	0	151
2.u. Quail	4	0	0	0	0	0	0	245	249
2.v. Other birds	7393	3565	12	12736	6621	1081	0	833	32241
2.w. Reptiles	454	0	0	0	0	0	0	0	454
2.x. Amphibians	2346	20	0	0	0	66	0	0	2432
2.y. Fish	6049	400	0	2518	2018	0	0	2970	13955
2.z. TOTAL	421162	208211	102425	18611	69006	25383	513	19007	864318

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

Products versus species

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

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	17719	72970	123899	130189	7073	351850
4.b. Rats	6348	42732	4325	33482	545	87432
4.c. Guinea-Pigs	380	326	0	2366	182	3254
4.d. Hamsters	20	21	50	357	0	448
4.e. Other Rodents	0	244	0	297	654	1195
4.f. Rabbits	82	262	54	1410	13	1821
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	12	0	0	17	0	29
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	31	31
4.l. Pigs	163	0	8	170	110	451
4.m. Goats	0	0	0	0	3	3
4.n. Sheep	31	0	0	42	16	89
4.o. Cattle	7	0	0	2	2	11
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	18	0	0	0	18
4.r. Old World Monkeys	0	2	0	41	0	43
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	6	6
4.u. Quail	0	0	0	0	249	249
4.v. Other birds	0	0	0	0	1358	1358
4.w. Reptiles	0	0	0	0	86	86
4.x. Amphibians	0	101	0	241	66	408
4.y. Fish	0	0	1629	66	3268	4963
4.z. TOTAL	24762	116676	129965	168680	13662	453745

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	6375	7376	0	100	13027	1845	28723
5.b. Rats	241	1730	0	0	64208	1814	67993
5.c. Guinea-Pigs	657	627	0	0	2634	0	3918
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	344	3773	0	0	714	12	4843
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	15	0	0	0	0	0	15
5.l. Pigs	99	0	0	0	0	0	99
5.m. Goats	1	0	0	0	0	0	1
5.n. Sheep	65	0	0	0	0	9	74
5.o. Cattle	6	0	0	0	0	0	6
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	51	0	51
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	13	34	0	0	0	0	47
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	853	11895	0	0	0	0	12748
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	2170	0	0	0	348	0	2518
5.z. TOTAL	10839	25435	0	100	80982	3680	121036

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

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

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

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

Regulatory requirements versus species

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

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

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

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

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

Types of tests versus species

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

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	184	350	12772	1469	4330	69	11879	79	625	513	701	0	2838	35809
8.b. Products/substances used or intended to be used mainly in agriculture	0	120	65	3	87	6	0	0	0	0	100	0	499	880
8.c. Products/substances used or intended to be used mainly in industry	0	224	361	26	215	15	200	0	244	194	189	0	96	1764
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	35	0	0	0	174	0	50	0	0	0	0	259
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	169	0	0	0	0	0	0	0	0	0	0	768	937
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	930	0	0	0	0	0	3099	0	0	0	470	0	1233	5732
8.i. Other toxicological or safety evaluations	510	5288	3428	0	0	0	2268	0	0	0	0	0	12131	23625
8.j. TOTAL	1624	6151	16661	1498	4632	90	17620	79	919	707	1460	0	17565	69006

CYPRUS

Statistical data submitted

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

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

Comments of the Cypriot authorities

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

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

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

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

Origin versus species

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

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

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

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

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

Purpose versus species

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

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**Main categories versus species**

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice		205	70	165		440
4.b. Rats						0
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	205	70	165	0	440

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice						320	320
5.b. Rats							0
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	0	320	320

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

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

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

LATVIA

Statistical data submitted

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

Comments of Latvian authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	1032	1952	2710			668	550		6912
2.b. Rats	325	460	1037			280	305		2407
2.c. Guinea-Pigs					32				32
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits			48						48
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	1357	2412	3795	0	32	948	855	0	9399

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

Products versus species

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

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	995	634	1353	548	122	3652
4.b. Rats	394	195	360	116		1065
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	1389	829	1713	664	122	4717

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice					2710		2710
5.b. Rats					1037		1037
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits					48		48
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	3795	0	3795

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

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

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

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

Regulatory requirements versus species

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

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

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

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

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

Types of tests versus species

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

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine				32										32
8.b. Products/substances used or intended to be used mainly in agriculture														0
8.c. Products/substances used or intended to be used mainly in industry														0
8.d. Products/substances used or intended to be used mainly in the household														0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	0	0	0	32	0	0	0	0	0	0	0	0	0	32

LITHUANIA

Statistical data submitted

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

Comments of Lithuanian authorities

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

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

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

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

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

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

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

No animals were re-used.

No primates were used.

No animals were used in the testing of cosmetic products.

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	718	1367	525		1213		4		3827
2.b. Rats	44	1070	33		26		21		1194
2.c. Guinea-Pigs	41	40		5	7				93
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits	8	148		5	7		31		199
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs		30					50		80
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds		40							40
2.w. Reptiles									0
2.x. Amphibians		43					106		149
2.y. Fish									0
2.z. TOTAL	811	2738	558	10	1253	0	212	0	5582

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

Products versus species

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

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	189		300	1496	100	2085
4.b. Rats	22		33	959	100	1114
4.c. Guinea-Pigs	39			22	20	81
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	30	24		82	20	156
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs	30					30
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds				20	20	40
4.w. Reptiles						0
4.x. Amphibians		43				43
4.y. Fish						0
4.z. TOTAL	310	67	333	2579	260	3549

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	525						525
5.b. Rats	33						33
5.c. Guinea-Pigs	5						5
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	5						5
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	568	0	0	0	0	0	568

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

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

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

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

Regulatory requirements versus species

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

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

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

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

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

Types of tests versus species

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

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	172													67	239
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														240	240
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations										246				528	774
8.j. TOTAL	172	0	0	0	0	0	0	0	0	246	0	0	835	1253	

LUXEMBOURG

Statistical data submitted

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

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

Comments of Luxembourg authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice		3280							3280
2.b. Rats		430							430
2.c. Guinea-Pigs		100							100
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits		20							20
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	0	3830	0	0	0	0	0	0	3830

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice					3280	3280
4.b. Rats					430	430
4.c. Guinea-Pigs					100	100
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits					20	20
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	0	0	0	3830	3830

HUNGARY

Statistical data submitted

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

Comments of the Hungarian authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice	50186	57384	23136	0	13495	3935	5706	4957	158799
2.b. Rats	24239	60144	0	0	2809	15	2143	25	89375
2.c. Guinea-Pigs	2304	629	3699	774	2006	0	235	96	9743
2.d. Hamsters	214	0	0	0	0	0	1	0	215
2.e. Other Rodents	356	0	0	0	0	0	0	0	356
2.f. Rabbits	1360	2183	0	618	3620	66	287	0	8134
2.g. Cats	6	34	0	0	0	0	0	0	40
2.h. Dogs	352	59	7	0	240	0	23	5	686
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	40	0	40
2.l. Pigs	399	292	0	159	156	130	57	0	1193
2.m. Goats	2	0	0	0	0	50	40	0	92
2.n. Sheep	10	26	0	82	0	0	82	0	200
2.o. Cattle	6	4	0	2	30	51	0	0	93
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	5	0	0	0	0	0	0	0	5
2.r. Old World Monkeys	1	0	0	0	0	0	0	0	1
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	16	0	0	0	0	0	0	16
2.u. Quail	13	0	0	0	0	0	0	0	13
2.v. Other birds	7558	8158	0	13390	462	10	576	2400	32554
2.w. Reptiles	0	50	0	0	0	0	58	0	108
2.x. Amphibians	120	0	0	0	0	0	1062	0	1182
2.y. Fish	345	0	0	0	1126	100	506	0	2077
2.z. TOTAL	87476	128979	26842	15025	23944	4357	10816	7483	304922

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	11093	0	0	0	0	0	288	0	2114	13495
3.b. Rats	1129	0	0	0	0	78	0	0	1602	2809
3.c. Guinea-Pigs	1236	0	0	0	0	0	0	0	770	2006
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	3428	0	0	0	0	0	0	0	192	3620
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	240	0	0	0	0	0	0	0	0	240
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	122	0	0	0	0	0	0	34	0	156
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	30	0	0	0	0	0	0	0	0	30
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	462	0	0	0	0	0	0	0	0	462
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	126	0	0	0	0	0	1000	0	1126
3.z. TOTAL	17740	126	0	0	0	78	288	1034	4678	23944

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	886	69114	8615	27448	5442	111505
4.b. Rats	2564	72436	1777	7621	0	84398
4.c. Guinea-Pigs	72	314	0	2482	65	2933
4.d. Hamsters	0	109	0	83	22	214
4.e. Other Rodents	0	290	0	66	0	356
4.f. Rabbits	447	613	0	1782	767	3609
4.g. Cats	0	30	0	0	10	40
4.h. Dogs	390	21	0	0	0	411
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	0	0
4.l. Pigs	194	0	0	0	627	821
4.m. Goats	2	0	0	0	50	52
4.n. Sheep	0	0	0	0	36	36
4.o. Cattle	0	0	0	0	61	61
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	5	0	0	0	0	5
4.r. Old World Monkeys	1	0	0	0	0	1
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	16	0	0	0	0	16
4.u. Quail	0	0	0	0	13	13
4.v. Other birds	0	0	0	0	15726	15726
4.w. Reptiles	0	50	0	0	0	50
4.x. Amphibians	0	120	0	0	0	120
4.y. Fish	0	0	0	0	445	445
4.z. TOTAL	4577	143097	10392	39482	23264	220812

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	9363	13523	0	0	250	0	23136
5.b. Rats	0	0	0	0	0	0	0
5.c. Guinea-Pigs	586	3887	0	0	0	0	4473
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	40	578	0	0	0	0	618
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	7	0	0	0	0	0	7
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	159	0	0	0	0	159
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	6	76	0	0	0	0	82
5.o. Cattle	0	2	0	0	0	0	2
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	11	13379	0	0	0	0	13390
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	10013	31604	0	0	250	0	41867

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	60	12533	0	0	460	442	13495
6.b. Rats	152	1657	0	0	910	90	2809
6.c. Guinea-Pigs	0	1236	0	0	770	0	2006
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	550	2878	0	0	192	0	3620
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	110	66	58	6	0	0	240
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	81	67	8	0	0	0	156
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	30	0	0	0	0	30
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	462	0	0	0	0	462
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	1000	126	0	0	0	0	1126
6.z. TOTAL	1953	19055	66	6	2332	532	23944

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	3307	4492	3194	0	0	0	160	0	0	323	0	0	2019	13495
7.b. Rats	30	26	1200	0	85	0	400	24	190	30	218	0	606	2809
7.c. Guinea-Pigs	0	0	976	0	420	0	490	0	120	0	0	0	0	2006
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	3420	41	4	28	0	0	127	0	0	0	0	3620
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	108	0	0	0	132	0	0	0	0	0	0	240
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	77	0	0	0	20	0	0	0	0	0	59	156
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	30	30
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	72	0	390	0	0	0	0	0	0	0	0	0	0	462
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	626	0	0	0	0	0	0	0	0	0	0	500	0	1126
7.z. TOTAL	4035	4518	9365	41	509	28	1202	24	437	353	218	500	2714	23944

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	3374	4492	6997	41	509	28	1202	0	437	353	218	0	89	17740
8.b. Products/substances used or intended to be used mainly in agriculture	126	0	0	0	0	0	0	0	0	0	0	0	0	126
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	26	28	0	0	0	0	24	0	0	0	0	0	78
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	288	288
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	500	0	34	0	0	0	0	0	0	0	0	500	0	1034
8.i. Other toxicological or safety evaluations	35	0	2306	0	0	0	0	0	0	0	0	0	2337	4678
8.j. TOTAL	4035	4518	9365	41	509	28	1202	24	437	353	218	500	2714	23944

MALTA

Statistical data submitted

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

Comments of Malta authorities

None

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

Origin versus species

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

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

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

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

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

Purpose versus species

2.1 Species	2.2 Biological studies of a fundamental nature	2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine)	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
2.a. Mice		50							50
2.b. Rats			44						44
2.c. Guinea-Pigs									0
2.d. Hamsters									0
2.e. Other Rodents									0
2.f. Rabbits									0
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish					600				600
2.z. TOTAL	0	50	44	0	600	0	0	0	694

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

Products versus species

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

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice		50				50
4.b. Rats			44			44
4.c. Guinea-Pigs						0
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits						0
4.g. Cats						0
4.h. Dogs						0
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breeds						0
4.l. Pigs						0
4.m. Goats						0
4.n. Sheep						0
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	0	50	44	0	0	94

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							0
5.b. Rats	44						44
5.c. Guinea-Pigs							0
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits							0
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds							0
5.l. Pigs							0
5.m. Goats							0
5.n. Sheep							0
5.o. Cattle							0
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys							0
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds							0
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL							0

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice							0
6.b. Rats							0
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits							0
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish	600						600
6.z. TOTAL	600	0	0	0	0	0	600

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

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

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

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

Types of tests versus species

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

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods												
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	600														600
8.b. Products/substances used or intended to be used mainly in agriculture															0
8.c. Products/substances used or intended to be used mainly in industry															0
8.d. Products/substances used or intended to be used mainly in the household															0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries															0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption															0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption															0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns															0
8.i. Other toxicological or safety evaluations															0
8.j. TOTAL	600	0	0	0	0	0	0	0	0	0	0	0	0	0	600

THE NETHERLANDS

Statistical data submitted

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

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

Comments of the Dutch authorities

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

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

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

- Animal experiments using LD₅₀/LC₅₀ methods are prohibited. However, for acute dermal and acute respiratory toxicity tests a general exemption is granted, due to the lack of validated alternative methods.
- Animal experiments for new or existing cosmetics are prohibited.
- Since 2003 animal experiments on great apes are prohibited.
- Every animal experiment to be performed has to be recommended by a recognised ethical review committee. Such a committee comprises at least seven members, one of whom is the chairperson. In addition, such a committee comprises in equal numbers experts in the fields of animal experiments, experts in the field of alternative methods, experts in the field of animal welfare and protection and experts in the field of ethical assessment. At least two of these experts are not involved in the conduct of experiments on animals. The chairperson and at least two members are not in the employment of any licence holder applying to the committee. The animal welfare officer is involved already at an early stage in the review of experiments and acts as a permanent advisor for the ethical review committee. At this moment 23 ethical review committees are recognized.

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

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

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

The creation of transgenic animals

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

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

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

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

Collection of data

87 establishments completed the 2008 registration form.

These establishments can be categorized as follows:

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

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

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

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

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

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

Total number of animals used

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

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

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

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

Discomfort

General

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

As a consequence of the animal experiments performed in 2008:

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

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

Origin versus species

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

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

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

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

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

Purpose versus species

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

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice	3224	201	1499	0	0	2598	0	0	0	7522
3.b. Rats	5838	4193	11700	48	0	1286	177	0	42	23284
3.c. Guinea-Pigs	134	0	49	0	0	0	0	0	0	183
3.d. Hamsters	30	0	0	0	0	0	0	0	0	30
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	2222	634	1681	0	0	6	0	0	0	4543
3.g. Cats	44	0	0	0	0	0	0	0	0	44
3.h. Dogs	471	48	0	0	0	0	0	0	0	519
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	26	0	0	0	0	0	162	0	0	188
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	353	0	365	0	0	0	0	2665	0	3383
3.z. TOTAL	12342	5076	15294	48	0	3890	339	2665	42	39696

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

Main categories versus species

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
4.a. Mice	16595	13267	47276	84369	11454	172961
4.b. Rats	4070	11472	1554	20855	46	37997
4.c. Guinea-Pigs	0	98	0	463	40	601
4.d. Hamsters	0	9	0	263	240	512
4.e. Other Rodents	0	27	0	619	0	646
4.f. Rabbits	369	5	56	476	38	944
4.g. Cats	0	0	0	6	39	45
4.h. Dogs	61	0	0	28	269	358
4.i. Ferrets	0	0	0	355	87	442
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	37	350	387
4.l. Pigs	293	0	36	263	3784	4376
4.m. Goats	106	0	0	75	4	185
4.n. Sheep	32	0	0	271	467	770
4.o. Cattle	0	0	0	129	997	1126
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	9	0	64	0	73
4.r. Old World Monkeys	0	0	0	72	0	72
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	1160	39694	40854
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	148	210	1003	95	1456
4.z. TOTAL	21526	25035	49132	110508	57604	263805

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	0	2725	0	1978	15087	1487	21277
5.b. Rats	0	4000	0	758	26194	68	31020
5.c. Guinea-Pigs	0	543	0	160	2400	1845	4948
5.d. Hamsters	0	0	0	0	2539	0	2539
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	0	1	0	0	1582	86	1669
5.g. Cats	27	0	0	0	58	0	85
5.h. Dogs	22	0	0	0	165	11	198
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	60	2057	2117
5.l. Pigs	0	0	0	0	1610	676	2286
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	2	0	0	0	10	2649	2661
5.o. Cattle	16	0	0	6	359	346	727
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	75	0	60	0	15474	5079	20688
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	142	7269	60	2902	65538	14304	90215

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	4	0	0	0	6870	648	7522
6.b. Rats	77	0	0	0	22654	553	23284
6.c. Guinea-Pigs	4	0	0	0	57	122	183
6.d. Hamsters	0	0	0	0	30	0	30
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	4540	3	4543
6.g. Cats	0	0	0	0	44	0	44
6.h. Dogs	0	0	0	0	519	0	519
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	13	175	188
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	77	0	0	0	2898	408	3383
6.z. TOTAL	162	0	0	0	37625	1909	39696

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

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

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

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

Types of tests versus species

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

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino- genicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	0406	03.645	0182	0832	028	02.490	0106	0	0673	0994	0	02.986	12342
8.b. Products/substances used or intended to be used mainly in agriculture	0	034	0390	030	044	03	0120	0	0703	0184	03.568	0	0	5076
8.c. Products/substances used or intended to be used mainly in industry	0365	0749	01.833	0465	01.193	0152	0288	0	07.141	0375	02.227	0	0506	15294
8.d. Products/substances used or intended to be used mainly in the household	0	016	032	0	0	0	0	0	0	0	0	0	0	48
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	06	0120	03	0	03	0951	0	02.293	0305	0167	0	042	3890
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	077	0	0	0	0100	0	0	0	0	0	0162	339
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0833	0421	0991	0119	0	0	0301	0	0	0	0	0	0	2665
8.i. Other toxicological or safety evaluations	0	0	0	0	0	0	0	0	0	042	0	0	0	42
8.j. TOTAL	1198	1632	7088	799	2069	186	4250	106	10137	1579	6956	0	3696	39696

AUSTRIA

Statistical data submitted

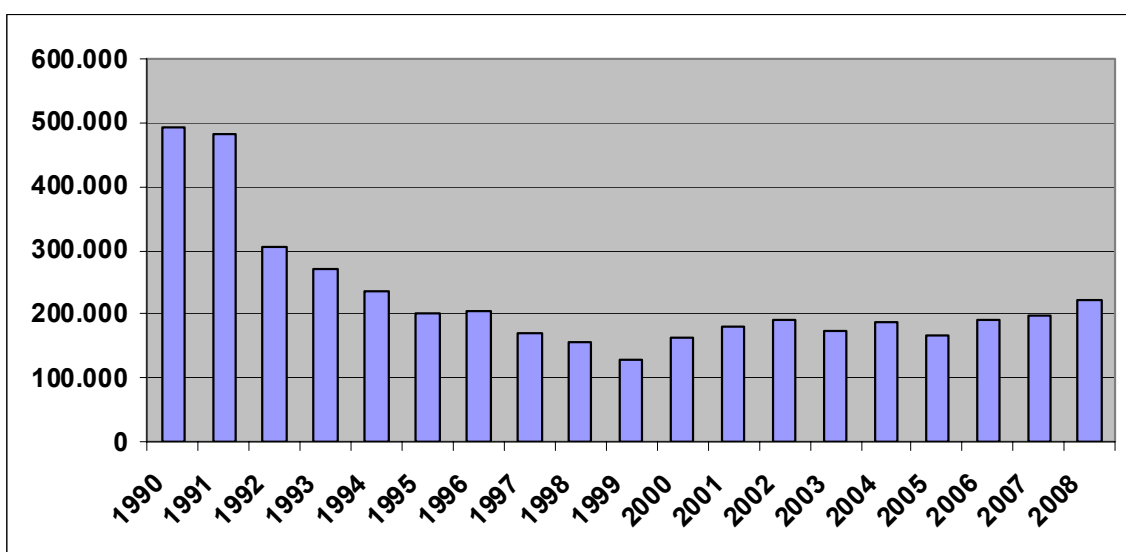
The statistical data have been submitted by the “*Bundesministerien für Gesundheit und Frauen-Land und Forstwirtschaft, Umwelt und Wasserwirtschaft – Wirtschaft und Arbeit - Bildung, Wissenschaft und Kultur*” (Federal Ministries for Health and Women -Agriculture Forestry, the Environment and Water Mangement – Economic Affairs and Labour - Education, Science and Culture).

Comments from the Austrian authorities

The number of animals used in procedures in Austria during 2008 has risen by 11,4% as compared to 2007. However, relative to international figures the Austrian number still remains low. The animal use statistics for 2008 show that in total 220,456 animals were used in procedures in Austria.

Compared to previous years, this total number lies within the range of variation of the last years, yet is still well below the number of the earliest years. Relative to 1990 (the year statistics were recorded for the first time, in which year 482,166 animals were used in procedures) the number of animals is reduced by about 55%. No great apes were used in 2008. No animals have been used for cosmetics testing. The statistics have been presented in the EU-wide standardized format.

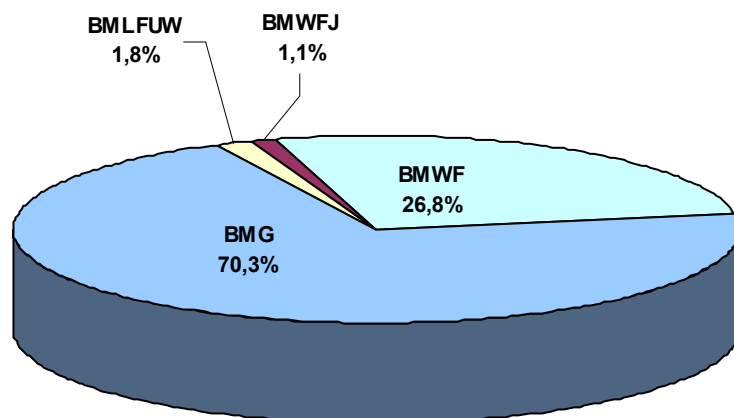
Development of the numbers of animals used since 1990



Breakdown according to areas of competence

A breakdown of the numbers according to areas of competence for administration of the Animal Experiments Law ranks them as follows:

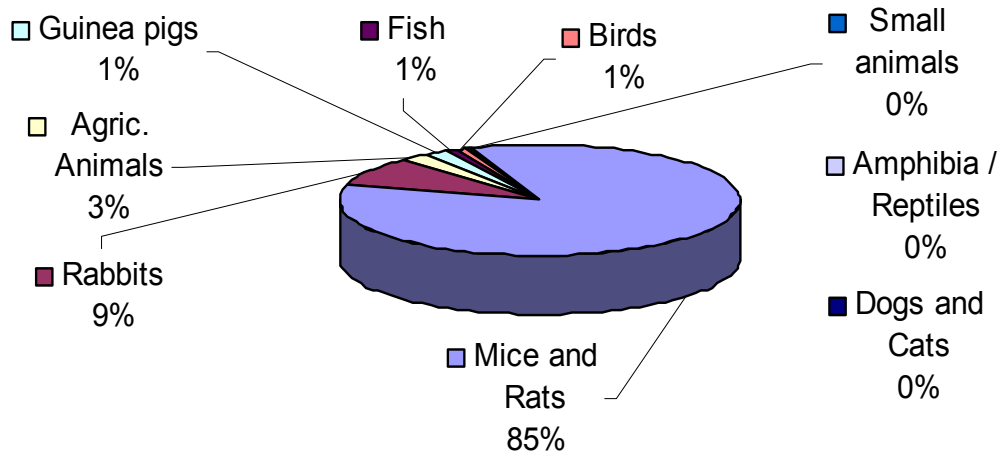
Health (BMG: Federal Ministry of Health - primarily R&D for pharmaceuticals, production and quality control of pharmaceuticals and medicinal products, animal health products) is placed first with 155,161 (70,3%) animals. Second is Science and Research (BMWF: Federal Ministry of Science and Research: universities, Austrian Academy of Sciences, etc. - primarily basic research, in particular health related research) with 58,971 (26,8%) animals. Environmental Protection and Agriculture (BMLFUW: Federal Ministry of Agriculture, Forestry, Environment and Water Management - primarily safety testing of chemicals and protection of the environment) follows with 3,872 (1,8%) animals and Industry (BMWFJ: Federal Ministry of Economy, Family and Youth - primarily basic research) is last with 2,452 (1,1%) animals used.



Predominantly mice and rats are used as experimental animals

Of the total number of 220,456 animals used in procedures in Austria during 2008 were:

187.472	85,0%	mice and rats
18.761	8,5%	rabbits
3.284	1,5%	guinea pigs
5.888	2,7%	agricultural animals
1.381	0,6%	birds
2.579	1,2%	fish
754	0,3%	small animals (hamsters, ferrets, other rodents)
294	0,1%	amphibia and reptiles
41		dogs
2		cats



■ Mice and Rats	■ Rabbits	■ Agric. Animals
■ Guinea pigs	■ Fish	■ Birds
■ Small animals	■ Amphibia / Reptiles	■ Dogs and Cats

Animal Tests for Humans and Animals

The number of animals used in procedures in 2008 - with 85% (187,472) predominantly mice and rats – is generally due to increased biomedical research in Austria as well as businesses active in biomedical, pharmaceutical and biological research and production. This research and development was directed to production and quality control of human and veterinary pharmaceuticals and medicinal products manufactured for the international market and for combating severe diseases such as cancer or cardiovascular diseases.

A significant part was also devoted to the development, production and quality control of vaccines for the international market, in particular vaccines for which there was a demand from health authorities all over the world.

In scientific and basic research the aims were *inter alia* improvement of the knowledge in the area of cancer research and development of effective therapies with reduced side effects or stress for the patients. Fundamental and applied research was conducted on cardiovascular diseases (myocardial infarction and its consequences) and neurological disorders (Alzheimer, Parkinson and prion-related diseases).

Increased biomedical research as well as the development of pharmaceuticals and medicinal products requires animal tests - as a first step and precondition for clinical testing on humans – in the interest of health and safety of humans and animals. The same is also true for quality control of pharmaceuticals and medicinal products.

Last but not least, animal tests are also required for animal health, meaning that for the development of veterinary pharmaceuticals it is necessary to conduct clinical studies on animal patients, and animal tests are similarly necessary for the development of diagnostic and therapeutic measures for animals.

Animal Test with Minimal Pain on Healthy Cattle for the Health of Agricultural Animals

An example of the fact that animal tests with minimal pain are sometimes necessary to improve the health of animals is provided by the number of cattle which appear in the 2008 Statistics due to a research project of the Federal Ministry of Agriculture, Forestry, Environment and Water Management dealing with “Full pastoral farming of dairy cattle under alpine production conditions”. In this research project merely blood samples were taken from healthy cows in agricultural productions units in order to investigate how the conversion to low-input pastoral farming affects fertility and animal health, milk production and quality and to find out which consequences for the output of the farm and for the environment might arise from the conversion.

No animal experiments for cosmetics

In accordance with the legal prohibition of animal experiments for cosmetics (§ 3 Abs. 5 Tierversuchsgesetz) in force since 1999 there were naturally no animal experiments carried out for cosmetics.

No great apes used

It is particularly gratifying that in 2008 in Austria no animal experiments on great apes were carried out, in accordance with the legal prohibition of animal experiments on great apes which has been in force since January 1, 2006 (BGBl. I, Nr. 162/2005). This also reflects a general trend in Europe to

restrict such experiments as far as possible and to avoid them altogether according to the best available science.

Statistics in EU-wide standardized format

In accordance with the amended Animal Experiments Law (BGBl. I, Nr. 169/1999) and the Ordinance on Animal Use Statistics (BGBl. II Nr. 199/2000) the Animal Use Statistics 2008 requires the use of eight statistical tables which should contain data in a standardized format and give details on, *inter alia*, the origin of the animals, the purposes for which they were used (basic research, R&D for medicines and medicinal products, for quality control, etc.).

Internationally Compared Low Animal Numbers in Austria

The number of animals used in procedures in Austria contributed less than 1,5% to the total number of 12.1 million vertebrate animals used in Europe, as can be seen from the EU-wide animal use statistics for 2005 (the last year for which the European Commission compiled such a statistical report). When comparing at an international level, the figures of animal numbers in Austria still remain low. These comparatively low numbers of animals are due to at least three interconnected developments in relation to animals experiments:

1. Application of „3R“

Firstly, scientists, researchers and users themselves apply the principles of the „3R“ (Replacement, Reduction, Refinement) - which also guide the Austrian Animal Experiments Law - to the widest possible extent, as well as using alternatives.

2. Restrictive authorization practice for projects

Second, all authorities issue permits for projects very restrictively in accordance with the strict provisions of the Animal Experiments Law and the Ordinance on Animal Experiments, which allow animal experiments only under very restrictive conditions and stipulate that projects may only be permitted, if no other satisfactory methods are available to achieve the aim without using live animals.

3. Support for research on Alternative Methods to Animal Testing

Finally, public financial support for developing and promoting alternative methods contributes to motivation of users and researchers:

3.1. Financial support for research projects aimed at developing alternative methods, totalling more than 2,562m EUR for 29 projects, as well as promoting the use of alternative methods nationally and internationally,

3.2. National Award for Alternative Methods, i.e. a specific award publicly recognizing scientific achievements in the area of 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>)	177544	41.468	133.479	116	2.481	61
1.b. Rats (<i>Rattus norvegicus</i>)	9928	4.140	5.652	0	136	20
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	3284	737	2.547	0	0	0
1.d. Hamsters (<i>Mesocricetus</i>)	693	0	693	0	0	0
1.e. Other Rodents (other <i>Rodentia</i>)	47	0	20	0	27	0
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	18761	14.886	3.857	0	18	0
1.g. Cats (<i>Felis catus</i>)	2	0	2	0	0	0
1.h. Dogs (<i>Canis familiaris</i>)	41	6	13	0	22	22
1.i. Ferrets (<i>Mustela putorius furo</i>)	14	0	0	0	14	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	47	16	20	0	11	20
1.l. Pigs (<i>Sus</i>)	5086	4889	6	0	191	0
1.m. Goats (<i>Capra</i>)	39	35	0	0	4	0
1.n. Sheep (<i>Ovis</i>)	142	98	0	0	44	23
1.o. Cattle (<i>Bos</i>)	574	539	14	0	21	4
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	0	0	0	0	0
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	14	14	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	1367	548	119	0	700	77
1.w. Reptiles (<i>Reptilia</i>)	17	0	0	0	17	0
1.x. Amphibians (<i>Amphibia</i>)	277	19	0	0	258	20
1.y. Fish (<i>Pisces</i>)	2579	1880	65	0	634	0
1.z. TOTAL	220456					

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	44.234	76.102	51.086	0	3.420	1.083	713	906	177544
2.b. Rats	4.106	3.036	68	0	2.352	0	366	0	9928
2.c. Guinea-Pigs	211	522	1.618	0	925	0	8	0	3284
2.d. Hamsters	0	185	358	0	150	0	0	0	693
2.e. Other Rodents	47	0	0	0	0	0	0	0	47
2.f. Rabbits	143	520	17.276	14	726	0	82	0	18761
2.g. Cats	2	0	0	0	0	0	0	0	2
2.h. Dogs	0	14	0	0	0	0	12	15	41
2.i. Ferrets	0	14	0	0	0	0	0	0	14
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breeds	35	0	0	0	0	12	0	0	47
2.l. Pigs	1.730	2.665	0	0	63	125	382	121	5086
2.m. Goats	0	1	3	0	0	0	35	0	39
2.n. Sheep	46	17	5	0	0	0	74	0	142
2.o. Cattle	334	14	0	0	0	5	176	45	574
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	0	0	0	0	0	0	0	0	0
2.u. Quail	14	0	0	0	0	0	0	0	14
2.v. Other birds	1.174	84	14	0	0	12	83	0	1367
2.w. Reptiles	17	0	0	0	0	0	0	0	17
2.x. Amphibians	277	0	0	0	0	0	0	0	277
2.y. Fish	2.053	0	0	0	416	60	0	50	2579
2.z. TOTAL	54423	83174	70428	14	8052	1297	1931	1137	220456

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contaminants in the general environment which do not appear in other columns	3.10 Other toxicological or safety evaluations	3.11 Total
3.a. Mice	2.720	0	0	0	0	0	0	0	700	3420
3.b. Rats	824	0	0	0	0	0	0	0	1.528	2352
3.c. Guinea-Pigs	250	0	0	0	0	0	0	0	675	925
3.d. Hamsters	150	0	0	0	0	0	0	0	0	150
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	580	0	0	0	0	0	0	0	146	726
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	0	0	0	0	0	0	0	0	0	0
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	63	0	0	0	0	0	0	0	0	63
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	0	0	0	0	0	132	284	416
3.z. TOTAL	4587	0	0	0	0	0	0	132	3333	8052

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	3.871	4.726	21.735	48.038	103	78473
4.b. Rats	893	598	1.683	3.482	27	6683
4.c. Guinea-Pigs	108	92	0	546	0	746
4.d. Hamsters	0	358	0	185	0	543
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	94	14	2	841	0	951
4.g. Cats	0	0	0	0	2	2
4.h. Dogs	0	0	0	0	35	35
4.i. Ferrets	0	0	0	14	0	14
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breeds	0	0	0	0	24	24
4.l. Pigs	275	10	0	200	154	639
4.m. Goats	0	0	0	1	0	1
4.n. Sheep	9	0	0	38	4	51
4.o. Cattle	0	0	0	0	344	344
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	149	541	690
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	7	6	6	0	0	19
4.y. Fish	1.794	0	0	0	60	1854
4.z. TOTAL	7051	5804	23426	53494	1294	91069

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	7.019	0	0	44.067	0	51086
5.b. Rats	60	8	0	0	0	0	68
5.c. Guinea-Pigs	0	236	0	0	1.382	0	1618
5.d. Hamsters	0	0	0	358	0	0	358
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	26	11.078	0	0	6.172	14	17290
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	0	0	0
5.m. Goats	0	0	0	3	0	0	3
5.n. Sheep	0	0	0	5	0	0	5
5.o. Cattle	0	0	0	0	0	0	0
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	4	0	0	10	0	0	14
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	90	18.341	0	376	51.621	14	70442

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	0	2596	0	0	824	0	3420
6.b. Rats	0	212	0	0	2045	95	2352
6.c. Guinea-Pigs	0	104	0	0	821	0	925
6.d. Hamsters	0	0	0	0	150	0	150
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	20	271	0	0	435	0	726
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	0	0	0
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	63	63
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	0	0	0	0	0	0
6.v. Other birds	0	0	0	0	0	0	0
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	132	0	0	0	284	0	416
6.z. TOTAL	152	3183	0	0	4559	158	8052

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	36	1670	0	522	0	0	0	0	266	0	0	926	3420
7.b. Rats	0	1124	136	12	0	0	629	0	0	0	0	0	451	2352
7.c. Guinea-Pigs	0	0	80	0	695	0	126	0	0	0	0	0	24	925
7.d. Hamsters	0	0	0	0	0	0	150	0	0	0	0	0	0	150
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	20	18	74	0	89	75	0	0	0	0	0	450	726
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	0	0	0	0	0	0	0	0
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	63	0	0	0	0	0	0	0	0	0	63
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y. Fish	0	0	0	0	0	0	0	0	0	0	0	416	0	416
7.z. TOTAL	0	1180	1904	149	1217	89	980	0	0	266	0	416	1851	8052

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	224	1.904	63	20	17	420	0	0	88	0	0	1.851	4587	224
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i. Other toxicological or safety evaluations	0	956	0	86	1.197	72	560	0	0	178	0	284	0	3333
8.j. TOTAL	0	1180	1904	149	1217	89	980	0	0	266	0	416	1851	8052

POLAND

Statistical data submitted

The statistical data have been submitted by the Ministry of Science and Higher Education Warsaw.

Comments of the Polish authorities

None

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	123897	122068	705	227	897	
1.b. Rats (<i>Rattus norvegicus</i>)	45824	44646	61	150	967	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	6495	6495	0	0	0	
1.d. Hamsters (<i>Mesocricetus</i>)	312	280	0	0	32	
1.e. Other Rodents (other <i>Rodentia</i>)	11966					
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	3086	2804	0	0	282	137
1.g. Cats (<i>Felis catus</i>)	83	21	0	0	62	0
1.h. Dogs (<i>Canis familiaris</i>)	230	9	0	0	221	18
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	520					
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	529					
1.l. Pigs (<i>Sus</i>)	11742					
1.m. Goats (<i>Capra</i>)	300					
1.n. Sheep (<i>Ovis</i>)	2217					
1.o. Cattle (<i>Bos</i>)	7540					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	0	0	0	0	0
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	1246					
1.u. Quail (<i>Coturnix coturnix</i>)	5100	5100	0	0	0	
1.v. Other birds (other <i>Aves</i>)	27391					
1.w. Reptiles (<i>Reptilia</i>)	248					
1.x. Amphibians (<i>Amphibia</i>)	1221					
1.y. Fish (<i>Pisces</i>)	25941					
1.z. TOTAL	275888					

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	61614	2649	12230	4911	7243	2855	1620	30775	123897
2.b. Rats	33700	1277	1703	0	4845	2519	891	889	45824
2.c. Guinea-Pigs	26	0	5309	323	815	0	9	13	6495
2.d. Hamsters	186	100	0	0	0	10	6	10	312
2.e. Other Rodents	11526	0	0	0	204	50	106	80	11966
2.f. Rabbits	718	167	853	587	358	65	171	167	3086
2.g. Cats	0	0	13	0	1	9	0	60	83
2.h. Dogs	25	0	0	0	0	180	0	25	230
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	510	0	0	0	0	0	0	10	520
2.k. Horses, donkeys and cross breeds	309	0	0	0	0	130	65	25	529
2.l. Pigs	3118	16	10	0	20	40	107	8431	11742
2.m. Goats	147	0	48	0	0	0	33	72	300
2.n. Sheep	1374	0	0	0	0	0	244	599	2217
2.o. Cattle	6380	0	60	0	0	0	1070	30	7540
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	1238	0	0	0	0	0	8	0	1246
2.u. Quail	4730	0	0	0	360	0	10	0	5100
2.v. Other birds	21006	88	524	0	97	222	650	4804	27391
2.w. Reptiles	246	0	0	0	0	0	2	0	248
2.x. Amphibians	697	0	0	0	0	0	524	0	1221
2.y. Fish	11022	0	0	0	3748	168	33	10970	25941
2.z. TOTAL	158572	4297	20750	5821	17691	6248	5549	56960	275888

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	2571	347	0	0	0	0	0	0	4325	7243
3.b. Rats	1397	472	230	0	0	920	0	897	929	4845
3.c. Guinea-Pigs	489	280	46	0	0	0	0	0	0	815
3.d. Hamsters	0	0	0	0	0	0	0	0	0	0
3.e. Other Rodents	0	0	0	0	0	0	0	204	0	204
3.f. Rabbits	177	129	44	8	0	0	0	0	0	358
3.g. Cats	1	0	0	0	0	0	0	0	0	1
3.h. Dogs	0	0	0	0	0	0	0	0	0	0
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	20	0	0	0	0	0	0	0	20
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	60	300	0	0	0	0	0	0	0	360
3.v. Other birds	0	0	0	0	0	0	0	97	0	97
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	1127	2260	169	52	0	0	0	140	0	3748
3.z. TOTAL	5822	3808	489	60	0	920	0	1338	5254	17691

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	1041	44644	7545	7020	1703	61953
4.b. Rats	1985	7400	493	7393	30	17301
4.c. Guinea-Pigs	0	0	0	0	0	0
4.d. Hamsters	0	0	176	40	0	216
4.e. Other Rodents	154	440	0	50	70	714
4.f. Rabbits	0	0	0	455	0	455
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	0	0	9	0	180	189
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	130	130
4.l. Pigs	40	0	0	87	0	127
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	24	0	24
4.o. Cattle	0	0	0	0	0	0
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	1800	0	12	292	2104
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	260	260
4.z. TOTAL	3220	54284	8223	15081	2665	83473

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	7974	5575	0	590	257	2745	17141
5.b. Rats	549	1062	0	60	32	0	1703
5.c. Guinea-Pigs	745	4658	0	195	0	34	5632
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	305	348	0	0	647	140	1440
5.g. Cats	12	1	0	0	0	0	13
5.h. Dogs	0	0	0	0	0	0	0
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	0	0	0	0	0	0
5.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	10	0	10
5.m. Goats	48	0	0	0	0	0	48
5.n. Sheep	0	0	0	0	0	0	0
5.o. Cattle	60	0	0	0	0	0	60
5.p. Prosimians	0	0	0	0	0	0	0
5.q. New World Monkeys	0	0	0	0	0	0	0
5.r. Old World Monkeys	0	0	0	0	0	0	0
5.s. Apes	0	0	0	0	0	0	0
5.t. Other Mammals	0	0	0	0	0	0	0
5.u. Quail	0	0	0	0	0	0	0
5.v. Other birds	524	0	0	0	0	0	524
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	10217	11644	0	845	946	2919	26571

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	2445	3920	0	0	0	878	7243
6.b. Rats	2135	2462	0	0	70	178	4845
6.c. Guinea-Pigs	66	749	0	0	0	0	815
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	204	0	0	0	0	0	204
6.f. Rabbits	30	298	0	0	0	30	358
6.g. Cats	0	1	0	0	0	0	1
6.h. Dogs	0	0	0	0	0	0	0
6.i. Ferrets	0	0	0	0	0	0	0
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breeds	0	0	0	0	0	0	0
6.l. Pigs	20	0	0	0	0	0	20
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	0	0	0	0	0	0
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	0	0	0
6.s. Apes	0	0	0	0	0	0	0
6.t. Other Mammals	0	0	0	0	0	0	0
6.u. Quail	0	360	0	0	0	0	360
6.v. Other birds	0	0	0	0	0	97	97
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	100	2598	0	0	0	1050	3748
6.z. TOTAL	5000	10388	0	0	70	2233	17691

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 Carcinog- enicity	7.8 Develop- mental toxicity	7.9 Muta- genicity	7.10 Repro- ductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	280	0	664	0	0	0	384	0	0	0	0	0	5915	7243
7.b. Rats	584	0	881	0	0	0	859	0	1692	0	545	0	284	4845
7.c. Guinea-Pigs	0	0	0	0	546	0	0	0	0	0	0	0	269	815
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e. Other Rodents	0	0	0	0	0	0	204	0	0	0	0	0	0	204
7.f. Rabbits	0	0	15	182	0	86	0	0	25	0	0	0	50	358
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	1	1
7.h. Dogs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	20	20
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n. Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u. Quail	360	0	0	0	0	0	0	0	0	0	0	0	0	360
7.v. Other birds	0	0	0	0	0	0	0	0	0	0	0	0	97	97
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	3326	0	0	0	0	0	0	0	0	0	100	232	90	3748
7.z. TOTAL	4550	0	1560	182	546	86	1447	0	1717	0	645	232	6726	17691

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcinog- enicity	8.8 Develop- mental toxicity	8.9 Muta- genicity	8.10 Repro- ductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	1307	0	1078	53	274	6	381	0	447	0	391	367	1518	5822
8.b. Products/substances used or intended to be used mainly in agriculture	2670	0	0	62	251	56	241	0	146	0	283	0	99	3808
8.c. Products/substances used or intended to be used mainly in industry	139	0	47	18	16	10	101	0	34	0	88	0	36	489
8.d. Products/substances used or intended to be used mainly in the household	52	0	0	4	0	4	0	0	0	0	0	0	0	60
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	106	0	814	0	0	0	0	920
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	381	0	0	0	0	860	0	0	0	0	0	97	1338
8.i. Other toxicological or safety evaluations	577	0	743	84	0	0	556	0	0	187	0	0	3107	5254
8.j. TOTAL	4745	381	1868	221	541	76	2245	0	1441	187	762	367	4857	17691

PORTUGAL

Statistical data submitted

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

Comments of the Portuguese authorities

1. Total number of animals used by species

In 2008, the total number of animals used for experimental and other scientific purposes in Portugal was 50,888.

Compared to the data of 2005, where the total number of used animals was 41,621, it means that with regard to 2008 there was an increase in the use of animals of 22,26%.

Mice are the most commonly used species representing 78,23% of the total number of animals.

The second most used group of animals was Rats (12,91%).

The third most used group is represented by the Cold-blooded animals (7,47%) and the fourth by the group of Artio and Perissodactyla with 0,52%.

Rodents with Rabbits represent 91,69% of the total number of animals used.

The Carnivores were not used in 2008 and, as in other previous reports, in Portugal, Non-human primates continued to not being used.

Comparison with the data of the previous report (data of 2005)

The percentages of classes of animals used in 2005 (41,621 animals) and in 2008 (50,888 animals) are represented in the following table:

<u>Class of animals (%)</u>	2005	2008
Mice	68,04	78,23
Rats	16,32	12,91
Guinea-pigs	0,91	0,30
Hamsters and other rodents	0,31	0,06

Rabbits	1,43	0,19
Cold-blooded animals	11,53	7,47
Quail and other birds	0,27	0,31
Artio Perissodactyla	1,11	0,52
Carnivores	0,09	0,00

In 2008, looking at the data by groups of animals, the percentage of all of them decreased. However the largest increase occurred, again, in mice and a slight increase in the Birds group (quail and other birds). The biggest decrease occurred in the use of cold-blooded animals (4,06%) followed in descending order, by the use of rats (3.41%) and in rabbits (1,24%).

Within the group of cold-blooded animals, fish were the only animals used.

Within the Artiodactyla, Pigs were the most used animals (61,67%).

2. Number of animals used by purposes of experiments

In 2008, the percentage of animals (total 50,888) used by purposes of experiments was the following:

- 83,82% of animals were used in “Fundamental biology”;
- 9,74% in “Research and development for human medicine, veterinary medicine, dentistry”;
- 0% in “Production and quality control of products and devices in human medicine and dentistry and veterinary medicine”;
- 0,61% in “Toxicological and other safety evaluation”;
- 1,44% in “Diagnosis of disease”;
- 1,83% in “Education and training”;
- 2,55% in “Other purposes”;

Referring to the use of species versus experimental purposes, the highest amount of use of mice and of rats is in “fundamental biology” and in “research and development for human medicine, veterinary medicine, dentistry”.

Comparison with the data of the previous report (data of 2005)

The most significant increase in 2008 is the number of animals that were used for “Fundamental biology”, which increased from 78,78%, in 2005, to 83,82%, in 2008.

The other increases that occurred were in the percentage of animals used in “Research and development for human medicine, veterinary medicine, dentistry” which increased from 6,78%, in 2005, to 9,74%, in 2008, and in “Other purposes” which increased from 1,39% in 2005, to 2,55% in 2008.

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

The percentage of animals used for “Production and quality control of products and devices in human medicine and dentistry and veterinary medicine” was the biggest decrease in 2008 as no animal was used for this purpose, compared to 2005 in which 5,09% of all animals were used to this same purpose.

The percentage of animals used for “Toxicological and other safety evaluation” decreased from 2,26% to 0,61%.

The percentage of animals used for “Education and training” decreased from 3,02% to 0,61%.

3. Number of animals used for “Toxicological and safety evaluation” by type of products

In 2008, the use of animals in “Toxicological and other safety evaluation” represents only 0,61%, which only refers to 310 animals (mice), of a total of 50,888 animals that were used for experimental purposes in Portugal.

“Potential or actual contaminants in the general environment which do not appear in other columns” represents 61,30% of the animals used for “Toxicological and other safety evaluation” and “Other toxicological or safety evaluations” represent 38,70%.

Comparison with the data of the previous report (data of 2005)

Compared to the data of 2005, in 2008 there was a decrease in the use of animals in “Toxicological and other safety evaluation”.

The percentage of animals used for “Toxicological and other safety evaluation” decreased from 2,26% to 0,61% (from 939 to 310 animals).

The data of 2008 refers to the same category of products that had been tested in 2005, except for the category of “Products/substances or devices for human medicine and dentistry and for veterinary medicine” where no animals were used in 2008.

“Potential or actual contaminants in the general environment which do not appear in other columns” represented, in 2005, 21,29% of the animals used for “Toxicological and other safety evaluation” and, in 2008, 61,30%; “Other toxicological or safety evaluations” represented 26,62% in 2005 while, in 2008, 38,70%, which means that there was an increase in 2008.

As in 2005, in 2008 the other groups of products/substances were not tested which means that, for example, there were no animals used for the purpose of evaluating the safety of cosmetics or additives in food for animal consumption.

4. Number of animals used for the study of diseases

In 2008, the number of animals used for the “Studies on human and animal diseases” was 14,753, which represents 29% of the total number of animals (50,888 animals) that were used.

The percentages of animals per type of diseases were:

- 2,70% in “Human cardiovascular diseases”;
- 15,66% in “Human nervous and mental disorders”;
- 2,22% in “Human cancer (excl. evaluation of carcino hazards)”;
- 75,57% in “Other human diseases”;
- 3,85% in “Specific animal diseases”.

The percentage of the number of animals used for studies of human diseases represents 96,15% (14,185 animals) of the total number of animals used for all studies of diseases (14,753 animals).

In 2008, the number of animals used to study animal diseases was only 568 (3.85%) while in 2005, that number had been 271 (1.40%), which means that in 2008, there was an increase on the use of animals for the study of animal diseases.

5. Number of animals used for “Toxicological and other safety evaluations” by the types of tests

As referred previously, in 2008, the use of animals in “Toxicological and other safety evaluation” represents only 0,61%, which only refers to 310 animals, of a total of 50,888 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2005)

The percentages of animals used in toxicity tests for “Toxicological and other safety evaluation” in 2005 (939 animals) and in 2008 (310 animals) are represented in the following table:

Type of tests (%)	2005	2008
Acute and sub-acute toxicity testing methods (including limit test)	37,6	0

Irritation/sensitization tests	27,8	0
Sub-chronic and chronic toxicity	0	0
Mutagenicity and Carcinogenicity	32	38,71
Reproductive and developmental toxicity	0	0
Toxicity of aquatic vertebrates not included in other columns	0	0
Other tests	2,7	61,29

In 2008, the uses of animals in toxicity tests only fell into the categories of “Carcinogenicity” and “Other tests” which means that there was a decrease in the other uses of tests compared to data of 2005, i.e., “Acute and sub-acute toxicity testing methods (including the 'limit test')” and “Irritation/sensitization tests” the percentage of which decreased to 0%.

6. Type of toxicity tests carried out for “Toxicological and other safety evaluations” of products

As pointed out previously, in 2008, the use of animals in “Toxicological and other safety evaluation” represents only 0,61%, which only refers to 310 animals, of a total of 50,888 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2005)

The numbers of animals used for “Toxicological and other safety evaluation” per types of products in 2005 (939 animals) and in 2008 (310 animals) are represented in the following tables:

Types of products (%)	2005	2008
Products/substances or devices for human medicine and dentistry and for veterinary medicine	689	120
Potential or actual contaminants in the general environment which do not appear in othe columns	0	190
Other toxicological or safety evaluations	250	0

In 2008, the number of animals used to test “Products/substances or devices for human medicine and dentistry and for veterinary medicine” were 120 animals in “Carcinogenicity” (in 2005, they were 200 animals);

In 2008, in comparision to 2005, there was an increase of the number of animals used to test “Potential or actual contaminants in the general environment which do not appear in other columns” from zero animals, in 2005, to 190, in 2008.

In 2008, there were no animals used to fill the category “Other toxicological or safety evaluations” which represent a decrease compared to 2005.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	39811	29109	9094		1608	60
1.b. Rats (<i>Rattus norvegicus</i>)	6571	1463	4819		289	24
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	152	137	15			8
1.d. Hamsters (<i>Mesocricetus</i>)	29	27	2			
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	99	94	5			
1.g. Cats (<i>Felis catus</i>)						
1.h. Dogs (<i>Canis familiaris</i>)						10
1.i. Ferrets (<i>Mustela putorius furo</i>)						
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	6					
1.l. Pigs (<i>Sus</i>)	222					
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)	28					
1.o. Cattle (<i>Bos</i>)	10					
1.p. Prosimians (<i>Prosimia</i>)						
1.q. New World Monkeys (<i>Ceboidea</i>)						
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)						
1.s. Apes (<i>Hominoidea</i>)						
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)						
1.v. Other birds (other <i>Aves</i>)	160					
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)	3800					
1.z. TOTAL	50888					

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	33487	4272			310	646	196	900	39811
2.b. Rats	5255	665				89	492	70	6571
2.c. Guinea-Pigs		15					8	129	152
2.d. Hamsters	20							9	29
2.e. Other Rodents									0
2.f. Rabbits	69	3					15	12	99
2.g. Cats									
2.h. Dogs									
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breeds							6		6
2.l. Pigs	4						198	20	222
2.m. Goats									
2.n. Sheep	20						8		28
2.o. Cattle							10		10
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals									
2.u. Quail									
2.v. Other birds								160	160
2.w. Reptiles									
2.x. Amphibians									
2.y. Fish	3800								3800
2.z. TOTAL	42655	4955	0	0	310	735	933	1300	50888

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami- nants in the general envi- ronment which do not appear in other columns	3.10 Other toxico- logical or safety evaluations	3.11 Total
3.a. Mice								190	120	310
3.b. Rats										
3.c. Guinea-Pigs										
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits										
3.g. Cats										
3.h. Dogs										
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breeds										
3.l. Pigs										
3.m. Goats										
3.n. Sheep										
3.o. Cattle										
3.p. Prosimians										
3.q. New World Monkeys										
3.r. Old World Monkeys										
3.s. Apes										
3.t. Other Mammals										
3.u. Quail										
3.v. Other birds										
3.w. Reptiles										
3.x. Amphibians										
3.y. Fish										
3.z. TOTAL								190	120	310

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	31	1443	262	10022	568	12326
4.b. Rats	327	868	65	928		2188
4.c. Guinea-Pigs				129		129
4.d. Hamsters				27		27
4.e. Other Rodents						0
4.f. Rabbits	40			41		81
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breeds						
4.l. Pigs				2		2
4.m. Goats						
4.n. Sheep						
4.o. Cattle						
4.p. Prosimians						
4.q. New World Monkeys						
4.r. Old World Monkeys						
4.s. Apes						
4.t. Other Mammals						
4.u. Quail						
4.v. Other birds						
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	398	2311	327	11149	568	14753

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

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		190			120		310
6.b. Rats							
6.c. Guinea-Pigs							
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits							
6.g. Cats							
6.h. Dogs							
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breeds							
6.l. Pigs							
6.m. Goats							
6.n. Sheep							
6.o. Cattle							
6.p. Prosimians							
6.q. New World Monkeys							
6.r. Old World Monkeys							
6.s. Apes							
6.t. Other Mammals							
6.u. Quail							
6.v. Other birds							
6.w. Reptiles							
6.x. Amphibians							
6.y. Fish							
6.z. TOTAL		190			120		310

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								120					190	310
7.b. Rats														
7.c. Guinea-Pigs														
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits														
7.g. Cats														
7.h. Dogs														
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breeds														
7.l. Pigs														
7.m. Goats														
7.n. Sheep														
7.o. Cattle														
7.p. Prosimians														
7.q. New World Monkeys														
7.r. Old World Monkeys														
7.s. Apes														
7.t. Other Mammals														
7.u. Quail														
7.v. Other birds														
7.w. Reptiles														
7.x. Amphibians														
7.y. Fish														
7.z. TOTAL								120					190	310

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								120						120
8.b. Products/substances used or intended to be used mainly in agriculture														
8.c. Products/substances used or intended to be used mainly in industry														
8.d. Products/substances used or intended to be used mainly in the household														
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h. Potential or actual contaminants in the general environment which do not appear in other columns													190	190
8.i. Other toxicological or safety evaluations														
8.j. TOTAL								120					190	310

ROMANIA

Statistical data submitted

International Relations and Community Programme Directorate, National Sanitary Veterinary and Food Safety Authority

Comments of Romania authorities

None

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (<i>Mus musculus</i>)	44585	44349			236	1483
1.b. Rats (<i>Rattus norvegicus</i>)	5171	4834			337	
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	6607	6060			547	824
1.d. Hamsters (<i>Mesocricetus</i>)	263	263				
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	2205	1755			450	444
1.g. Cats (<i>Felis catus</i>)	0					
1.h. Dogs (<i>Canis familiaris</i>)	0					
1.i. Ferrets (<i>Mustela putorius furo</i>)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	14	14				
1.l. Pigs (<i>Sus</i>)	2	2				
1.m. Goats (<i>Capra</i>)						
1.n. Sheep (<i>Ovis</i>)	131	131				11
1.o. Cattle (<i>Bos</i>)	3	3				
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (<i>Ceboidea</i>)	0					
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0					
1.s. Apes (<i>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (<i>Coturnix coturnix</i>)	9	9				
1.v. Other birds (other <i>Aves</i>)	1196	943			253	12
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (<i>Amphibia</i>)						
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	60186					

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	1448	2620	8243	8008	5378	17559	140	1189	44585
2.b. Rats	952	263			540	3266	150		5171
2.c. Guinea-Pigs		56	2622	148	671	1447	1663		6607
2.d. Hamsters	263								263
2.e. Other Rodents									0
2.f. Rabbits		65	1409	80	79	526	5	41	2205
2.g. Cats									0
2.h. Dogs									0
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breeds		2	9	3					14
2.l. Pigs				2					2
2.m. Goats									0
2.n. Sheep			112	2				17	131
2.o. Cattle			3						3
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						9			9
2.v. Other birds		66		747		286		97	1196
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	2663	3072	12398	8990	6668	23093	1958	1344	60186

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	4808		50	170	50				300	5378
3.b. Rats	50	370	50	20	50					540
3.c. Guinea-Pigs	671									671
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	79									79
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	5608	370	100	190	100	0	0	0	300	6668

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	259	236	300	443	1620	2858
4.b. Rats	56	430	250	221		957
4.c. Guinea-Pigs				25	4	29
4.d. Hamsters	103	40		120		263
4.e. Other Rodents						0
4.f. Rabbits	3				1	4
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	421	706	550	809	1625	4111

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						16251	16251
5.b. Rats							0
5.c. Guinea-Pigs						2770	2770
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits						1489	1489
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breeds						12	12
5.l. Pigs						2	2
5.m. Goats							0
5.n. Sheep						114	114
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						747	747
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	0	0	0	0	0	21388	21388

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						5378	5378
6.b. Rats						540	540
6.c. Guinea-Pigs						671	671
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits						79	79
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breeds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	0	0	0	0	0	6668	6668

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	40	1842	82	30	30	30	1682							1642	5378
7.b. Rats	370	20					5							145	540
7.c. Guinea-Pigs							2								671
7.d. Hamsters															0
7.e. Other Rodents															0
7.f. Rabbits														79	79
7.g. Cats															0
7.h. Dogs															0
7.i. Ferrets															0
7.j. Other Carnivores															0
7.k. Horses, donkeys and cross breeds															0
7.l. Pigs															0
7.m. Goats															0
7.n. Sheep															0
7.o. Cattle															0
7.p. Prosimians															0
7.q. New World Monkeys															0
7.r. Old World Monkeys															0
7.s. Apes															0
7.t. Other Mammals															0
7.u. Quail															0
7.v. Other birds															0
7.w. Reptiles															0
7.x. Amphibians															0
7.y. Fish															0
7.z. TOTAL	410	1862	82	30	699	30	1689	0	0	0	0	0	1866	6668	

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	320	50	70	30	30	30	50							5028	5608
8.b. Products/substances used or intended to be used mainly in agriculture														370	370
8.c. Products/substances used or intended to be used mainly in industry	50		50												100
8.d. Products/substances used or intended to be used mainly in the household														190	190
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	40	5	55												100
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														300	300
8.j. TOTAL	410	55	175	30	30	30	50	0	0	0	0	0	0	5888	6668

SLOVENIA

Statistical data submitted

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

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 (ZZiv-UPB2; UL RS 43/2007). Competent administrative authority for data collection is the Veterinary Administration of the Republic of Slovenia (VARs), 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 paralyzing 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>Hominoidea</i>)	0					
1.t. Other Mammals (other <i>Mammalia</i>)	0					
1.u. Quail (<i>Coturnix coturnix</i>)	0					
1.v. Other birds (other <i>Aves</i>)	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 breeds									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 breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	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 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
Total:	75

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>Hominioidea</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 breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds			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>Hominoidea</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 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	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 breeds	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 breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish											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	0	798	0	297	1481

SWEDEN

Statistical data submitted

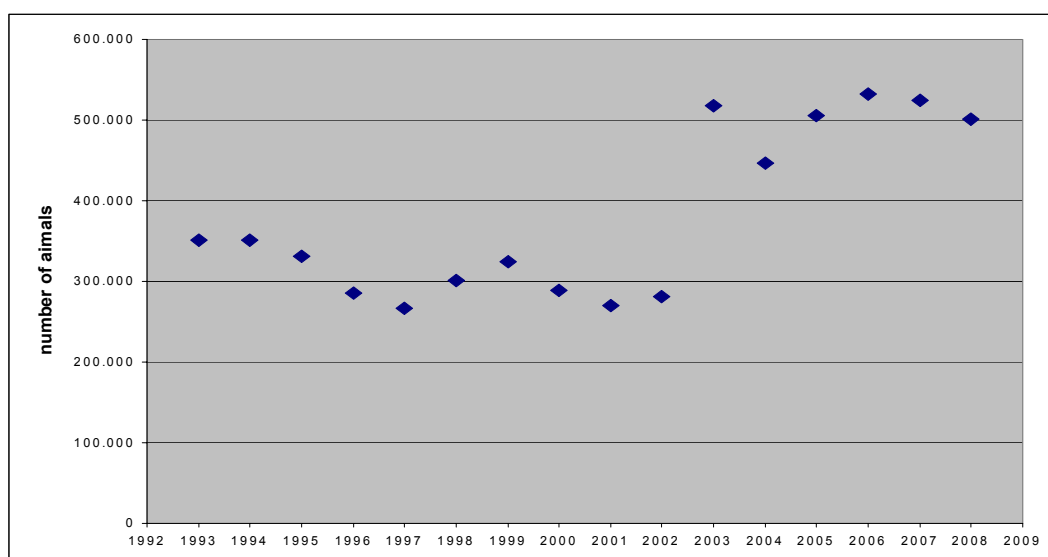
The statistical data have been submitted by the National Board for Laboratory Animals.

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>Hominoidea</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 breeds														0
7.l. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish											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 increase 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 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	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 breeds	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 breeds	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

