COUNCIL OF THE EUROPEAN UNION

Brussels, 24 January 2005

5633/05 ADD 1

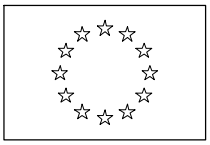
ENV 27

ADDENDUM to COVER NOTE

from:	Secretary-General of the European Commission, signed by Ms Patricia BUGNOT, Director
date of receipt:	21 January 2005
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	**COMMISSION STAFF WORKING DOCUMENT** *Annex to the*: Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union in the year 2002

Delegations will find attached Commission document SEC(2005) 45.

Encl.: SEC(2005) 45



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.1.2005
SEC(2005) 45

COMMISSION STAFF WORKING DOCUMENT

Annex to the **:**

Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union in the year 2002

{COM(2005)7 final}

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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 purposes[1], the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The first Report[2], published in 1994, covered data on animals used for experimental purposes in the year 1991 in the Member States of the Community. The second Report[3] was published 1999 and covered the data from 1996[4].

At the end of 1997, the Commission services reached an agreement with the competent authorities of the Member States to submit data on animals used for experimental purposes in a standardized format constituted by a set of eight harmonized statistical tables. Although most of the data for 1996 had then already been collected, a few Member States were able to submit the 1996 data in the new agreed format for the second Report.

The third Report[5] was published in 2003 and covered the data about the animals used in the year 1999. 14 Member States submitted their data in accordance with the agreed EU Tables, only one Member State provided the data in a different format due to an amendment which was still needed in the existing federal law.

The present fourth Report is based on the data from the year 2002 with the exception of one Member State who collected data in 2001. For the first time, all fifteen Member States reported their data in the agreed EU format.

This Commission Staff Working Paper accompanies the "Report from the Commission to the Council and the European Parliament – Fourth Report on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union" (COM (2004) XXX). The Report summarises the data and conclusions presented in this Staff Working Paper.

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1 OJ L 358, 18.12.1986, p.1.
2 COM (94) 195 final
3 COM (1999) 191 final
4 including 1997 data from France
5 COM (2003) 19 final

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

For the first time all Member States submitted their data for 2002 in the agreed EU format.

Regarding the quality of data, by comparison with 1999, Member States have in most cases applied a quality control check on the set of data submitted for 2002. As a result, the coherence of the data has greatly improved. This has allowed extending the analysis to all eight EU tables in this report. In 1999, Tables 5 and 8 had not been interpreted further.

While examining table 8 for the data of 2002, a fourth (new) relationship appeared between EU Tables 3 and 8. This relationship had not been detected before because the data were not sufficiently reliable in 1999:

> 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 type of products/endpoints, EU Table 3, into Regulatory requirements, EU Table 6, and into type of toxicological tests, EU Table 7.
>
> A third relationship is between the sum of column 2.4 and 2.5 of EU Table 2 and with the total of EU Table 5.
>
> In the fourth relationship, the total row of EU table 3 "animals used for toxicological and other safety evaluation by types of products" should equal to the total column of table 8.

For the present report it was generally considered that the criteria of the first three relationships had sufficiently been respected to allow an analysis at European level of seven first EU tables. EU Table 8 has some incoherence with Table 3, therefore the analysis of Table 8 can only be indicative.

II.2. General assessment

Each Member State is requested, pursuant to Articles 13 and 26 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. This report contains data from the year 2002, except for France who reported data from 2001.

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 purposes[6] allows the use of animals in experiments for education and training, but where the purposes of such experiments are not covered by the Directive i.e. they are not experimental or scientific

[6] OJ C 331, 23.12.86, p. 2.

in the sense of the Directive, Member States will according to the Resolution apply national provisions which are no less severe than those of the Directive. 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 2002. Because previous reports have been compiled on the basis of non-harmonized data it was only possible to make very limited comparisons with the results of the previous reports.

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

The main difference with the previous reports is that the data submitted by the Member States now cover the complete range of procedures and purposes as agreed in 1997. The purposes of experiments are described in more detail including aspects such as regulatory requirements and types of tests versus products. This allows for a more precise and comprehensive picture to be drawn at the EU level for the first time.

The lessons learned from the previous reports have allowed obtaining far more coherence in the data reported for 2002. Nevertheless, coherence still requires improvement for the next report. The accession of the ten new Member States will require additional efforts in order to adjust to the new situation.

The estimated total number of animals used for experimental and other scientific purposes in 2002 is 10.7 million (with data from France of 2001). This indicates an increase in the number of animals in comparison to 1999, which amounted to 9.8 million, but it is still a decrease in comparison with the data of 1996 of 11.6 million.

As in previous reports, by far the biggest group of animals used was rodents and rabbits. A significant increase in the use of fish has made the group of cold-blooded animals account for over 15% of all animals used. Readers are invited to further examine the distribution between the different groups of species in Chapter III.1.2.

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 2002.

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 beginning of each sub-chapter.

For the first time, an attempt is made to compare the results of 2002 with previous results. However, it is important to keep in mind that:

In the 1999 report, only Table 1 included actual numbers from all 15 Member States. Tables 2 to 7 covered figures from 14 Member States. Germany provided the data for 1999 under a different format. Thus, a comparison on actual numbers is only possible

for Table 1. The comparison of Tables 2 – 7 has therefore been made on the basis of percentages.

The complete data for 2002 include statistics from the year 2001 in 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 figures in Part A of the report is 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 2002

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

III.1.1. The data

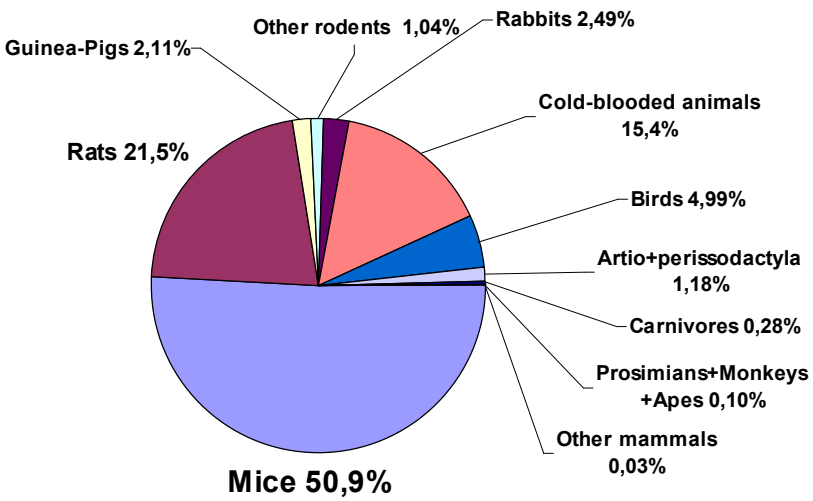
Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by the 15 Member States of the Community for 2002, France reporting for 2001.

The total number of animals used in 2002 is 10.7 million.

III.1.2. Treatment and interpretation of the data

In order to present an overall evaluation and subsequently a graphical analysis animals were grouped in classes. The result of this exercise is presented in table 1.2 of this report; figure 1.1 shows the percentages of animals in the different classes.

Figure 1.1
Classes of animals



Mice (51 %) and rats (21.5 %) are by far the most used species. Rodents together with rabbits represent the majority of animals with some 78 %.

Cold-blooded animals (15.4 %) were used much more than compared to the previous report (6.6 %).

The Artio and Perissodactyla group including horses, donkeys and cross-breds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represent only 1.2 % of the total number of animals used.

Carnivores represent 0.3 % of the total number of animals used and primates represent 0.1 % of the animals used in 2002.

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

In this chapter, and the following chapters dealing with comparisons, the reader is invited to take note of the fact that in 1996 and in 2002 one Member State (France) has reported data respectively for 1997 and for 2001. 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 in percent.

Table 1.3: Comparison between the numbers and proportions of classes of animals used in 1996, 1999 and 2002

	1996	1999	2002
Total number of animals used	11,646,130 *	9,814,171	10,731,020 **
% Rodents-rabbits	81.3	86.9	78.04
% Cold-blooded animals	12.9	6.6	15.4

* 14 Member States reporting for 1996, one for 1997
** 14 Member States reporting for 2002, one for 2001

The percentages of rodents and rabbits show some fluctuation around 80 %. For cold-blooded animals the proportion used in 1996 and 2002 is about 14 %, with a significant low in 1999 of 7 %.

By looking in terms of numbers of animals used, more important variations are observed. The data show primarily that there is an increase of 9.3 % in the total number of animal used in 2002 by comparison with 1999. By examining the data by classes of animals, the major increase observed in 2002 is the additional use of about 970,000 fish, amounting to a total of almost 1.6 million fish being used in 2002. It is worth noting that the increase of 970,000 fish is higher than the increase of the total number of animals between 1999 and 2002.

Within the largest class, composed of rodents and rabbits, a decrease is observed in 2002 in the number of rats and guinea-pigs. There is only a relatively low increase in the use of mice but a more pronounced increase in the number of rabbits. It is also necessary to point out an increase of the use of old world monkeys. However, in 2002 no great apes have been used. Furthermore, although one Member State reported new and old world monkeys together in 1999, one can nevertheless make the qualitative observation that in 2002 there is a decrease in the use of new world monkeys.

An increase is similarly observed in the number of sheep, cattle and the number of other birds than quails used in 2002 by comparison with 1999. Goats on the other hand indicate a decrease.

Table 1.1: Total number of animals used for experimental purposes in the EU Member States

Data of 2002 (*)

Species		BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PT	FI	SE	UK	Total
1.a.	Mice (Mus musculus)	460487	221557	1071282	3589	200821	1370293	16790	466640	3000	288706	153034	27616	98078	163041	914795	5459729
1.b.	Rats (Rattus norvegicus)	116340	80518	483470	4021	38544	471234	8282	377573	2200	128975	13175	12302	27563	73862	473285	2311344
1.c.	Guinea-Pigs (Cavia porcellus)	34305	7613	39913	310	1932	59184	35	18722	100	8752	7566	633	757	2738	43779	226339
1.d.	Hamsters (Mesocricetus)	2645	264	11678	135	385	20527	6	3854	0	6306	63	93	0	479	5947	52382
1.e.	Other Rodents (other Rodentia)	16670	6702	12379		202	3572		5252		1482	69		3822	804	7873	58827
1.f.	Rabbits (Oryctolagus cuniculus)	10805	5542	132833	1492	2292	53545	130	12481	20	8093	15560	908	1235	2165	20574	267675
1.g.	Cats (Felis catus)	100	43	767	13	26	1383	46	10	0	342	280		0	182	616	3808
1.h.	Dogs (Canis familiaris)	1071	220	5304	22	101	5516	195	1061	0	1045	108	34	59	646	5734	21116
1.i.	Ferrets (Mustela putorius furo)	20	0	123		14	619	21	0	0	84	0		25	151	1021	2078
1.j.	Other Carnivores (other Carnivora)	0	531	274			0		0		497	0		410	70	1328	3110
1.k.	Horses, donkeys and cross breds (Equidae)	138	55	1239	1		536	19	33		1918	34	6	98	178	422	4677
1.l.	Pigs (Sus)	3587	5582	15687	2751	940	7808	65	2397		7892	324	250	2286	2341	9254	61164
1.m.	Goats (Capra)	102	134	217	65	4	842	2	54		1032	18	65	0	156	325	3016
1.n.	Sheep (Ovis)	524	230	2409	294	175	5936	1656	798		3425	110	55	437	43	14887	30979
1.o.	Cattle (Bos)	1135	620	3315	30	19	2648	3778	489		6494	50	18	148	704	7121	26569
1.p.	Prosimians (Prosimia)	0	0	506		0	589	0	0	0		0		0	0	-	1095
1.q.	New World Monkeys (Ceboidea)	20	0	289		0	179	0	18	0	61	0		0	12	613	1192
1.r.	Old World Monkeys (Cercopithecoidea)	547	5	1049		74	3072	0	402	0	209	78		0	79	2560	8075
1.s.	Apes (Hominoidea)	0	0	0		0	0	0	0	0		0		0	0	-	0
1.t.	Other Mammals (other Mammalia)	8	10	1147			48	132	11		91	0		690	97	1384	3618
1.u.	Quail (Coturnix coturnix)	326	0	2313		3	5027	0	201	0	4801	0	30	50	38	195	12984
1.v.	Other birds (other Aves)	20026	5275	76569	340	1622	89905		28691		138299	417	168	6822	14015	139834	521983
1.w.	Reptiles (Reptilia)	15	34	725		18	1214		694		217	0	30	0	0	221	3168
1.x.	Amphibians (Amphibia)	1601	937	25162	860	232	12218		2517		5377	294	113	165	1692	8521	59689
1.y.	Fish (Pisces)	24619	35200	182918	501500	14638	96399	21046	2991		26832	882	2256	502235	17691	157196	1586403
1.z.	TOTAL	695091	371072	2071568	515423	262042	2212294	52203	924889	5320	640930	192062	44577	644880	281184	1817485	10731020

(*) France reported data for 2001

Table 1.2: Classes of animals used for experimental purposes in the EU Member States

Data of 2002 (*)

Species	BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PT	FI	SE	UK	Total
Mice	460487	221557	1071282	3589	200821	1370293	16790	466640	3000	288706	153034	27616	98078	163041	914795	5459729
Rats	116340	80518	483470	4021	38544	471234	8282	377573	2200	128975	13175	12302	27563	73862	473285	2311344
Guinea-Pigs	34305	7613	39913	310	1932	59184	35	18722	100	8752	7566	633	757	2738	43779	226339
Golden hamsters + other rodents	19315	6966	24057	135	587	24099	6	9106	0	7788	132	93	3822	1283	13820	111209
Rabbits	10805	5542	132833	1492	2292	53545	130	12481	20	8093	15560	908	1235	2165	20574	267675
Cold-blooded animals (1)	26235	36171	208805	502360	14888	109831	21046	6202	0	32426	1176	2399	502400	19383	165938	1649260
Birds (2)	20352	5275	78882	340	1625	94932	0	28892	0	143100	417	198	6872	14053	140029	534967
Artio + Perissodactyla (3)	5486	6621	22867	3141	1138	17770	5520	3771	0	20761	536	394	2969	3422	32009	126405
Carnivores (4)	1191	794	6468	35	141	7518	262	1071	0	1968	388	34	494	1049	8699	30112
Prosimians + monkeys + apes	567	5	1844	0	74	3840	0	420	0	270	78	0	0	91	3173	10362
Other Mammals	8	10	1147			48	132	11		91	0		690	97	1384	3618
Total	695091	371072	2071568	515423	262042	2212294	52203	924889	5320	640930	192062	44577	644880	281184	1817485	10731020

Species % total	BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PT	FI	SE	UK	Mean
Mice	66.25	59.71	51.71	0.70	76.64	61.94	32.16	50.45	56.39	45.04	79.68	61.95	15.21	57.98	50.33	50.88
Rats	16.74	21.70	23.34	0.78	14.71	21.30	15.86	40.82	41.35	20.12	6.86	27.60	4.27	26.27	26.04	21.54
Guinea-Pigs	4.94	2.05	1.93	0.06	0.74	2.68	0.07	2.02	1.88	1.37	3.94	1.42	0.12	0.97	2.41	2.11
Golden hamsters + other rodents	2.78	1.88	1.16	0.03	0.22	1.09	0.01	0.98	0.00	1.22	0.07	0.21	0.59	0.46	0.76	1.04
Rabbits	1.55	1.49	6.41	0.29	0.87	2.42	0.25	1.35	0.38	1.26	8.10	2.04	0.19	0.77	1.13	2.49
Cold-blooded animals (1)	3.77	9.75	10.08	97.47	5.68	4.96	40.32	0.67	0.00	5.06	0.61	5.38	77.91	6.89	9.13	15.37
Birds (2)	2.93	1.42	3.81	0.07	0.62	4.29	0.00	3.12	0.00	22.33	0.22	0.44	1.07	5.00	7.70	4.99
Artio + Perissodactyla (3)	0.79	1.78	1.10	0.61	0.43	0.80	10.57	0.41	0.00	3.24	0.28	0.88	0.46	1.22	1.76	1.18
Carnivores (4)	0.17	0.21	0.31	0.01	0.05	0.34	0.50	0.12	0.00	0.31	0.20	0.08	0.08	0.37	0.48	0.28
Prosimians + monkeys + apes	0.08	0.00	0.09	0.00	0.03	0.17	0.00	0.05	0.00	0.04	0.04	0.00	0.00	0.03	0.17	0.10
Other Mammals	0.00	0.00	0.06	0.00	0.00	0.00	0.25	0.00	0.00	0.01	0.00	0.00	0.11	0.03	0.08	0.03
Total	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00	100,00

(*) France reported data for 2001
(1) = Reptiles +amphibians + fish
(2) = Quails and other birds
(3) = Horses, donkeys and cross bred + 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

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 15 Member States are reported in table 1.4 of the present report.

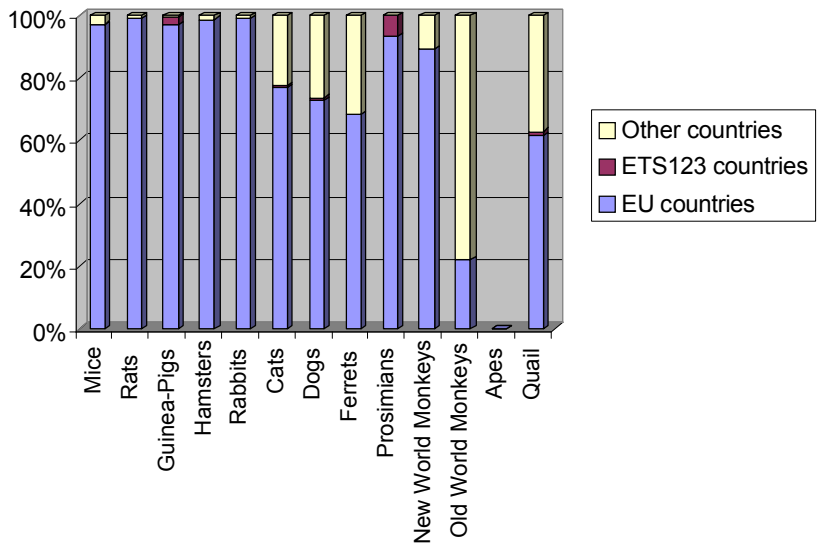
EU Table 1 also requires reporting the origin of some experimental animals. In addition, EU Table 1 requires that Member States report the number of animals re-used in experiments.

III.2.2. Treatment and interpretation of the data

The data of column 1.3 and 1.4 of table 1.4 of this report have been grouped to represent animals coming from the Community.

Figure 1.2 represents the percentage of origin of animals versus the species. (The origin must be reported only for certain species).

Figure 1.2: Origin of species



It is evident that the majority of the species originated from the EU. However, for certain species shown on the right side of the graph there is clear shift towards non-European origin. In 2002 no apes were used which accounts for the gap in the chart.

III.2.3. Comparison with data of 1999

When comparing this chart with the chart of 1999, one can observe that there is an increase in the proportion of new world monkeys and quails from European origin. However, one must underline a decrease of the proportion of hamsters and old world monkeys from European origin.

Table 1.4: Number of animals used in relation to their place of origin

Data of 2002

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 (Mus musculus)	5459729	4738718	546090	19449	155472	6311
1.b.	Rats (Rattus norvegicus)	2311344	2061312	226666	3555	22089	5787
1.c.	Guinea-Pigs (Cavia porcellus)	226339	181293	38067	6039	940	10
1.d.	Hamsters (Mesocricetus)	52382	47346	4325	0	711	30
1.f.	Rabbits (Oryctolagus cuniculus)	267675	242288	22960	30	2377	11440
1.g.	Cats (Felis catus)	3808	2139	790	18	861	1463
1.h.	Dogs (Canis familiaris)	21116	13204	2202	171	5539	3384
1.i.	Ferrets (Mustela putorius furo)	2078	1327	94	0	657	57
1.p.	Prosimians (Prosimia)	1095	762	259	74	0	39
1.q.	New World Monkeys (Ceboidea)	1192	1005	59	0	128	295
1.r.	Old World Monkeys (Cercopithecoidea)	8075	1371	392	0	6312	957
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.u.	Quail (Coturnix coturnix)	12984	7921	99	160	4801	
1.z.	TOTAL	8367817	7298686	842003	29496	199887	

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 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 the column 1.2.

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

III.3.1. The data

The consolidated results on purposes of the experiments for 15 Member States are presented in table 2.1 of this report. The percentage of the number of animals used for selected purposes is presented in Figure 2.1.

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 15 Member States in 2002. For the sake of a better presentation of results some species and some purposes were grouped in classes. The data in table 2.2 are represented in Fig. 2.2.

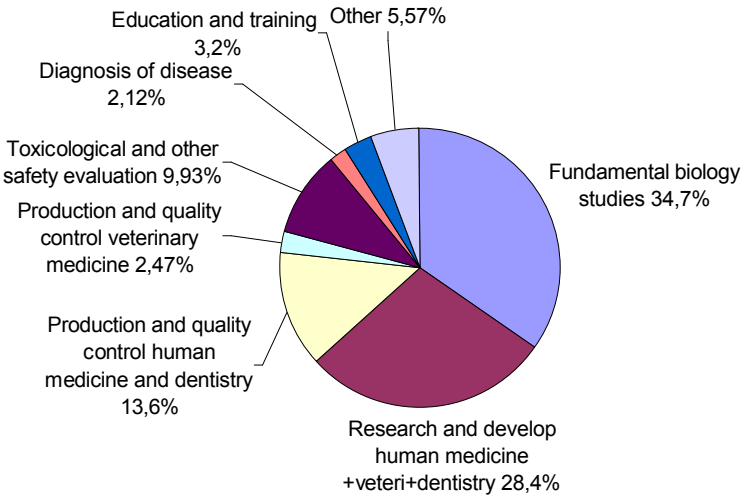
Table 2.2: Number of animals used for selected purposes versus species

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)	Diagnosis of disease	Education and training	Other	Total
Mice	2125001	2473444	358090	187231	54716	261297	5459779
Rats	638337	1196783	375656	8548	52062	39908	2311294
Other rodents	47140	201372	69792	2931	2435	13878	337548
Rabbits	19621	178776	45067	8232	2095	13884	267675
Carnivores	5754	9202	13188	712	408	848	30112
Artio+perissodactyla	56065	37871	3227	10528	6741	11973	126405
Prosimians+monkeys+apes	1738	1580	6832	34	7	171	10362
Other mammals	2886	58	0	0	3	671	3618
Birds	141623	197706	18975	6631	4934	165098	534967
Cold-blooded animals	690261	472495	175220	2486	218566	90232	1649260
TOTAL	3728426	4769287	1066047	227333	341967	597960	10731020

Table 2.1: Number of animals used in experiments for selected purposes
Purposes 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
1.a.	Mice (Mus musculus)	2125001	1475748	885987	111709	358090	187231	54716	261297	5459779
1.b.	Rats (Rattus norvegicus)	638337	894279	286186	16318	375656	8548	52062	39908	2311294
1.c.	Guinea-Pigs (Cavia porcellus)	15920	47205	76979	11318	66226	1698	1608	5385	226339
1.d.	Hamsters (Mesocricetus)	14567	22992	111	7838	3151	407	421	2895	52382
1.e.	Other Rodents (other Rodentia)	16653	34925	0	4	415	826	406	5598	58827
1.f.	Rabbits (Oryctolagus cuniculus)	19621	28207	142912	7657	45067	8232	2095	13884	267675
1.g.	Cats (Felis catus)	1009	1378	27	490	223	393	105	183	3808
1.h.	Dogs (Canis familiaris)	1491	4801	129	1093	12826	262	243	271	21116
1.i.	Ferrets (Mustela putorius furo)	912	559	328	12	133	53	60	21	2078
1.j.	Other Carnivores (other Carnivora)	2342	0	0	385	6	4	0	373	3110
1.k.	Horses, donkeys and cross breds (Equidae)	1292	578	1685	388	102	191	353	88	4677
1.l.	Pigs (Sus)	24440	13285	353	4762	2271	6958	4576	4519	61164
1.m.	Goats (Capra)	1869	137	197	2	48	163	133	354	2903
1.n.	Sheep (Ovis)	12421	2216	5880	621	368	3065	730	5791	31092
1.o.	Cattle (Bos)	16043	5597	116	2054	438	151	949	1221	26569
1.p.	Prosimians (Prosimia)	599	14	0	0	482	0	0	0	1095
1.q.	New World Monkeys (Ceboidea)	544	330	22	0	248	32	0	16	1192
1.r.	Old World Monkeys (Cercopithecoidea)	595	899	315	0	6102	2	7	155	8075
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	2886	58	0	0	0	0	3	671	3618
1.u.	Quail (Coturnix coturnix)	1653	170	1950	0	6914	0	787	1510	12984
1.v.	Other birds (other Aves)	139970	63734	51782	80070	12061	6631	4147	163588	521983
1.w.	Reptiles (Reptilia)	2668	15	8	0	15	0	460	2	3168
1.x.	Amphibians (Amphibia)	28891	5411	0	0	5535	5	14057	5790	59689
1.y.	Fish (Pisces)	658702	446918	0	20143	169670	2481	204049	84440	1586403
1.z.	TOTAL	3728426	3049456	1454967	264864	1066047	227333	341967	597960	10731020

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 biology studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 16 % of the total number of animals reported in 2002.

Toxicological and other safety evaluation represents the third important group of experimental purposes with 9.9 % of animals used.

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

Table 2.3 gives a comparison of the relative percentages of animals used for selected purposes in 1996, 1999 and 2002.

Table 2.3: Comparison between the relative percentages of animal used for selected purposes in 1996, 1999 and 2002

Purpose	1996 *	1999 **	2002
Research, development and quality control in human medicine, veterinary medicine and dentistry	44%	52%	44.5%
Fundamental biology studies	25%	30%	35%
Toxicological and safety evaluation	9%	10%	9.9%

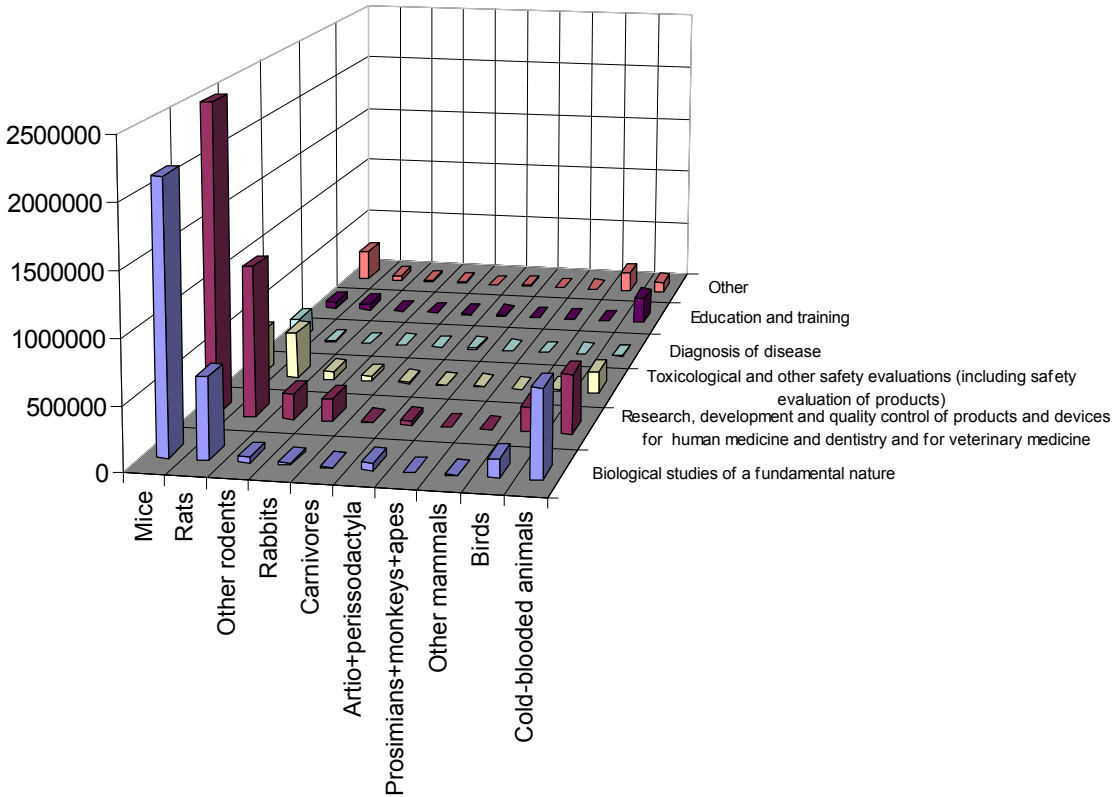
* 13 Member States reported purposes of experiments
** 14 Member Sates reported purposes of experiments

The percentage of animals used for research, development and quality control in human medicine, dentistry and veterinary medicine reached a high of 52 % in 1999,

but was about 45 % in the other years. For fundamental biology studies the percentage increased from 25 to 35 % since 1996. By comparison, the percentages of animals used for toxicological and safety evaluation remains very stable at about 10 %.

Figure 2.2 presents the number of animals used for selected purposes by species. In comparison to the data of 1999 (N.B.: Such data was not reported by Germany in 1999) the global pattern has not changed much except for an increase of 27 % of the number of mice used in biological studies and for an average increase of about 14 % of the number of cold-blooded animals used for fundamental biological studies, for research of products in human medicine, dentistry and veterinary science, for toxicological evaluation and also for education and training.

Figure 2.2
Species and purposes



III.3.4. Diagnosis of disease

Column 2.7 of EU Table 2 presents the number of animals used in the diagnosis of diseases, a parameter of importance in the light of the recent epidemics of farm animals such as mad cow disease, foot and mouth disease and swine fever.

III.3.5. Comparison with the data of 1999

Table 2.4: percentages of the number of animals used for the diagnosis of diseases in 1999 and 2002

Species	% in1999	% in 2002	Difference (%)
Rodents +rabbits	79.12	91.03	11.91
Carnivores	0.16	0.31	0.16
Equids	0.07	0.08	0.02
Pigs	1.07	3.06	1.99
Goats	0.15	0.07	-0.08
Sheep	1.07	1.35	0.27
Cattle	0.19	0.07	-0.12
Prosim+primates	0.02	0.01	-0.01
Birds	2.93	2.92	-0.02
Cold-blooded animals	15.22	1.09	-14.13
	100.00	100.00	

In 2002 the percentage of use of rodents and rabbits increased by almost 12 %-points, the use of cold-blooded animals decreased by 14 %-points. The use of other animals did not change notably.

III.4. Results of EU Table 3: *Toxicological or safety evaluation for type of products/endpoints*

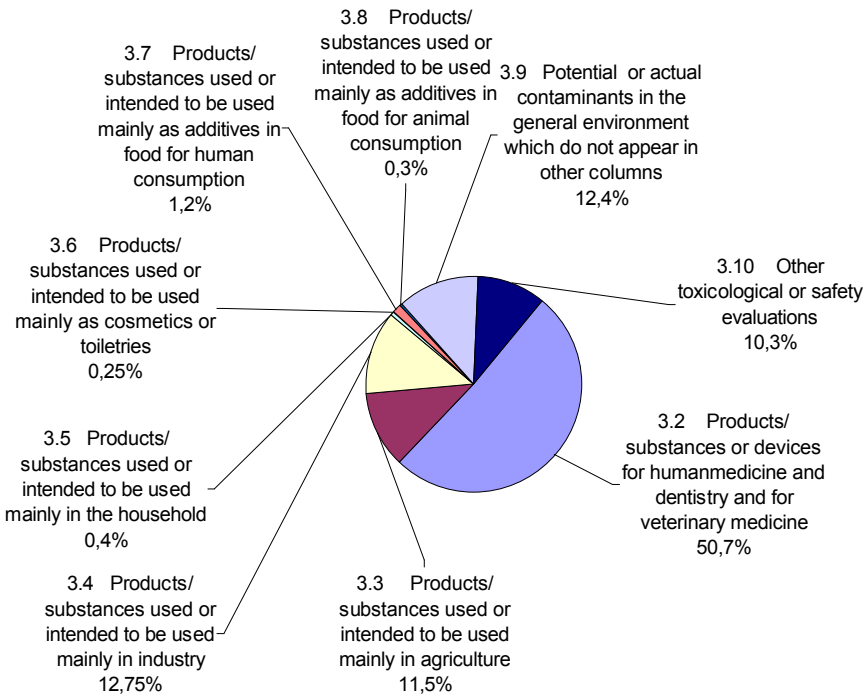
III.4.1. The data

The consolidated table giving the number of animals used in toxicological and other safety evaluation of products (EU Table 3) in 15 Member States is presented in table 3.1 of this report.

The percentage of the number of animals used for different types of products is presented in Figure 3.1.

III.4.2. Treatment and interpretation of the data

Figure 3.1 Animals used in toxicological or other safety evaluations of products



In table 3.1 the number of animals used for toxicological or other safety evaluation is broken down into type of products for which testing was required.

It must first be underlined that only 10 % of the total number of animals used for experimental purposes are used for toxicological and other safety evaluation.

The percentage of animals used for toxicological evaluation of 4 groups of products/substances, i.e., animal feed, additives for human food consumption, cosmetics and household, is very small (2,1 %) when compared to the other products or endpoints.

Products or devices used for human medicine, veterinary medicine and dentistry represent 50.7 % of the animal used for that purpose.

The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used 24.2 % of the animals for toxicological and other safety evaluations.

III.4.3. Comparison with the data of 1999

The proportion of animals used for toxicological and other safety evaluation of products to be used mainly in industry and agriculture has increased from 19 to 24%. Similarly, the proportion of animals used for the evaluation of potential or actual contaminants in the general environment has increased form 7 to 12%.

III.4.4. Species versus type of products

For convenience of presentation, some products of EU Table 3 have been grouped as well as some animal species in table 3.2 of this report.

Table 3.1: Number of animals used in toxicological and other safety evaluation
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 contaminents in the general environment which do not appear in other columns	3.10 Other toxicological or safety evaluations	3.11 Total
1.a.	Mice (Mus musculus)	222002	16047	24879	1697	494	6126	140	5750	80955	358090
1.b.	Rats (Rattus norvegicus)	210626	61227	63593	905	569	6876	1297	10796	19767	375656
1.c.	Guinea-Pigs (Cavia porcellus)	32630	8283	21963	498	883	107	0	101	1761	66226
1.d.	Hamsters (Mesocricetus)	2807	194	26	0	65	0	0	0	59	3151
1.e.	Other Rodents (other Rodentia)	286	0	0	0	0	0	0	64	65	415
1.f.	Rabbits (Oryctolagus cuniculus)	34658	2575	6198	349	680	31	0	23	553	45067
1.g.	Cats (Felis catus)	216	0	0	0	0	0	0	0	7	223
1.h.	Dogs (Canis familiaris)	11641	900	132	0	0	54	0	0	99	12826
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0	0	0	133	133
1.j.	Other Carnivores (other Carnivora)	0	0	0	0	0	0	0	0	6	6
1.k.	Horses, donkeys and cross breds (Equidae)	70	31	0	0	0	0	0	0	1	102
1.l.	Pigs (Sus)	1860	37	0	0	0	0	120	32	222	2271
1.m.	Goats (Capra)	37	11	0	0	0	0	0	0	0	48
1.n.	Sheep (Ovis)	362	6	0	0	0	0	0	0	0	368
1.o.	Cattle (Bos)	252	185	0	0	0	0	0	1	0	438
1.p.	Prosimians (Prosimia)	482	0	0	0	0	0	0	0	0	482
1.q.	New World Monkeys (Ceboidea)	248	0	0	0	0	0	0	0	0	248
1.r.	Old World Monkeys (Cercopithecoidea)	6001	0	0	0	0	0	0	0	101	6102
1.s.	Apes (Hominoidea)	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
1.u.	Quail (Coturnix coturnix)	0	6761	153	0	0	0	0	0	0	6914
1.v.	Other birds (other Aves)	7681	1215	1275	0	0	0	1890	0	0	12061
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0	15	15
1.x.	Amphibians (Amphibia)	97	168	0	0	0	0	0	5270	0	5535
1.y.	Fish (Pisces)	8703	25577	17665	804	0	0	0	110289	6632	169670
1.z.	TOTAL	540659	123217	135884	4253	2691	13194	3447	132326	110376	1066047

Table 3.2: Number of animals used in toxicological and other safety evaluation of products

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	3.5-3.8 Products/substances used for additives in animal feed and food for human consumption, in cosmetics and toiletries and in the household	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
Mice	222002	16047	24879	8457	5750	80955	358090
Rats	210626	61227	63593	9647	10796	19767	375656
Other rodents	35723	8477	21989	1553	165	1885	69792
Rabbits	34658	2575	6198	1060	23	553	45067
Carnivores	11857	900	132	54	0	245	13188
Artio + perisodactyla	2581	270	0	120	33	223	3227
Prosimians+monkeys+apes	6731	0	0	0	0	101	6832
Other mammals	0	0	0	0	0	0	0
Birds	7681	7976	1428	1890	0	0	18975
cold-blooded animals	8800	25745	17665	804	115559	6647	175220
TOTAL	540659	123217	135884	23585	132326	110376	1066047

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

III.5.1. The data

The consolidated table of results on animals used for studies of diseases (EU Table 4) for 15 Member States is presented in table 4.1 of this report.

III.5.2. Treatment and interpretation of the data

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

The number of animals used for studies of diseases of both humans and animals represents 58 % of the total number of animals used for experimental purposes.

III.5.3. Comparison with the data of 1999

In 2002 the pattern of uses is similar to that observed in 1999, except for an increase (from 10 to 14.5 %) of the proportion of animals used to study specific animal diseases and a marked decrease from (50 to 42 %) of the proportion of animals used for studying other human diseases.

Figure 4.1
Proportion of animals used in studies of diseases

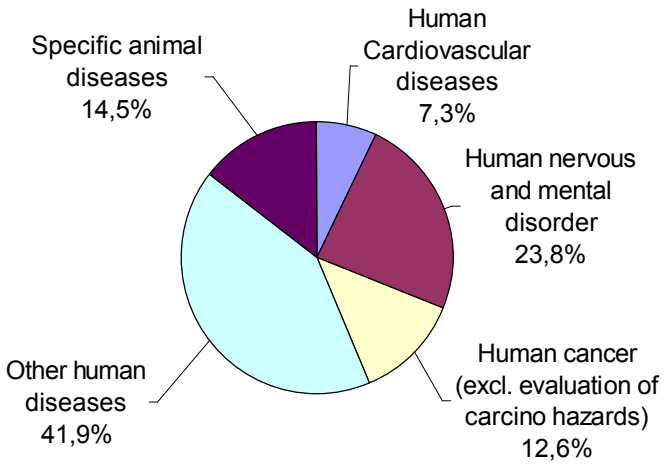


Table 4.1: Number of animals used in experiments for studies on human and animal diseases

Main category versus species

4.1	Species	4.2 Human cardiovascular diseases	4.3Human nervous and mental disorders	4.4Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5Other human diseases	4.6Studies specific to animal diseases	4.7Total
1.a.	Mice (Mus musculus)	217412	799645	713214	1679866	109627	3519764
1.b.	Rats (Rattus norvegicus)	182356	611444	56454	603700	6033	1459987
1.c.	Guinea-Pigs (Cavia porcellus)	9477	10586	430	64180	4820	89493
1.d.	Hamsters (Mesocricetus)	6215	3874	1874	15559	10660	38182
1.e.	Other Rodents (other Rodentia)	365	34131	1813	9281	1516	47106
1.f.	Rabbits (Oryctolagus cuniculus)	16875	2096	1761	28305	3891	52928
1.g.	Cats (Felis catus)	52	492	6	256	1508	2314
1.h.	Dogs (Canis familiaris)	2559	493	194	5338	1775	10359
1.i.	Ferrets (Mustela putorius furo)	98	305	2	1271	44	1720
1.j.	Other Carnivores (other Carnivora)	8	0	0	949	650	1607
1.k.	Horses, donkeys and cross breds (Equidae)	0	8	0	519	1234	1761
1.l.	Pigs (Sus)	6857	498	376	16101	9249	33081
1.m.	Goats (Capra)	244	10	9	310	937	1510
1.n.	Sheep (Ovis)	1007	1297	65	10526	8381	21276
1.o.	Cattle (Bos)	89	240	1	5241	14315	19886
1.p.	Prosimians (Prosimia)	99	86	56	288	60	589
1.q.	New World Monkeys (Ceboidea)	42	304	23	632	1	1002
1.r.	Old World Monkeys (Cercopithecoidea)	144	659	166	2959	16	3944
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	130	250	39	570	227	1216
1.u.	Quail (Coturnix coturnix)	84	395	142	571	173	1365
1.v.	Other birds (other Aves)	2378	5871	947	30303	185806	225305
1.w.	Reptiles (Reptilia)	75	236	128	993	3	1435
1.x.	Amphibians (Amphibia)	2679	1019	552	8825	130	13205
1.y.	Fish (Pisces)	4583	596	1070	110976	537139	654364
1.z.	TOTAL	453828	1474535	779322	2597519	898195	6203399

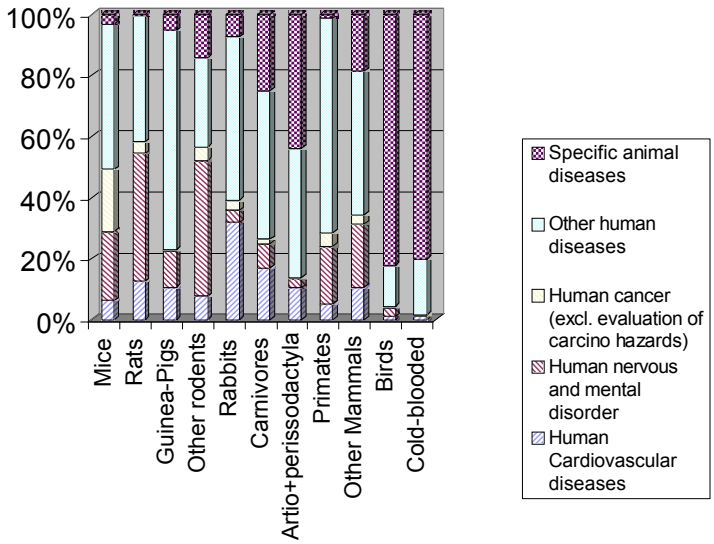
Table 4.2: Animals used in studies of diseases by classes of animals

Species	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	217412	799645	713214	1679866	109627	3519764
Rats	182356	611444	56454	603700	6033	1459987
Guinea-Pigs	9477	10586	430	64180	4820	89493
Other rodents	6580	38005	3687	24840	12176	85288
Rabbits	16875	2096	1761	28305	3891	52928
Carnivores	2717	1290	202	7814	3977	16000
Artio+Perissodactyla	8197	2053	451	32697	34116	77514
Primates	285	1049	245	3879	77	5535
Other Mammals	130	250	39	570	227	1216
Birds	2462	6266	1089	30874	185979	226670
Cold-blooded animals	7337	1851	1750	120794	537272	669004
TOTAL	453828	1474535	779322	2597519	898195	6203399

Species %	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	6.18	22.72	20.26	47.73	3.11	100.00
Rats	12.49	41.88	3.87	41.35	0.41	100.00
Guinea-Pigs	10.59	11.83	0.48	71.72	5.39	100.00
Other rodents	7.72	44.56	4.32	29.12	14.28	100.00
Rabbits	31.88	3.96	3.33	53.48	7.35	100.00
Carnivores	16.98	8.06	1.26	48.84	24.86	100.00
Artio+perissodactyla	10.57	2.65	0.58	42.18	44.01	100.00
Primates	5.15	18.95	4.43	70.08	1.39	100.00
Other Mammals	10.69	20.56	3.21	46.88	18.67	100.00
Birds	1.09	2.76	0.48	13.62	82.05	100.00
Cold-blooded animals	1.10	0.28	0.26	18.06	80.31	100.00

Species of Table 4.1 were grouped into classes of animals to give table 4.2. The relative percentage of species/animal groups used in studies per type of diseases has been calculated and is also presented in the lower part of table 4.2.

Figure 4.2
Species of animals used in studies of diseases



The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Two groups of animals i.e. birds and cold-blooded animals are used to more than 80 % for such specific studies. Some Member States indicated that both birds and fish are used for the purpose of vaccine testing, others could not confirm this.

It can be observed that the pattern has not significantly changed from 1999 except for an increase in the percentage of use of cold-blooded animals for studies of animal diseases (from 56 to 80 %).

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

The consolidated table for the 15 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 of this report.

III.6.2. Treatment and interpretation of the data

The number of animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine represents 16 % of the total number of animals used for experimental purposes.

Figure 5.1 gives the percentages of the animals used for different regulatory purposes in the production and quality control of products for human medicine and dentistry and for veterinary medicine.

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

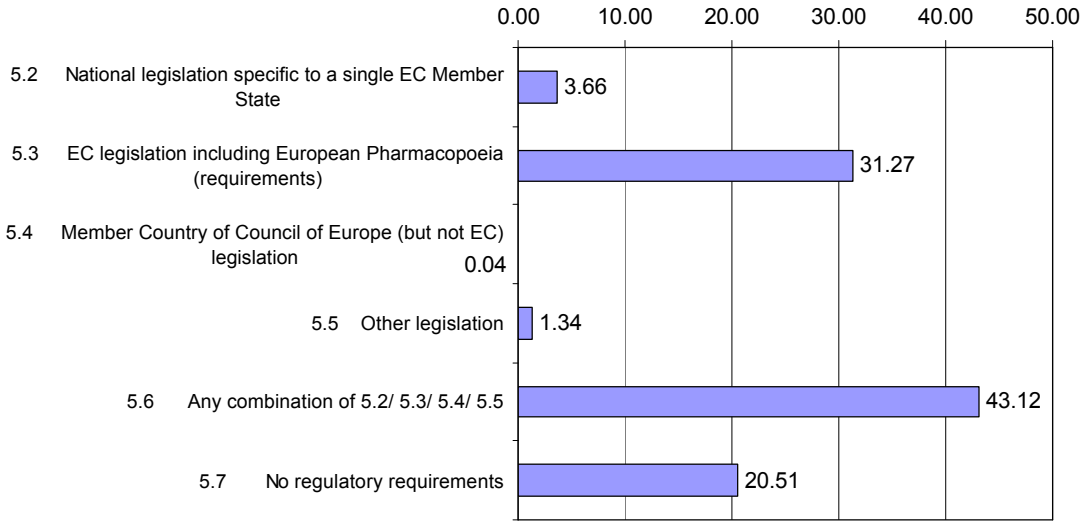
5.1	Species	5.2 National legislation specific to a single EC Member State1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 total
1.a.	Mice (Mus musculus)	41473	243569	90	8663	439377	264524	997696
1.b.	Rats (Rattus norvegicus)	12069	129001	1	1287	143591	16555	302504
1.c.	Guinea-Pigs (Cavia porcellus)	4897	31190	0	4282	39320	8608	88297
1.d.	Hamsters (Mesocricetus)	524	5033	0	0	2241	151	7949
1.e.	Other Rodents (other Rodentia)	0	4	0	0	0	3	7
1.f.	Rabbits (Oryctolagus cuniculus)	1612	88838	0	8761	16358	34997	150566
1.g.	Cats (Felis catus)	0	393	20	0	64	40	517
1.h.	Dogs (Canis familiaris)	5	984	30	0	24	179	1222
1.i.	Ferrets (Mustela putorius furo)	0	12	0	0	10	318	340
1.j.	Other Carnivores (other Carnivora)	0	187	0	0	198	0	385
1.k.	Horses, donkeys and cross breds (Equidae)	19	174	0	0	78	1802	2073
1.l.	Pigs (Sus)	1330	2265	279	0	965	276	5115
1.m.	Goats (Capra)	12	0	0	1	46	140	199
1.n.	Sheep (Ovis)	7	510	2	0	493	5489	6501
1.o.	Cattle (Bos)	95	891	194	4	527	459	2170
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	0	0	0	0	22	22
1.r.	Old World Monkeys (Cercopithecoidea)	0	0	0	12	276	27	315
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0	0	0	0	0	0	0
1.u.	Quail (Coturnix coturnix)	0	1950	0	0	0	0	1950
1.v.	Other birds (other Aves)	1927	20771	12	105	91217	17820	131852
1.w.	Reptiles (Reptilia)	6	2	0	0	0	0	8
1.x.	Amphibians (Amphibia)	0	0	0	0	0	0	0
1.y.	Fish (Pisces)	0	12062	0	0	6729	1352	20143
1.z.	TOTAL	62926	537836	628	23115	741514	352762	1719831

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

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

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

Figure 5.1: Percentage of animals used for regulatory requirements in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine



The largest proportion (43 %) of animals in this area was used to simultaneously satisfy requirements from several legislations (national, Community, Council of Europe, and others). Some 21 % of the animals were not required for any regulatory purposes. To explain this relatively high proportion Member States reported a range of reasons, such as early stages in developmental processes or pilot studies, or additional tests to confirm earlier ambiguous test results. Member States also considered that some unclear data reporting may have been a reason.

Remark: In 1999 the data provided by the Member States for EU table 5 showed too much variability. Therefore, no interpretation of the data was provided in the report of 1999, and consequently no comparison is possible with those data.

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

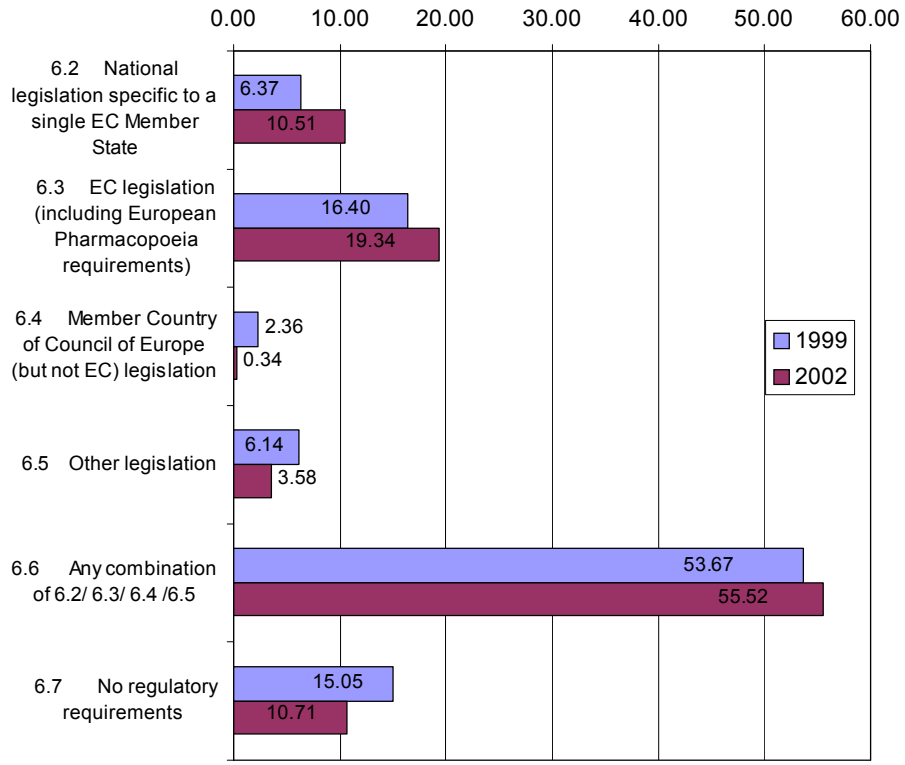
III.7.1. The data

The consolidated table for the 15 Member States reporting on the origin of regulatory requirements in relation to animals used in toxicological and other safety evaluations (EU Table 6) is presented in table 6.1 of this report.

III.7.2. Treatment and interpretation of the data

The use of animals for regulatory requirements in the area of toxicology and other safety evaluations follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine (figure 5.1).

Figure 6.1: Comparison of percentages of animals used for regulatory requirements for toxicological or other safety evaluation in 1999 and 2002



III.7.3. Comparison with the data of 1999

Animals used to simultaneously satisfy regulatory requirements from several legislations cover over half of the animal use in this area and have basically remained at the same level (53.7 % respectively 55.5 %).

The testing to satisfy national legislation specific to a single Member State related for example to national health and safety requirements at the work place. Testing for such purposes appears to have increased from 6% to 11%, but Member States considered that this effect might partly be due to the complexity of data collected from the reporting institutions.

Contrary to the animals used in the areas of human medicine, dentistry and in veterinary medicine (see fig. 5.1), the proportion of animals for which no regulatory requirement was identified in the area of toxicology and other safety evaluations appears to have decreased from 15.1 % to 10.7 %. Member States reported a number of possible reasons for this effect, similar to the explanations for the area of human medicine and dentistry and for veterinary medicine (see fig. 5.1).

Table 6.1: 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 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 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 total
1.a.	Mice (Mus musculus)	30611	73056	235	5114	210461	38613	358090
1.b.	Rats (Rattus norvegicus)	23744	60964	1774	20930	240212	28032	375656
1.c.	Guinea-Pigs (Cavia porcellus)	2006	15108	0	4501	43623	988	66226
1.d.	Hamsters (Mesocricetus)	68	870	0	0	1869	344	3151
1.e.	Other Rodents (other Rodentia)	0	0	0	0	65	350	415
1.f.	Rabbits (Oryctolagus cuniculus)	1162	17602	72	1579	23972	680	45067
1.g.	Cats (Felis catus)	69	68	0	18	68	0	223
1.h.	Dogs (Canis familiaris)	667	1324	10	42	10621	162	12826
1.i.	Ferrets (Mustela putorius furo)	0	133	0	0	0	0	133
1.j.	Other Carnivores (other Carnivora)	0	0	0	0	0	6	6
1.k.	Horses, donkeys and cross breds (Equidae)	8	63	0	0	31	0	102
1.l.	Pigs (Sus)	235	533	0	118	1255	130	2271
1.m.	Goats (Capra)	15	17	0	0	6	10	48
1.n.	Sheep (Ovis)	25	182	0	0	67	94	368
1.o.	Cattle (Bos)	12	260	3	0	163	0	438
1.p.	Prosimians (Prosimia)	0	203	0	0	279	0	482
1.q.	New World Monkeys (Ceboidea)	0	0	0	0	244	4	248
1.r.	Old World Monkeys (Cercopithecoidea)	0	368	16	0	5714	4	6102
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0	0	0	0	0	0	0
1.u.	Quail (Coturnix coturnix)	0	1390	0	0	5524	0	6914
1.v.	Other birds (other Aves)	328	7235	0	60	4390	48	12061
1.w.	Reptiles (Reptilia)	15	0	0	0	0	0	15
1.x.	Amphibians (Amphibia)	29	70	0	0	158	5278	5535
1.y.	Fish (Pisces)	53020	26771	1464	5819	43198	39398	169670
1.z.	TOTAL	112014	206217	3574	38181	591920	114141	1066047

Examples: 6.2 - France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 - Spain is testing due to a Hungarian requirement

6.5 - Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

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

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

III.8. Results of EU Table 7: *Animals used in toxicity test for toxicological or other safety evaluations*

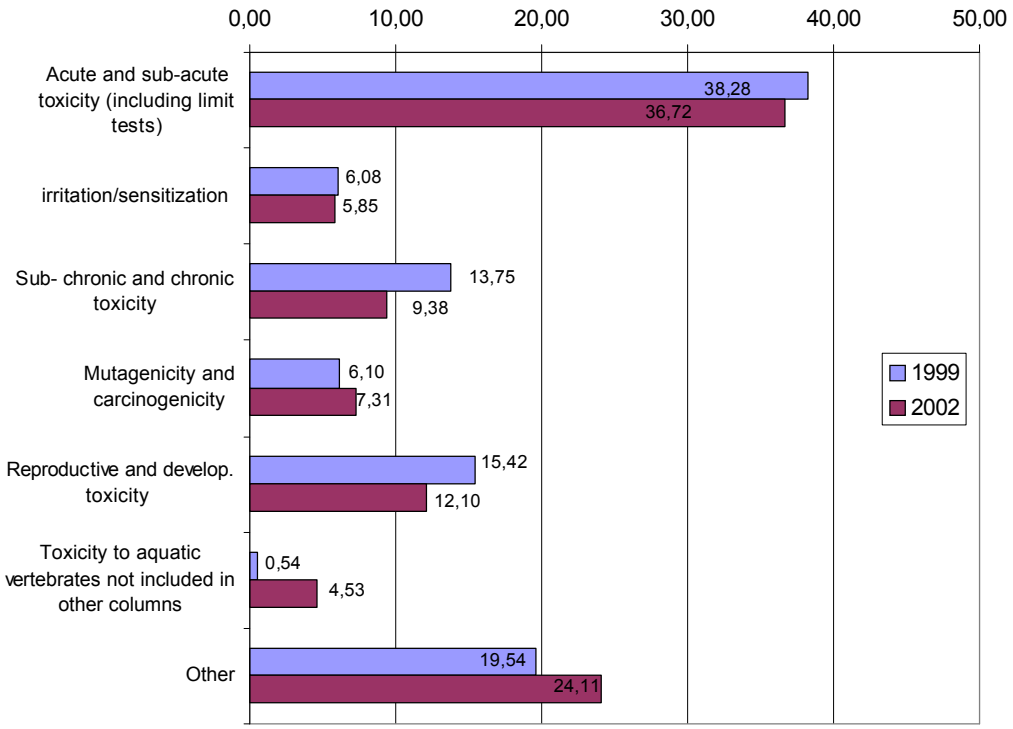
III.8.1. The data

The consolidated table for the 15 Member States reporting on animals used in toxicity tests for the purpose of toxicological or other safety evaluations of products (EU Table 7) is presented in table 7.1 of this report.

III.8.2. Treatment and interpretation of the data

For convenience of presentation, some of the toxicity tests of table 7.1 have been grouped according to systemic and local toxicity and CMR effects in table 7.2 of this report. A graph showing the percentage of animals used per toxicity test group in 1999 and 2002 is presented in figure 7.1.

Figure 7.1
Comparison of the percentages of animals used in toxicity tests for toxicological or other safety evaluation in 1999 and 2002



III.8.3. Comparison with the data of 1999

As pointed out earlier, the number of animals used in toxicological and other safety evaluation represents 10 % of the total number of animals used for experimental purposes in the EU.

The largest percentage of animals is due to acute and sub-acute toxicity tests, 36.7 % in 2002 and 38.3 % in 1999. With the addition of sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for 46 % and 52 % respectively in 2002 and 1999. About 20 % of animals are used for testing carcinogenicity, mutagenicity and toxicity to reproduction in both years.

In comparison with the data of 1999, there is a certain decrease in the percentage of animals used for sub-chronic and chronic toxicity tests from 13.7 % to 9.4 % and for reproductive and developmental toxicity from 15.4 % to 12.1 %, and an increase in the percentage of animals used in detecting toxicity to aquatic vertebrates from 0.5 % to 4.5 %.

An increase is also observed, from 19.5 % to 24.1 %, in the percentage of animals used for "other" toxicity tests than those listed in the statistical table. 24.1 % is about ¼ of all such animals and thus a considerable proportion. Member States considered that this may be due to a variety of tests conducted by universities or institutions, which may not follow specific guidelines and were therefore summed up by researchers under "other". Member States also indicated that "other" might include tests linked to haemotoxicology, toxicokinetics, pyrogenicity, biocompatibility, immunotoxicology, enzyme induction and allergic reactions of animals.

Table 7.1: Number of animals used in toxicological and other safety evaluations

Type of tests versus species

7.1. Spieces			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 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 (Mus musculus)	35015	59826	61786	366	10065	56	22412	17758	2955	18508	2160	313	126870	358090
1.b.	Rats (Rattus norvegicus)	13060	17680	89193	856	46	866	59058	25760	27550	13727	54909	1440	71511	375656
1.c.	Guinea-Pigs (Cavia porcellus)	755	337	8491	249	40210	46	250	0	0	0	0	317	15571	66226
1.d.	Hamsters (Mesocricetus)	0	0	405	0	0	0	821	26	0	15	0	0	1884	3151
1.e.	Other Rodents (other Rodentia)	65	0	0	0	0	0	0	0	0	0	0	0	350	415
1.f.	Rabbits (Oryctolagus cuniculus)	16	101	1136	5442	66	4041	1520	0	8048	0	3756	68	20991	45185
1.g.	Cats (Felis catus)	0	0	51	0	0	0	0	0	0	0	0	70	102	223
1.h.	Dogs (Canis familiaris)	109	617	4634	21	4	0	5558	0	7	0	0	52	1706	12708
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0	0	0	0	0	0	0	133	133
1.j.	Other Carnivores (other Carnivora)	0	0	0	0	0	0	0	0	0	0	0	0	6	6
1.k.	Horses, donkeys and cross breds (Equidae)	1	2	7	0	0	0	0	0	0	0	0	20	72	102
1.l.	Pigs (Sus)	5	16	221	13	0	0	867	0	23	0	0	56	1070	2271
1.m.	Goats (Capra)	0	0	0	0	0	0	0	0	0	0	0	0	48	48
1.n.	Sheep (Ovis)	6	14	62	0	0	0	74	0	0	0	0	0	212	368
1.o.	Cattle (Bos)	0	0	52	0	0	0	8	0	0	0	0	22	356	438
1.p.	Prosimians (Prosimia)	123	0	152	0	0	0	172	0	0	0	0	0	35	482
1.q.	New World Monkeys (Ceboidea)	0	0	129	0	0	0	78	0	0	0	0	0	41	248
1.r.	Old World Monkeys (Cercopithecoidea)	603	0	1592	0	0	0	2417	0	0	0	0	0	1490	6102
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 (Coturnix coturnix)	1203	404	12	0	0	0	0	0	4719	0	576	0	0	6914
1.v.	Other birds (other Aves)	947	164	4759	0	0	0	1890	0	1275	10	248	0	2768	12061
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0	0	0	15	15
1.x.	Amphibians (Amphibia)	82	35	1126	0	0	0	65	0	90	0	0	4100	37	5535
1.y.	Fish (Pisces)	43692	34457	8266	0	0	0	4841	1000	4954	1100	17761	41882	11717	169670
1.z.	TOTAL	95682	113653	182074	6947	50391	5009	100031	44544	49621	33360	79410	48340	256985	1066047

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

7.1. Spieces		Acute and sub-acute toxicity (including limit tests)	irritation/sensitization	Sub- chronic and chronic toxicity	Muta and carcinogenicity	Reproductive and develop. Toxicity	Toxicity to aquatic vertebrates not included in other columns	Other	Total
1.a.	Mice (Mus musculus)	156627	10487	22412	36266	5115	313	126870	358090
1.b.	Rats (Rattus norvegicus)	119933	1768	59058	39487	82459	1440	71511	375656
1.c.	Guinea-Pigs (Cavia porcellus)	9583	40505	250	0	0	317	15571	66226
1.d.	Hamsters (Mesocricetus)	405	0	821	41	0	0	1884	3151
1.e.	Other Rodents (other Rodentia)	65	0	0	0	0	0	350	415
1.f.	Rabbits (Oryctolagus cuniculus)	1253	9549	1520	0	11804	68	20991	45185
1.g.	Cats (Felis catus)	51	0	0	0	0	70	102	223
1.h.	Dogs (Canis familiaris)	5360	25	5558	0	7	52	1706	12708
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0	133	133
1.j.	Other Carnivores (other Carnivora)	0	0	0	0	0	0	6	6
1.k.	Horses, donkeys and cross breds (Equidae)	10	0	0	0	0	20	72	102
1.l.	Pigs (Sus)	242	13	867	0	23	56	1070	2271
1.m.	Goats (Capra)	0	0	0	0	0	0	48	48
1.n.	Sheep (Ovis)	82	0	74	0	0	0	212	368
1.o.	Cattle (Bos)	52	0	8	0	0	22	356	438
1.p.	Prosimians (Prosimia)	275	0	172	0	0	0	35	482
1.q.	New World Monkeys (Ceboidea)	129	0	78	0	0	0	41	248
1.r.	Old World Monkeys (Cercopithecoidea)	2195	0	2417	0	0	0	1490	6102
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 (Coturnix coturnix)	1619	0	0	0	5295	0	0	6914
1.v.	Other birds (other Aves)	5870	0	1890	10	1523	0	2768	12061
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	15	15
1.x.	Amphibians (Amphibia)	1243	0	65	0	90	4100	37	5535
1.y.	Fish (Pisces)	86415	0	4841	2100	22715	41882	11717	169670
1.z.	TOTAL	391409	62347	100031	77904	129031	48340	256985	1066047

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

III.9.1. The data

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products, for the 15 Member States reporting (EU Table 8) is presented in table 8.1 of this report.

III.9.2. Treatment and interpretation of the data

As pointed out earlier it is important to keep in mind that animals used in toxicological and other safety evaluation represent 10 % of the total number of animals used for experimental purposes in the EU.

Figure 8.1 represents the number of animals used in toxicological testing or other safety evaluations in relation to the type of products or purposes. It shows that a substantial number of toxicity tests are performed for products or devices for human medicine, dentistry and veterinary medicine. Other notable groups of products requiring toxicological testing are products used mainly in agriculture and products intended mainly for industry.

Remark: Because in 1999 the data provided by the Member States for EU table 8 showed too much variability, these data were not interpreted in the report of 1999. Consequently no comparison can be made with those data.

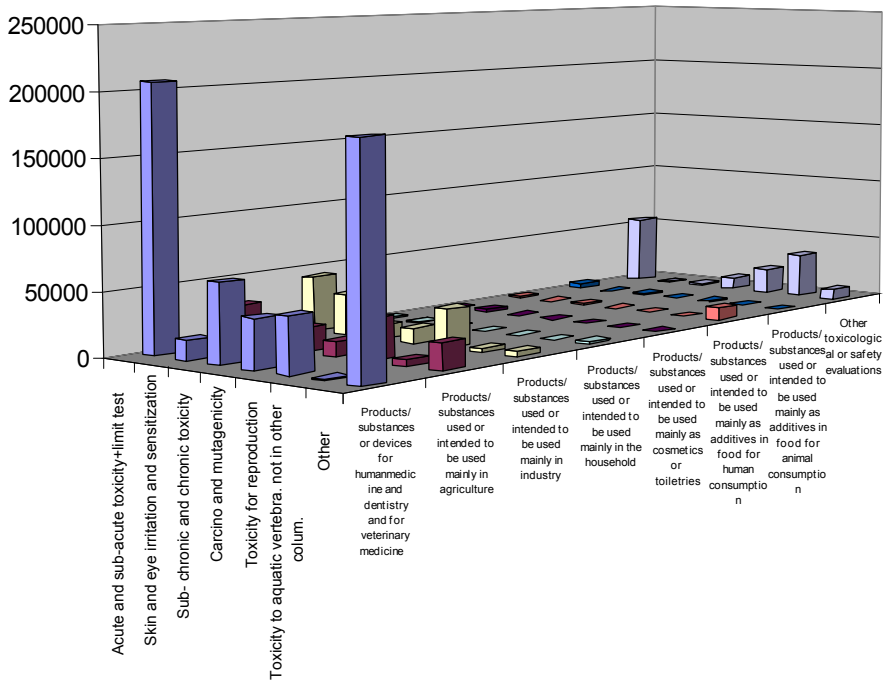
Table 8.1: Number of animals used in toxicological and other safety evaluations

Type 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 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	26046	32982	148067	1929	11756	1746	61857	20562	15899	18122	27923	1400	176342	544631
8.b. Products/ substances used or intended to be used mainly in agriculture	18929	4402	5882	777	8486	620	18350	7605	11882	3672	20641	5294	20776	126696
8.c. Products/ substances used or intended to be used mainly in industry	18180	8535	16472	3510	26851	2149	10624	1965	17366	9674	12912	3138	4705	136081
8.d. Products/ substances used or intended to be used mainly in the household	356	210	479	231	494	135	10	12	0	26	40	0	1871	3864
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	210	262	74	450	1253	142	188	0	0	0	0	0	112	2691
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	273	144	620	6	0	2	1568	0	0	23	184	0	10610	13430
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	51	3932	84	0	0	0	791	0	0	0	455	0	120	5433
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	18247	28553	7448	0	80	254	1598	9023	5042	277	14587	35413	7741	128263
8.i. Other toxicological or safety evaluations	13977	35342	2834	69	2342	79	6309	4549	572	364	851	4442	32608	104338
8.j. TOTAL	96269	114362	181960	6972	51262	5127	101295	43716	50761	32158	77593	49687	254885	1066047

Figure 8.1

Numbers of animals used in toxicity tests versus type of products



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

BELGIUM

Statistical data submitted

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

Comments of Belgian authorities

General comments

In 2002, a total of 695 091 animals were used for experimental and other scientific purposes. This represents a slight increase over 2001 (+ 39 874 animals).

Nonetheless, an examination of the general trend in the number of animals used in Belgium between 1999 (the year of the last Commission report on the number of animals used for experimental and other scientific purposes in the EU Member States) and 2002 points to a reduction of around 12%. Another general observation regarding this period is that rodents and rabbits continued to be the animals used most frequently, representing on average 92% of the total. Also, the proportion of carnivores and primates used in research has remained stable, averaging 0.18% and 0.08% respectively of the total number of animals used each year.

Comments specific to 2002

Comparison of the 2002 data with the 2001 data yields the following significant findings:

The number of rodents and rabbits used remained relatively stable (+ 3.6%). These animals are used essentially for fundamental biology studies and in the production and quality control of products. They are also the group most widely used for all types of experiments and tests.

The number of cats and dogs rose slightly (+ 60 animals). This group represented 0.18% of all animals used for experimental purposes in 2002; it is used above all for fundamental biology studies, product research and development, and regulatory tests relating to toxicology and product safety.

The number of primates fell 20% compared with 2001. These animals are used in particular for regulatory tests relating to the production and quality control of products and for evaluating the safety of vaccines and products.

The increase between 2001 and 2002 in the overall number of animals used (+ 6%) is due essentially to a rise in the number of fish used in fundamental biology studies (+ 13 108) and in the number of birds used in fundamental biology studies (+ 573), regulatory tests relating to the production and quality control of products (+ 838) and zootechnical tests (+ 936).

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 (*Mus musculus*)	460487	302990	138374	79	19044	
1.b. Rats (*Rattus norvegicus*)	116340	36807	76370	10	3153	
1.c. Guinea-Pigs (*Cavia porcellus*)	34305	19010	15230	5	60	
1.d. Hamsters (*Mesocricetus*)	2645	567	1988	0	90	
1.e. Other Rodents (other *Rodentia*)	16670					
1.f. Rabbits (*Oryctolagus cuniculus*)	10805	4337	6460	0	8	472
1.g. Cats (*Felis catus*)	100	78	4	18	0	25
1.h. Dogs (*Canis familiaris*)	1071	138	933	0	0	375
1.i. Ferrets (*Mustela putorius furo*)	20	0	0	0	20	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	138					
1.l. Pigs (*Sus*)	3587					
1.m. Goats (*Capra*)	102					
1.n. Sheep (*Ovis)*	524					
1.o. Cattle (*Bos*)	1135					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	20	0	0	0	20	20
1.r. Old World Monkeys (*Cercopithecoidea*)	547	0	21	0	526	29
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	8					
1.u. Quail (*Coturnix coturnix)*	326	326	0	0	0	
1.v. Other birds (other *Aves*)	20026					
1.w. Reptiles (*Reptilia*)	15					
1.x. Amphibians (*Amphibia*)	1601					
1.y. Fish (*Pisces*)	24619					
1.z. TOTAL	695091					

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	132744	147402	118912	7092	26788	21010	3239	3300	460487
2.b. Rats	24046	60796	14844	145	12846	718	1981	964	116340
2.c. Guinea-Pigs	386	6494	19675	897	6122	314	417	0	34305
2.d. Hamsters	664	30	3	1010	893	24	21	0	2645
2.e. Other Rodents	89	16141	0	0	286	0	45	109	16670
2.f. Rabbits	1513	534	7547	78	591	104	183	255	10805
2.g. Cats	75	5	0	20	0	0	0	0	100
2.h. Dogs	172	433	0	30	420	0	13	3	1071
2.i. Ferrets	0	20	0	0	0	0	0	0	20
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	8	27	0	4	0	0	99	0	138
2.l. Pigs	1721	277	102	152	122	39	77	1097	3587
2.m. Goats	16	25	54	0	0	6	1	0	102
2.n. Sheep	372	100	14	2	0	2	34	0	524
2.o. Cattle	343	246	0	185	0	0	18	343	1135
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	20	0	0	0	0	0	0	0	20
2.r. Old World Monkeys	24	1	211	0	311	0	0	0	547
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	8	8
2.u. Quail	326	0	0	0	0	0	0	0	326
2.v. Other birds	7906	1801	51	78	0	0	244	9946	20026
2.w. Reptiles	15	0	0	0	0	0	0	0	15
2.x. Amphibians	442	0	0	0	0	0	1159	0	1601
2.y. Fish	20793	57	0	0	3705	0	62	2	24619
2.z. TOTAL	191675	234389	161413	9693	52084	22217	7593	16027	695091

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	24848	0	0	0	0	0	84	0	1856	26788
3.b. Rats	11401	0	44	0	0	0	0	0	1401	12846
3.c. Guinea-Pigs	6122	0	0	0	0	0	0	0	0	6122
3.d. Hamsters	893	0	0	0	0	0	0	0	0	893
3.e. Other Rodents	286	0	0	0	0	0	0	0	0	286
3.f. Rabbits	591	0	0	0	0	0	0	0	0	591
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	420	0	0	0	0	0	0	0	0	420
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	122	0	0	0	0	0	0	0	0	122
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	311	0	0	0	0	0	0	0	0	311
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	900	732	0	0	0	0	0	1563	510	3705
3.z. TOTAL	45894	732	44	0	0	0	84	1563	3767	52084

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	8492	51692	33381	200060	8988	302613
4.b. Rats	4204	30991	2607	41796	173	79771
4.c. Guinea-Pigs	1283	241	0	19048	71	20643
4.d. Hamsters	355	0	56	59	0	470
4.e. Other Rodents	0	14844	0	1378	28	16250
4.f. Rabbits	405	244	23	250	282	1204
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	325	35	0	127	31	518
4.i. Ferrets	0	0	0	20	0	20
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	0	0
4.l. Pigs	543	0	0	28	667	1238
4.m. Goats	6	0	0	0	0	6
4.n. Sheep	143	0	0	7	68	218
4.o. Cattle	2	0	0	0	328	330
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	1	0	214	0	215
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	189	2087	2276
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	77	77
4.z. TOTAL	15758	98048	36067	263176	12800	425849

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	720	26759	0	3266	94165	1094	126004
5.b. Rats	2593	395	0	0	9834	2167	14989
5.c. Guinea-Pigs	0	2369	0	2650	15543	10	20572
5.d. Hamsters	0	1010	0	0	0	3	1013
5.e. Other Rodents	0	0	0	0	0	3	3
5.f. Rabbits	0	115	0	113	7366	28	7622
5.g. Cats	0	0	20	0	0	0	20
5.h. Dogs	0	0	30	0	0	0	30
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 breds	0	0	0	0	0	4	4
5.l. Pigs	0	82	70	0	102	0	254
5.m. Goats	0	0	0	0	46	8	54
5.n. Sheep	0	0	2	0	14	0	16
5.o. Cattle	0	0	173	0	0	12	185
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	211	0	211
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	60	12	0	51	6	129
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	3313	30790	307	6029	127332	3335	171106

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	1878	1023	0	1340	20462	2085	26788
6.b. Rats	580	6	0	815	7970	3475	12846
6.c. Guinea-Pigs	0	0	0	107	5844	171	6122
6.d. Hamsters	0	0	0	0	893	0	893
6.e. Other Rodents	0	0	0	0	0	286	286
6.f. Rabbits	0	4	0	0	584	3	591
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	7	0	0	413	0	420
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 breds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	122	0	122
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	311	0	311
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	0	0	0	0	2142	1563	3705
6.z. TOTAL	2458	1040	0	2262	38741	7583	52084

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1451	1650	21356	0	0	0	0	0	0	1418	0	0	913	26788
7.b. Rats	0	44	5615	0	0	0	1444	286	550	0	776	0	4131	12846
7.c. Guinea-Pigs	0	0	5680	0	105	0	0	0	0	0	0	0	337	6122
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	893	893
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	286	286
7.f. Rabbits	0	0	149	48	4	15	0	0	331	0	0	0	44	591
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	348	0	0	0	59	0	7	0	0	0	6	420
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	122	122
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	311	0	0	0	0	0	0	0	0	0	0	311
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	1272	0	0	0	0	0	130	0	0	0	170	2133	0	3705
7.z. TOTAL	2723	1694	33459	48	109	15	1633	286	888	1418	946	2133	6732	52084

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	1389	0	33375	48	109	15	682	286	888	1418	776	900	4747	44633
8.b. Products/substances used or intended to be used mainly in agriculture	562	0	0	0	0	0	0	0	0	0	170	0	1261	1993
8.c. Products/substances used or intended to be used mainly in industry	0	44	0	0	0	0	0	0	0	0	0	0	0	44
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	84	0	0	0	0	0	0	0	0	0	0	84
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	200	0	0	0	0	0	130	0	0	0	0	1233	0	1563
8.i. Other toxicological or safety evaluations	572	1650	0	0	0	0	821	0	0	0	0	0	724	3767
8.j. TOTAL	2723	1694	33459	48	109	15	1633	286	888	1418	946	2133	6732	52084

DENMARK

Statistical data submitted

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

Comments of Danish authorities

In 2002, 371 072 animals were used for experimental purposes in Denmark, 13 006 more than in 2001. This is a modest increase of 3.6% and is probably due to random changes and a general increase in activity. Approximately 5 000 of these were fish. Attention should be drawn to one particular figure: the increase in the use of animals for research and education. 3 513 animals were used for this purpose in 2001, but 5 954 in 2002, an increase of over 69%. The increase concerned the use of rodents and rabbits. This increase must be seen in the context of the Order on qualification requirements for persons who handle experimental animals issued by the Ministry of Justice in December 2001. The increased training requirements in the Order and the courses which have to be followed are therefore reflected in the use of experimental animals.

When collecting the statistical information for 2002, the Animal Experiments Inspectorate also asked for data on which and how many of the animals were transgenic/genetically modified. A total of 10 194 mice and 20 rats included in the statistics were used for *in vivo* experimental purposes. 1 780 mice not included in the statistics, were used for *in vitro* experimental 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 (*Mus musculus*)	221557	199890	21083	136	448	686
1.b. Rats (*Rattus norvegicus*)	80518	63813	15357	24	1324	83
1.c. Guinea-Pigs (*Cavia porcellus*)	7613	5500	1963	150	0	10
1.d. Hamsters (*Mesocricetus*)	264	124	140	0	0	0
1.e. Other Rodents (other *Rodentia*)	6702	0	0	0	0	0
1.f. Rabbits (*Oryctolagus cuniculus*)	5542	4426	1086	30	0	1063
1.g. Cats (*Felis catus*)	43	5	28	0	10	4
1.h. Dogs (*Canis familiaris*)	220	9	176	0	35	45
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	531	0	0	0	0	0
1.k. Horses, donkeys and cross breds (*Equidae*)	55	0	0	0	0	0
1.l. Pigs (*Sus*)	5582	0	0	0	0	0
1.m. Goats (*Capra*)	134	0	0	0	0	0
1.n. Sheep (*Ovis)*	230	0	0	0	0	0
1.o. Cattle (*Bos*)	620	0	0	0	0	0
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	16
1.r. Old World Monkeys (*Cercopithecoidea*)	5	0	0	0	5	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	10	0	0	0	0	0
1.u. Quail (*Coturnix coturnix)*	0	0	0	0	0	0
1.v. Other birds (other *Aves*)	5275	0	0	0	0	0
1.w. Reptiles (*Reptilia*)	34	0	0	0	0	0
1.x. Amphibians (*Amphibia*)	937	0	0	0	0	0
1.y. Fish (*Pisces*)	35200	0	0	0	0	0
1.z. TOTAL	371072					

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	46169	133015	16762	314	3929	12610	1451	7307	221557
2.b. Rats	15714	50423	1844	0	5505	2632	3321	1079	80518
2.c. Guinea-Pigs	98	1857	2651	544	1891	452	42	78	7613
2.d. Hamsters	120	114	0	0	20	10	0	0	264
2.e. Other Rodents	56	5098	0	0	0	0	0	1548	6702
2.f. Rabbits	393	776	1304	0	472	2436	148	13	5542
2.g. Cats	35	0	3	0	0	0	5	0	43
2.h. Dogs	21	14	0	0	176	0	9	0	220
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	329	0	0	198	0	4	0	0	531
2.k. Horses, donkeys and cross breds	30	0	0	6	0	6	13	0	55
2.l. Pigs	2592	1111	0	125	554	239	514	447	5582
2.m. Goats	4	7	0	0	0	121	0	2	134
2.n. Sheep	207	0	0	3	0	20	0	0	230
2.o. Cattle	426	0	0	46	0	1	51	96	620
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	5	0	0	0	0	0	0	0	5
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	10	0	0	0	0	0	0	0	10
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	3221	0	0	4	1890	160	0	0	5275
2.w. Reptiles	34	0	0	0	0	0	0	0	34
2.x. Amphibians	751	6	0	0	0	0	180	0	937
2.y. Fish	20755	7625	0	0	2280	0	220	4320	35200
2.z. TOTAL	90970	200046	22564	1240	16717	18691	5954	14890	371072

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	2748	0	1153	0	0	23	0	0	5	3929
3.b. Rats	2698	665	952	246	0	0	0	0	944	5505
3.c. Guinea-Pigs	1711	30	110	0	40	0	0	0	0	1891
3.d. Hamsters	20	0	0	0	0	0	0	0	0	20
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	447	0	0	9	0	0	0	0	16	472
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	176	0	0	0	0	0	0	0	0	176
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	546	0	0	0	0	0	0	0	8	554
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	1890	0	0	1890
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	2280	0	0	0	0	0	0	2280
3.z. TOTAL	8346	695	4495	255	40	23	1890	0	973	16717

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	2646	87279	28031	42410	3935	164301
4.b. Rats	3764	34460	1480	21234	171	61109
4.c. Guinea-Pigs	25	784	0	761	14	1584
4.d. Hamsters	0	0	0	114	113	227
4.e. Other Rodents	0	5098	0	0	0	5098
4.f. Rabbits	171	173	0	495	6	845
4.g. Cats	0	35	0	0	0	35
4.h. Dogs	0	9	0	5	9	23
4.i. Ferrets	0	0	0	0	0	0
4.j. Other Carnivores	0	0	0	0	311	311
4.k. Horses, donkeys and cross breds	0	0	0	0	30	30
4.l. Pigs	326	122	20	1112	952	2532
4.m. Goats	0	0	0	2	0	2
4.n. Sheep	0	0	0	0	159	159
4.o. Cattle	0	0	0	0	8	8
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	0	0	0
4.r. Old World Monkeys	0	0	0	0	0	0
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	0	0	0
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	0	1663	1663
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	6	0	0	24	30
4.y. Fish	0	0	0	0	13510	13510
4.z. TOTAL	6932	127966	29531	66133	20905	251467

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	1194	0	0	14839	1043	17076
5.b. Rats	8	0	0	160	1514	162	1844
5.c. Guinea-Pigs	544	22	0	0	2388	241	3195
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	126	0	50	769	359	1304
5.g. Cats	0	0	0	0	3	0	3
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	198	0	198
5.k. Horses, donkeys and cross breds	0	0	0	0	0	6	6
5.l. Pigs	95	0	0	0	30	0	125
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	3	0	3
5.o. Cattle	42	0	0	0	4	0	46
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	0	0	0	0	4	0	4
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	689	1342	0	210	19752	1811	23804

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	0	0	0	2561	1368	3929
6.b. Rats	0	15	0	0	2639	2851	5505
6.c. Guinea-Pigs	0	0	0	0	1830	61	1891
6.d. Hamsters	0	0	0	0	20	0	20
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	0	0	0	447	25	472
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	0	0	0	0	176	0	176
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 breds	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	554	0	554
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	1890	0	0	0	0	1890
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	0	0	0
6.y. Fish	0	0	0	2280	0	0	2280
6.z. TOTAL	0	1905	0	2280	8227	4305	16717

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	690	1747	0	0	0	262	0	0	173	186	0	871	3929
7.b. Rats	0	0	1588	0	0	0	1118	569	285	0	1166	0	779	5505
7.c. Guinea-Pigs	0	0	281	0	1610	0	0	0	0	0	0	0	0	1891
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	20	20
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	5	0	0	0	265	0	0	0	0	0	202	472
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	40	0	0	0	127	0	0	0	0	0	9	176
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	68	0	0	0	486	0	0	0	0	0	0	554
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	1890	0	0	0	0	0	0	1890
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	2280	0	0	0	0	0	0	0	0	0	0	0	0	2280
7.z. TOTAL	2280	690	3729	0	1610	0	4148	569	285	173	1352	0	1881	16717

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	690	3163	0	1430	0	2250	0	285	90	98	0	340	8346
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	21	0	30	0	1890	224	0	0	312	0	108	2585
8.c. Products/substances used or intended to be used mainly in industry	2280	0	135	0	110	0	0	61	0	60	824	0	1025	4495
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	12	0	0	40	0	203	255
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	40	0	0	0	0	0	0	0	0	40
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	23	0	0	0	23
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 contaminents 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	410	0	0	0	8	272	0	0	78	0	205	973
8.j. TOTAL	2280	690	3729	0	1610	0	4148	569	285	173	1352	0	1881	16717

GERMANY

Statistical data submitted

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

Comments of German authorities

The German Government is seeking to achieve a further reduction in the number of animal experiments to the absolute minimum required in accordance with the state of the art. A key factor being applied by the scientific community and the authorities in this area is the use of databases. The Government is also actively promoting the development of alternatives to animal experiments. For example, until 2002 it had already allocated EUR 82 million to the research priority "Alternatives to animal experiments" alone. In addition, work on the recognition of alternatives to animal testing is continuing at the national and international level.

The data on the use of experimental animals in Germany for 2002 was collected for the third time on the basis of the Experimental Animals Notification Order of 4 November 1999 ("Versuchstiermeldeverordnung", BGBl. I, p. 2156). Since 2000, the data collected have therefore complied with the procedure agreed by the Member States and the Commission of the European Communities pursuant to Article 26 of Directive 86/609/EEC.

During the 2002 reporting period, a total of 2 071 568 animals were used for experimental or other scientific purposes. This represents an increase of 51 694 compared with the figure for 2001 and 366 039 compared with the figure for 2000.

The number of animals used cannot be compared with the figures for the preceding years, as data on animals from which tissue or organs were removed to produce or obtain substances or products used for education, training or further training were not collected until 1999.

Of the 2.07 million animals used, 78% were rodents, 6% rabbits, 4% birds, 9% fish and 3% other animals, such as dogs (5 304), cats (767), monkeys (1 338) and prosimians (506). As in previous years, apes were not used.

A total of 1 154 290 animals were used in studies of human and animal diseases; this represents 55.72% of the total number of animals used.

Statutory testing in the production and quality control of products for the medical sector and the safety evaluation of other products involved the use of 474 945 animals (22.9%).

Compared with the previous year, the number of animals used in biological studies of a fundamental nature fell by 99 565, and the number used in the field of education and training by 7 221. However, there was an increase in the use of animals for the research and development of products and devices for human medicine, dentistry and

veterinary medicine (27 519), production and quality control of products and devices for human medicine, dentistry and veterinary medicine (28 185), toxicological and other safety evaluation (17 515), diagnosis of disease (24 192) and for other purposes (61 069).

The trend in the numbers of experimental animals over the last three years is being monitored with concern, although the increase from 2001 to 2002 was smaller than between 2000 and 2001.

In a new departure, experts were therefore asked to analyse the notified annual data on the use of experimental animals with a view to identifying areas in which animal experiments can be reduced or, for example, replaced by alternative methods. The results are to be used in developing a programme to reduce the number of animals used in experiments.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (*Mus musculus*)	1071282	906537	142283	16588	5874	
1.b. Rats (*Rattus norvegicus*)	483470	419977	59337	3348	808	
1.c. Guinea-Pigs (*Cavia porcellus*)	39913	38202	1551	0	160	
1.d. Hamsters (*Mesocricetus*)	11678	10524	1067	0	87	
1.e. Other Rodents (other *Rodentia*)	12379					
1.f. Rabbits (*Oryctolagus cuniculus*)	132833	131283	1482	0	68	5475
1.g. Cats (*Felis catus*)	767	415	203	0	149	233
1.h. Dogs (*Canis familiaris*)	5304	3564	711	1	1028	1177
1.i. Ferrets (*Mustela putorius furo*)	123	109	14	0	0	0
1.j. Other Carnivores (other *Carnivora*)	274					
1.k. Horses, donkeys and cross breds (*Equidae*)	1239					
1.l. Pigs (*Sus*)	15687					
1.m. Goats (*Capra*)	217					
1.n. Sheep (*Ovis)*	2409					
1.o. Cattle (*Bos*)	3315					
1.p. Prosimians (*Prosimia*)	506	173	259	74	0	39
1.q. New World Monkeys (*Ceboidea*)	289	275	14	0	0	78
1.r. Old World Monkeys (*Cercopithecoidea*)	1049	82	178	0	789	312
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	1147					
1.u. Quail (*Coturnix coturnix)*	2313	2054	99	160	0	
1.v. Other birds (other *Aves*)	76569					
1.w. Reptiles (*Reptilia*)	725					
1.x. Amphibians (*Amphibia*)	25162					
1.y. Fish (*Pisces*)	182918					
1.z. TOTAL	2071568					

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	550286	286211	77021	24604	37992	41462	14999	38707	1071282
2.b. Rats	155594	203099	33252	4750	60283	2111	10576	13805	483470
2.c. Guinea-Pigs	3476	7559	12867	2751	10276	38	588	2358	39913
2.d. Hamsters	5502	3931	6	1063	463	67	294	352	11678
2.e. Other Rodents	6702	2043	0	4	0	127	276	3227	12379
2.f. Rabbits	4891	9487	99310	3885	12690	110	264	2196	132833
2.g. Cats	253	329	15	2	61	53	13	41	767
2.h. Dogs	449	1889	24	493	2190	136	88	35	5304
2.i. Ferrets	67	41	0	12	0	0	0	3	123
2.j. Other Carnivores	87	0	0	187	0	0	0	0	274
2.k. Horses, donkeys and cross breds	1064	37	0	0	0	84	51	3	1239
2.l. Pigs	3917	4536	50	498	435	4531	1008	712	15687
2.m. Goats	141	23	2	0	6	2	32	11	217
2.n. Sheep	828	552	243	32	105	272	259	118	2409
2.o. Cattle	1236	1390	0	367	31	77	163	51	3315
2.p. Prosimians	10	14	0	0	482	0	0	0	506
2.q. New World Monkeys	136	141	0	0	0	0	0	12	289
2.r. Old World Monkeys	125	73	0	0	777	0	7	67	1049
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	1137	0	0	0	0	0	3	7	1147
2.u. Quail	4	0	0	0	2113	0	4	192	2313
2.v. Other birds	6581	9964	43101	12427	1039	996	499	1962	76569
2.w. Reptiles	516	15	0	0	0	0	194	0	725
2.x. Amphibians	8640	5286	0	0	4235	5	1423	5573	25162
2.y. Fish	75087	0	0	492	74333	629	1663	30714	182918
2.z. TOTAL	826729	536620	265891	51567	207511	50700	32404	100146	2071568

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	27481	3839	6584	0	0	0	0	62	26	37992
3.b. Rats	34668	11273	13220	47	0	44	0	556	475	60283
3.c. Guinea-Pigs	3384	2786	3986	0	0	0	0	80	40	10276
3.d. Hamsters	448	15	0	0	0	0	0	0	0	463
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	10893	723	1074	0	0	0	0	0	0	12690
3.g. Cats	61	0	0	0	0	0	0	0	0	61
3.h. Dogs	1954	134	92	0	0	0	0	0	10	2190
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	435	0	0	0	0	0	0	0	0	435
3.m. Goats	0	6	0	0	0	0	0	0	0	6
3.n. Sheep	105	0	0	0	0	0	0	0	0	105
3.o. Cattle	29	1	0	0	0	0	0	1	0	31
3.p. Prosimians	482	0	0	0	0	0	0	0	0	482
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	777	0	0	0	0	0	0	0	0	777
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	1960	153	0	0	0	0	0	0	2113
3.v. Other birds	484	555	0	0	0	0	0	0	0	1039
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	7	168	0	0	0	0	0	4060	0	4235
3.y. Fish	590	10447	5436	0	0	0	0	51738	6122	74333
3.z. TOTAL	81798	31907	30545	47	0	44	0	56497	6673	207511

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	52454	160816	138247	352354	8524	712395
4.b. Rats	59779	143830	12418	107879	557	324463
4.c. Guinea-Pigs	2827	1522	8	5731	89	10177
4.d. Hamsters	2746	1936	1461	1989	7	8139
4.e. Other Rodents	0	2638	1722	3199	202	7761
4.f. Rabbits	5334	647	542	4249	511	11283
4.g. Cats	0	162	0	84	175	421
4.h. Dogs	862	21	28	284	756	1951
4.i. Ferrets	0	4	0	61	3	68
4.j. Other Carnivores	8	0	0	0	42	50
4.k. Horses, donkeys and cross breds	0	8	0	358	451	817
4.l. Pigs	2686	169	150	5379	2241	10625
4.m. Goats	23	10	0	0	0	33
4.n. Sheep	277	306	0	505	72	1160
4.o. Cattle	6	0	0	83	1479	1568
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	30	41	0	147	0	218
4.r. Old World Monkeys	8	22	0	38	0	68
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	129	84	0	0	0	213
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	117	2	3300	8274	11693
4.w. Reptiles	0	21	0	18	0	39
4.x. Amphibians	1929	656	0	299	5	2889
4.y. Fish	3000	46	978	39176	5059	48259
4.z. TOTAL	132098	313056	155556	525133	28447	1154290

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	82724	0	1855	14583	2463	101625
5.b. Rats	0	37902	0	0	100	0	38002
5.c. Guinea-Pigs	0	14720	0	672	13	213	15618
5.d. Hamsters	0	1063	0	0	0	6	1069
5.e. Other Rodents	0	4	0	0	0	0	4
5.f. Rabbits	0	68290	0	7872	58	26975	103195
5.g. Cats	0	17	0	0	0	0	17
5.h. Dogs	0	473	0	0	0	44	517
5.i. Ferrets	0	12	0	0	0	0	12
5.j. Other Carnivores	0	187	0	0	0	0	187
5.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0
5.l. Pigs	0	468	0	0	30	50	548
5.m. Goats	0	0	0	0	0	2	2
5.n. Sheep	0	17	0	0	27	231	275
5.o. Cattle	0	255	0	0	96	16	367
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	0	2213	0	0	52493	822	55528
5.w. Reptiles	0	0	0	0	0	0	0
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	132	0	0	0	360	492
5.z. TOTAL	0	208477	0	10399	67400	31182	317458

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

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

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

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

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

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	0	25518	94	923	8780	2677	37992
6.b. Rats	102	31985	0	229	25556	2411	60283
6.c. Guinea-Pigs	0	4724	0	85	5400	67	10276
6.d. Hamsters	0	463	0	0	0	0	463
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	11588	0	0	1066	36	12690
6.g. Cats	23	28	0	0	10	0	61
6.h. Dogs	8	843	0	0	1339	0	2190
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 breds	0	0	0	0	0	0	0
6.l. Pigs	0	272	0	97	52	14	435
6.m. Goats	0	6	0	0	0	0	6
6.n. Sheep	0	33	0	0	0	72	105
6.o. Cattle	0	31	0	0	0	0	31
6.p. Prosimians	0	203	0	0	279	0	482
6.q. New World Monkeys	0	0	0	0	0	0	0
6.r. Old World Monkeys	0	0	0	0	777	0	777
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	1390	0	0	723	0	2113
6.v. Other birds	0	621	0	0	418	0	1039
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	68	4167	4235
6.y. Fish	39066	12281	0	40	13548	9398	74333
6.z. TOTAL	39199	89986	94	1374	58016	18842	207511

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

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

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

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

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

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	5760	4886	5407	70	3414	6	1445	980	0	9410	1249	0	5365	37992
7.b. Rats	8293	5175	15327	47	11	608	8191	1101	4510	3700	5228	0	8092	60283
7.c. Guinea-Pigs	608	200	1446	0	7837	0	0	0	0	0	0	0	185	10276
7.d. Hamsters	0	0	12	0	0	0	0	0	0	15	0	0	436	463
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	12	158	920	50	580	193	0	1103	0	1365	0	8309	12690
7.g. Cats	0	0	51	0	0	0	0	0	0	0	0	0	10	61
7.h. Dogs	109	387	569	21	0	0	925	0	0	0	0	0	179	2190
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	4	61	0	0	0	184	0	0	0	0	0	186	435
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	6	6
7.n. Sheep	0	0	0	0	0	0	72	0	0	0	0	0	33	105
7.o. Cattle	0	0	0	0	0	0	8	0	0	0	0	0	23	31
7.p. Prosimians	123	0	152	0	0	0	172	0	0	0	0	0	35	482
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	603	0	19	0	0	0	155	0	0	0	0	0	0	777
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	1121	404	12	0	0	0	0	0	0	0	576	0	0	2113
7.v. Other birds	767	8	8	0	0	0	0	0	0	0	128	0	128	1039
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	68	0	0	0	0	0	60	0	0	0	0	4100	7	4235
7.y. Fish	15071	16781	447	0	0	0	3490	0	300	20	20	33796	4408	74333
7.z. TOTAL	32523	27857	23669	1058	11312	1194	14895	2081	5913	13145	8566	37896	27402	207511

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	8345	8534	18690	212	3505	483	6362	2081	1207	5896	4872	500	21111	81798
8.b. Products/substances used or intended to be used mainly in agriculture	12688	887	1571	184	3157	149	3920	0	3479	1665	934	2237	1036	31907
8.c. Products/substances used or intended to be used mainly in industry	8228	1655	2941	647	4530	308	2603	0	739	5311	2716	214	653	30545
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	15	0	0	0	0	0	0	0	0	32	47
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	44	0	0	44
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 contaminents in the general environment which do not appear in other columns	3085	16781	467	0	80	254	330	0	488	28	0	30503	4481	56497
8.i. Other toxicological or safety evaluations	177	0	0	0	40	0	1680	0	0	245	0	4442	89	6673
8.j. TOTAL	32523	27857	23669	1058	11312	1194	14895	2081	5913	13145	8566	37896	27402	207511

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 General of Veterinary Services).

Comments of Greek authorities

The legal basis for the collection of statistics on the number and the 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 the year 2002, the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 of 24.6.1997 were used. The Ministry of Agriculture, Directorate-General for Veterinary Affairs, Directorate for Veterinary Care, Drugs & Practice sent them directly to the educational establishments (universities and colleges of technology), research centres and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. The competent department of the Ministry of Health and Social Welfare sent them to Greek hospitals, for which it is administratively responsible. 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.

Together with the relevant documents from the European Commission, our department sent written explanations relating in particular to how to fill in the tables and the correlation between certain tables (e.g. in which tables data on the use of animals for toxicological and other safety studies should be entered), and stressed that a licence from the Veterinary Directorate of the Prefecture in which the agency is based was needed in order to carry out any experiments.

The total number of animals used in experiments in Greece in 2002 was 515 423.

97.2% (501 500 animals) were **fish**, of which 60.11% were used for biological studies of a fundamental nature, and 39.89% for educational and training purposes.

1.56% (8 055 animals) were **rodents** (3 589 mice – 44.5%, 4 021 rats – 49.9%, 310 guinea pigs – 3.84%, and 135 golden hamsters – 1.68%), of which 25.6% were used for biological studies of a fundamental nature, 4.85% for research and development of products and devices for human medicine, dentistry and veterinary medicine, 12.09% for toxicological and other safety studies (exclusively rats in this case), 50.93% for diagnosis of disease (83.75% of all rodents used in all categories were used for the diagnosis of disease) and 6.5% for educational and training purposes.

N.B.: One research institute reports that 2 500 mice which it used this year belonged to the category of transgenic animals.

0.29% of the animals used were **rabbits**, (1 492 animals, of which 61 had been reused), of which 10.79% were used for biological studies of a fundamental nature, 1.67% for research and development of products and devices for human medicine, dentistry and veterinary medicine, 1.88% for production and quality control of products and devices for human medicine and dentistry, 5.02% for production and quality control of products and devices for veterinary medicine, 4.29% for toxicological and other safety studies, 53.15% for diagnosis of disease, 16.76% for educational and training purposes, and 6.43% for other purposes.

0.53% of the animals used were **pigs** (2 751 animals), of which 0.69% were used for biological studies of a fundamental nature, 41.8% for research and development of products and devices for human medicine, dentistry and veterinary medicine, 38.16% for production and quality control of products and devices for veterinary medicine, 5.45% for toxicological and other safety studies, 8.98% for diagnosis of disease and 4.9% for educational and training purposes.

0.05% of the animals used were **sheep** (294 animals), of which 7.48% were used for biological studies of a fundamental nature, 24.48% for diagnosis of disease and 68% for educational and training purposes.

0.0025% were **cats** (13 animals), 100% of which were used for diagnosis of disease.

0.0042% were **dogs** (22 animals), of which 86.36% were used for diagnosis of disease (and it was declared that these animals were re-used) and 13.64% for educational and training purposes.

0.012% were **goats** (65 animals), of which 69.23% were used for biological studies of a fundamental nature and 30.77% for educational and training purposes.

0.005% were **cattle** (30 animals), all of which were used for educational and training purposes.

0.066% were **hens** (340 animals), of which 2.94% were used for diagnosis of disease and 97,06% for educational and training purposes.

0.167% were **amphibians** (860 animals), of which 23.26% were used for biological studies of a fundamental nature and 76.74% for educational and training purposes.

Finally, one **horse** was used by a university anatomy and physiology laboratory for student education.

The above data show that the two main purposes of the experiments carried out in Greece were education and training and biological studies of a fundamental nature. Vertebrate animals are therefore used mainly:

- to study the fundamental biological characteristics of each species and in particular of fish endemic to the waters of the Mediterranean Sea (the main source of the large number of fish referred to above);

to educate students and to draw up postgraduate or other research programmes at tertiary education establishments.

Main observations

Toxicological and other Safety Tests

89.32% of the rats were used for the testing of products or substances intended mainly for use in agriculture (870 animals, of which 780 were used by a public research establishment for studies of the toxicity of plant protection products on living organisms – mutagenicity – and 90 by a university toxicology laboratory for reproductive toxicity studies) and 10.68% for other types of testing.

100% of the rabbits were used for the testing of products and devices for human medicine, dentistry and veterinary medicine.

100% of the pigs were used for other toxicological tests.

NUMBER OF ANIMALS USED

1.1 Species	1.2 Total	1.3 % Percentages
1a-e. Rodents	8055	1,56
1.f. Rabbits (Oryctolagus cuniculus)	1492	0,29
1.g. Cats (Felis catus)	13	0,0025
1.h. Dogs (Canis familiaris)	22	0,0042
1.i. Ferrets (Mustela putorius furo)		
1.j. Other Carnivores (other Carnivora)		
1.k. Horses, donkeys and cross breds (Equidae)	1	0,0001
1.l. Pigs (Sus)	2751	0,53
1.m. Goats (Capra)	65	0,012
1.n. Sheep (Ovis)	294	0,05
1.o. Cattle (Bos)	30	0,005
1.p. Prosimians (Prosimia)		
1.q. New World Monkeys (Ceboidea)		
1.r. Old World Monkeys (Cercopithecoidea)		
1.s. Apes (Hominoidea)		
1.t. Other Mammals (other Mammalia)		
1.u. Quail (Coturnix coturnix)		
1.v. Other birds (other Aves)	340	0,066
1.w. Reptiles (Reptilia)		
1.x. Amphibians (Amphibia)	860	0,167
1.y. Fish (Pisces)	501500	97,2
1.z. TOTAL	515423	100

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 (*Mus musculus*)	3589	3399	20		170	
1.b. Rats (*Rattus norvegicus*)	4021	3805	50		166	
1.c. Guinea-Pigs (*Cavia porcellus*)	310				310	
1.d. Hamsters (*Mesocricetus*)	135	135				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	1492	1284	4		184	61
1.g. Cats (*Felis catus*)	13				13	
1.h. Dogs (*Canis familiaris*)	22				22	19
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	1					
1.l. Pigs (*Sus*)	2751					
1.m. Goats (*Capra*)	65					
1.n. Sheep (*Ovis)*	294					
1.o. Cattle (*Bos*)	30					
1.p. Prosimians (*Prosimia*)						
1.q. New World Monkeys (*Ceboidea*)						
1.r. Old World Monkeys (*Cercopithecoidea*)						
1.s. Apes (*Hominoidea*)						
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*						
1.v. Other birds (other *Aves*)	340					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	860					
1.y. Fish (*Pisces*)	501500					
1.z. TOTAL	515423					

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	423	120				3006	40		3589
2.b. Rats	1610	136			974	827	474		4021
2.c. Guinea-Pigs	30					270	10		310
2.d. Hamsters		135							135
2.e. Other Rodents									0
2.f. Rabbits	161	25	28	75	64	793	250	96	1492
2.g. Cats						13			13
2.h. Dogs						19	3		22
2.i. Ferrets									0
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds							1		1
2.l. Pigs	19	1150		1050	150	247	135		2751
2.m. Goats	40						25		65
2.n. Sheep	22					72	200		294
2.o. Cattle							30		30
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						10	330		340
2.w. Reptiles									0
2.x. Amphibians	200						660		860
2.y. Fish	301500						200000		501500
2.z. TOTAL	423	120				3006	40		3589

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

Products versus species

3.1 Species	3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3 Products/ substances used or intended to be used mainly in agriculture	3.4 Products/ substances used or intended to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice										0
3.b. Rats		870							104	974
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	64									64
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs									150	150
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	64	870	0	0	0	0	0	0	254	1188

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		510	80	2266	150	3006
4.b. Rats		51	287	489		827
4.c. Guinea-Pigs					270	270
4.d. Hamsters						0
4.e. Other Rodents						0
4.f. Rabbits	267	50		421	55	793
4.g. Cats					13	13
4.h. Dogs					19	19
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	71	46		130		247
4.m. Goats						0
4.n. Sheep					72	72
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					10	10
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish						0
4.z. TOTAL	338	657	367	3306	589	5257

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	10	93					103
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs	1050						1050
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	10	93	0	0	0	0	1153

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice							0
6.b. Rats	974						974
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		64					64
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs	150						150
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	1124	64	0	0	0	0	1188

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice														0
7.b. Rats										780	186		8	974
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits											64			64
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs													150	150
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	0	0	0	0	0	0	0	0	780	250	0	158	1188

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											64			64
8.b. Products/substances used or intended to be used mainly in agriculture										780	90			870
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											96		158	254
8.j. TOTAL	0	0	0	0	0	0	0	0	0	780	250	0	158	1188

SPAIN

Statistical data submitted

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

Comments of Spanish authorities

1. The statistics have been gathered by the competent authorities of the various administrations in Spain and have been forwarded to the Sub-directorate for the Orders of Exploitation (Ministry for Agriculture, Fisheries and Food) for processing.

2. The following national legislation applies in Spain:

Royal Decree 223/1988 of 14 March 1998 on the protection of animals used for experimental and other scientific purposes;

Order of 13 October 1989 laying down rules for the registration of State-owned breeding establishments, suppliers and users of animals in experiments, pursuant to Royal Decree 223/1988 of 14 March 1998.

3. Currently we are working on an amendment of the regulation which, among others, will establish a new database of the establishements registered in Spain and the procedures that they carry out.

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 (*Mus musculus*)	200821	155354	4741		40726	
1.b. Rats (*Rattus norvegicus*)	38544	35317	133		3094	
1.c. Guinea-Pigs (*Cavia porcellus*)	1932	1932				
1.d. Hamsters (*Mesocricetus*)	385	385				
1.e. Other Rodents (other *Rodentia*)	202					
1.f. Rabbits (*Oryctolagus cuniculus*)	2292	2248	44			
1.g. Cats (*Felis catus*)	26	26				
1.h. Dogs (*Canis familiaris*)	101	95			6	
1.i. Ferrets (*Mustela putorius furo*)	14	4	10			
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)						
1.l. Pigs (*Sus*)	940					
1.m. Goats (*Capra*)	4					
1.n. Sheep (*Ovis)*	175					
1.o. Cattle (*Bos*)	19					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	74	4	70			
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*	3					
1.v. Other birds (other *Aves*)	1622					
1.w. Reptiles (*Reptilia*)	18					
1.x. Amphibians (*Amphibia*)	232					
1.y. Fish (*Pisces*)	14638					
1.z. TOTAL	262042					

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	88362	22302		14941	38391	30823	2888	3114	200821
2.b. Rats	26732	6630	74		193	750	3375	790	38544
2.c. Guinea-Pigs	154	120		1457	116	50	25	10	1932
2.d. Hamsters	306	13				25	41		385
2.e. Other Rodents	202								202
2.f. Rabbits	592	324	30	852	257	145	25	67	2292
2.g. Cats	26								26
2.h. Dogs	34	39					28		101
2.i. Ferrets	14								14
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds									0
2.l. Pigs	119	326		12	61		206	216	940
2.m. Goats					4				4
2.n. Sheep	7	17			13	3	22	113	175
2.o. Cattle								19	19
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys	46	22						6	74
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail	3								3
2.v. Other birds	393					29		1200	1622
2.w. Reptiles	18								18
2.x. Amphibians	162	15					55		232
2.y. Fish	4444	1406			50	500	188	8050	14638
2.z. TOTAL	121614	31214	104	17262	39085	32325	6853	13585	262042

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	1878					20		3876	32617	38391
3.b. Rats	75							118		193
3.c. Guinea-Pigs	116									116
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	251								6	257
3.g. Cats										0
3.h. Dogs										0
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs	61									61
3.m. Goats	4									4
3.n. Sheep	13									13
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		50								50
3.z. TOTAL	2398	50	0	0	0	20	0	3994	32623	39085

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	1591	7876	39756	15746	4993	69962
4.b. Rats	2468	2102	1957	3954	244	10725
4.c. Guinea-Pigs	8	44		32	170	254
4.d. Hamsters		92		32	10	134
4.e. Other Rodents		160		20		180
4.f. Rabbits	43	3	107	43	39	235
4.g. Cats						0
4.h. Dogs	8					8
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	88			35	222	345
4.m. Goats						0
4.n. Sheep				17		17
4.o. Cattle						0
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys		45		9		54
4.s. Apes						0
4.t. Other Mammals						0
4.u. Quail						0
4.v. Other birds				1		1
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					456	456
4.z. TOTAL	4206	10322	41820	19889	6134	82371

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	14841					14941
5.b. Rats	74						74
5.c. Guinea-Pigs		1451				6	1457
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits	12	840			30		882
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs	12						12
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	198	17132	0	0	30	6	17366

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		5967		48	32281	95	38391
6.b. Rats		31		48	12	102	193
6.c. Guinea-Pigs		40			76		116
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		217			34	6	257
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs		61					61
6.m. Goats		4					4
6.n. Sheep		13					13
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						50	50
6.z. TOTAL	0	6333	0	96	32403	253	39085

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	48	36513	190										1640	38391
7.b. Rats	63		12								16		102	193
7.c. Guinea-Pigs													116	116
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits			34										223	257
7.g. Cats														0
7.h. Dogs														0
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs													61	61
7.m. Goats													4	4
7.n. Sheep													13	13
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													50	50
7.z. TOTAL	111	36513	236	0	0	0	0	0	0	0	16	0	2209	39085

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	111		236										2051	2398
8.b. Products/substances used or intended to be used mainly in agriculture													50	50
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		20												20
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption		3876												3876
8.h. Potential or actual contaminants in the general environment which do not appear in other columns											16		102	118
8.i. Other toxicological or safety evaluations		32617											6	32623
8.j. TOTAL	111	36513	236	0	0	0	0	0	0	0	16	0	2209	39085

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

Unexpected events

This survey took longer than was expected on the basis of previous experience. The reason for this is that, since 1999, many laboratories have merged their facilities and pooled their zoological staff, with the paradoxical result that getting the questionnaires to the right people is now more difficult than it used to be. The questionnaires were sent to the laboratory heads listed in our updated database from 1999. The laboratory heads then forwarded them (though in some cases they did not as they felt they were no longer concerned) to the directors of the animal centres who, after asking their research staff to complete the tables, produced a summary document. When the questionnaires were returned, however, EFICOM Markétudes found that the information was excessively summarised, often giving no details for the list of beneficiaries of the animal centres, as a result of which detailed checks were needed to avoid duplication and unnecessary further investigation.

Nonetheless, we are pleased to say that all persons responsible for animal experiment establishments in France gave detailed replies in a helpful and professional manner in the documents used for the survey. They should be thanked for the huge amount of work they were asked to do which is vital for the success of this document. EFICOM Markétudes, which has acted in an efficient, dedicated and courteous manner throughout this operation, is also closely associated with this document being a success.

Downward trend confirmed

The results of this survey on the number of animals used for experimental purposes in 2001 confirm the downward trend noted since 1993. However, the decrease (4%) is less than that seen in previous surveys. It is likely that the level attained in 2001 is close to the minimum below which public and private research bodies would be unable to fulfil the goals in respect of progress and safety which society has asked them to meet.

The general downward trend observed since 1990, 42% in the case of rodents and 39% for all animals is predominantly marked in the public sector (falls of 50% and 47%, respectively). The fall is slightly lower in the private sector (39% and 36%), which used 74% of the total number of animals (61% in 1999, 75% in 1997, and 72% in 1993).

No breakthrough in alternatives

The changes in the figures for animals used to obtain tissue for in vitro studies show that, since 1997, the number has constantly been 11.5% of the total number of animals used for experimental purposes. This shows that in vitro procedures do require the sacrifice of a large number of animals and that these procedures are still complementary to in vivo procedures, for which there is no visible trend towards alternatives.

Rodents and lagomorphs account for 89.4% of the total number of animals used for in vivo experiments and 93% of the total in vitro.

Difficult to make predictions

Trends cannot be identified from the changes seen in the surveys unless large samples are compared (rodents, rabbits, birds, amphibians, fish); no one could have predicted the 98% increase in the number of amphibians used between 1999 and 2001, given that the number had been constantly falling since 1990. For other animals, where only small numbers are concerned, changes must be treated even more cautiously. For example, the number of cats and pigs has fallen by 50% since 1990, while the number of non-human primates rose by 23% during the same period. What is the conclusion to be drawn from this? Similarly, the number of dogs fell by 29% since 1990, remaining at a steady 0.2% of the total, but what is to be made of the increase of 28% since 1997? Again, in the case of rabbits, the sizeable increase in the public sector in 1999 has fallen back and the figure for 2001 was the same as for 1997. The large increase seen in the private sector in 2001 must also be viewed in the context of these changes, without making any predictions about the future, simply noting that the figure for 2001 is still lower than that for 1997.

The case for national breeding establishments

As regards the places of origin of the animals, however, the figures are meaningful and do make it possible to identify difficulties concerning animal use. While it is understandable that 90.2% of Old World monkeys come from non-EU countries, it is surprising to note that, even though productive breeding establishments could easily be set up in France, 46.9% of New World monkeys, 46.6% of dogs and 43.6% of cats are obliged to make a long journey by air to reach our laboratories, even if the conditions in which they are transported are totally acceptable.

Forceful objectives

The tables, which indicate the aims of the experiments, show that 18.6% of animals were used for basic research and 74.3% for research, development and production and for the safety testing of medical and veterinary products. 0.12% of the total related to cosmetic products, and 55.5% to studies of human and animal diseases. Lastly, 11.2% of the total number of animals were used for toxicological and safety evaluations, 97.2% of this figure being rodents, lagomorphs and fish. These figures clearly show the major challenges of animal experimentation: to explore methods of treatment and guarantee medical, veterinary and environmental safety.

The need for animal experimentation

These figures, as a whole, show that researchers are constantly striving to reduce the number of vertebrate animals used for experimental purposes. They also show the clear, well-founded legitimacy of experimentation, but reveal the fundamental difficulty which biologists face when trying to understand how life works: they have no option other than to use live 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 (*Mus musculus*)	1370293	1293800	12475	1294	62724	5580
1.b. Rats (*Rattus norvegicus*)	471234	457734	3469	37	9994	5704
1.c. Guinea-Pigs (*Cavia porcellus*)	59184	52562	6598	0	24	0
1.d. Hamsters (*Mesocricetus*)	20527	19914	334	0	279	30
1.e. Other Rodents (other *Rodentia*)	3572					
1.f. Rabbits (*Oryctolagus cuniculus*)	53545	53332	69	0	144	336
1.g. Cats (*Felis catus*)	1383	780	0	0	603	598
1.h. Dogs (*Canis familiaris*)	5516	2783	161	0	2572	427
1.i. Ferrets (*Mustela putorius furo*)	619	11	70	0	538	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	536					
1.l. Pigs (*Sus*)	7808					
1.m. Goats (*Capra*)	842					
1.n. Sheep (*Ovis)*	5936					
1.o. Cattle (*Bos*)	2648					
1.p. Prosimians (*Prosimia*)	589	589	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	179	76	19	0	84	18
1.r. Old World Monkeys (*Cercopithecoidea*)	3072	301	0	0	2771	54
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	48					
1.u. Quail (*Coturnix coturnix)*	5027	5027	0	0	0	
1.v. Other birds (other *Aves*)	89905					
1.w. Reptiles (*Reptilia*)	1214					
1.x. Amphibians (*Amphibia*)	12218					
1.y. Fish (*Pisces*)	96399					
1.z. TOTAL	2212294					

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	243080	472657	459466	33465	99417	26828	24164	11216	1370293
2.b. Rats	85118	235389	45209	0	82017	541	21933	1027	471234
2.c. Guinea-Pigs	3457	7016	20501	1288	26699	16	207	0	59184
2.d. Hamsters	2779	13757	12	3042	883	0	54	0	20527
2.e. Other Rodents	328	3244	0	0	0	0	0	0	3572
2.f. Rabbits	2959	7046	15245	1040	16358	42	877	9978	53545
2.g. Cats	161	760	9	367	73	0	13	0	1383
2.h. Dogs	411	1048	75	511	3447	0	17	7	5516
2.i. Ferrets	408	78	0	0	133	0	0	0	619
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	10	235	94	166	26	0	0	5	536
2.l. Pigs	1316	2268	22	1318	307	0	1649	928	7808
2.m. Goats	538	39	66	2	25	0	12	160	842
2.n. Sheep	1476	759	3045	223	70	53	52	258	5936
2.o. Cattle	1695	495	0	236	22	0	62	138	2648
2.p. Prosimians	589	0	0	0	0	0	0	0	589
2.q. New World Monkeys	54	50	0	0	75	0	0	0	179
2.r. Old World Monkeys	148	359	0	0	2517	0	0	48	3072
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	32	16	0	0	0	0	0	0	48
2.u. Quail	1000	170	1950	0	0	0	730	1177	5027
2.v. Other birds	14841	10161	8254	13844	44	631	1215	40915	89905
2.w. Reptiles	1164	0	0	0	0	0	50	0	1214
2.x. Amphibians	2576	0	0	0	100	0	9542	0	12218
2.y. Fish	48618	32696	0	0	14675	0	320	90	96399
2.z. TOTAL	412758	788243	553948	55502	246888	28111	60897	65947	2212294

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	77777	5246	10258	70	494	197	0	825	4550	99417
3.b. Rats	62413	7425	9383	133	509	453	51	457	1193	82017
3.c. Guinea-Pigs	16160	1997	6268	105	843	0	0	0	1326	26699
3.d. Hamsters	792	0	26	0	65	0	0	0	0	883
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	12928	613	1913	100	680	0	0	11	113	16358
3.g. Cats	73	0	0	0	0	0	0	0	0	73
3.h. Dogs	3195	246	0	0	0	0	0	0	6	3447
3.i. Ferrets	0	0	0	0	0	0	0	0	133	133
3.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breds	26	0	0	0	0	0	0	0	0	26
3.l. Pigs	255	0	0	0	0	0	0	32	20	307
3.m. Goats	25	0	0	0	0	0	0	0	0	25
3.n. Sheep	70	0	0	0	0	0	0	0	0	70
3.o. Cattle	22	0	0	0	0	0	0	0	0	22
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	75	0	0	0	0	0	0	0	0	75
3.r. Old World Monkeys	2517	0	0	0	0	0	0	0	0	2517
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	26	18	0	0	0	0	0	0	0	44
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	100	0	100
3.y. Fish	4369	8152	2154	0	0	0	0	0	0	14675
3.z. TOTAL	180723	23697	30002	408	2591	650	51	1425	7341	246888

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	84887	266219	120469	229515	41475	742565
4.b. Rats	56155	142892	10162	110833	1006	321048
4.c. Guinea-Pigs	3052	1025	384	4930	1098	10489
4.d. Hamsters	2316	685	287	9404	3844	16536
4.e. Other Rodents	328	3214	0	30	0	3572
4.f. Rabbits	7188	73	411	2205	170	10047
4.g. Cats	5	53	2	72	789	921
4.h. Dogs	677	1	0	283	498	1459
4.i. Ferrets	1	10	2	473	0	486
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	18	227	245
4.l. Pigs	1340	0	170	594	1480	3584
4.m. Goats	31	0	0	93	453	577
4.n. Sheep	507	0	65	959	757	2288
4.o. Cattle	0	0	1	77	2112	2190
4.p. Prosimians	99	86	56	288	60	589
4.q. New World Monkeys	1	44	1	57	1	104
4.r. Old World Monkeys	89	138	0	264	16	507
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	1	2	39	6	0	48
4.u. Quail	84	200	142	571	173	1170
4.v. Other birds	168	387	907	1103	23068	25633
4.w. Reptiles	75	180	128	778	3	1164
4.x. Amphibians	420	88	54	1913	101	2576
4.y. Fish	1495	69	42	1214	78494	81314
4.z. TOTAL	158919	415366	133322	365680	155825	1229112

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	24205	67024	0	210	182539	218953	492931
5.b. Rats	8494	32190	0	0	2663	1862	45209
5.c. Guinea-Pigs	29	3924	0	0	11713	6123	21789
5.d. Hamsters	504	2550	0	0	0	0	3054
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	106	3368	0	35	5566	7210	16285
5.g. Cats	0	376	0	0	0	0	376
5.h. Dogs	0	511	0	0	0	75	586
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 breds	0	162	0	0	0	98	260
5.l. Pigs	0	1318	0	0	20	2	1340
5.m. Goats	0	0	0	1	0	67	68
5.n. Sheep	6	223	0	0	0	3039	3268
5.o. Cattle	0	236	0	0	0	0	236
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	1950	0	0	0	0	1950
5.v. Other birds	0	13839	0	0	8215	44	22098
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	33344	127671	0	246	210716	237473	609450

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	5484	19649	0	435	72600	1249	99417
6.b. Rats	5202	20355	0	154	52063	4243	82017
6.c. Guinea-Pigs	413	6256	0	357	19306	367	26699
6.d. Hamsters	68	373	0	0	214	228	883
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	403	2708	0	0	13201	46	16358
6.g. Cats	0	22	0	0	51	0	73
6.h. Dogs	12	408	0	0	2913	114	3447
6.i. Ferrets	0	133	0	0	0	0	133
6.j. Other Carnivores	0	0	0	0	0	0	0
6.k. Horses, donkeys and cross breds	4	22	0	0	0	0	26
6.l. Pigs	12	45	0	0	201	49	307
6.m. Goats	11	3	0	0	1	10	25
6.n. Sheep	25	31	0	0	2	12	70
6.o. Cattle	0	22	0	0	0	0	22
6.p. Prosimians	0	0	0	0	0	0	0
6.q. New World Monkeys	0	0	0	0	71	4	75
6.r. Old World Monkeys	0	6	0	0	2511	0	2517
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	44	44
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	29	70	0	0	0	1	100
6.y. Fish	0	3158	0	0	111	11406	14675
6.z. TOTAL	11663	53261	0	946	163245	17773	246888

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	3795	5528	7353	0	3901	0	11285	6376	2098	344	12	313	58412	99417
7.b. Rats	2285	5643	16662	255	35	100	22795	3479	6561	2872	3860	1440	16030	82017
7.c. Guinea-Pigs	0	0	504	52	12959	46	244	0	0	0	0	317	12577	26699
7.d. Hamsters	0	0	187	0	0	0	584	26	0	0	0	0	86	883
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	6	16	78	1945	0	1544	751	0	2683	0	983	68	8284	16358
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	24	49	73
7.h. Dogs	0	0	604	0	0	0	2271	0	0	0	0	52	520	3447
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	133	133
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	1	2	3	0	0	0	0	0	0	0	0	20	0	26
7.l.. Pigs	5	12	22	0	0	0	149	0	0	0	0	56	63	307
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	25	25
7.n. Sheep	6	14	18	0	0	0	2	0	0	0	0	0	30	70
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	22	0	22
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	9	0	0	0	62	0	0	0	0	0	4	75
7.r. Old World Monkeys	0	0	157	0	0	0	1401	0	0	0	0	0	959	2517
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	44	0	0	0	0	0	0	0	0	0	0	44
7.w. Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. Amphibians	14	35	46	0	0	0	5	0	0	0	0	0	0	100
7.y. Fish	2756	4369	0	0	0	0	396	1000	0	1000	3000	2154	0	14675
7.z. TOTAL	8868	15619	25687	2252	16895	1690	39945	10881	11342	4216	7855	4466	97172	246888

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	4056	11819	24892	786	4417	753	23573	5178	5030	2961	4068	0	93190	180723
8.b. Products/substances used or intended to be used mainly in agriculture	3285	887	18	90	1764	148	7612	3080	2167	0	1589	3057	0	23697
8.c. Products/substances used or intended to be used mainly in industry	1171	2804	253	861	8377	674	5913	1504	5202	0	381	2603	259	30002
8.d. Products/substances used or intended to be used mainly in the household	216	0	0	60	101	31	0	0	0	0	0	0	0	408
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	210	262	74	450	1213	142	128	0	0	0	0	0	112	2591
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	231	112	0	0	0	0	307	0	0	0	0	0	0	650
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	51	0	0	0	0	0	0	0	0	0	0	0	0	51
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	90	0	0	0	366	180	0	0	0	199	590	1425
8.i. Other toxicological or safety evaluations	45	404	222	54	1894	60	3310	111	83	53	0	0	1105	7341
8.j. TOTAL	9265	16288	25549	2301	17766	1808	41209	10053	12482	3014	6038	5859	95256	246888

IRELAND

Statistical data submitted

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

Comments of Irish authorities

General

- A total of 52,203 animals were used. This represents a reduction of 29% compared to 1999 (the last published figures).
- There were 492 valid licences during the period 1 January 2002 – 31 December 2002.
- 152 new licences were issued in 2002. This represents a reduction of 32% compared to the number of licences issued the previous year.
- Rodents accounted for 48% of all animals used.
- No primates were used. This was in accordance with Ireland's policy not to licence for the use of primates.
- Of the animals used, 40% (20,661) were bred in registered breeding establishments in Ireland.
- Universities and Colleges accounted for 43% (22,374) of all animals used in scientific procedures.
- 79% of all procedures (40,996) used no anaesthesia (Certificate A). Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.
- 13% of animals (6,651) were used in procedures involving anaesthesia with permitted recovery (Certificate B).
- 949 genetically modified animals were used in experimental activity. This represents approximately 2% of the total numbers used.

Animals Used for Selected Purposes

- 11% of animals (5,647) were involved in studies specific to animal diseases.
- 21,000 fish (99.8% of all fish used) were used in the regulatory monitoring of infection in farmed stocks.
- Of the 65 pigs used in 2002, 60% (39) were involved in studies on human and animal diseases.
- 46 cats were used, all of which were used in toxicology and other safety evaluations.
- 195 dogs were used, of which 20 were used in studies on animal disease.

– 16% of the animals were used for studies on human nervous and mental disorders.

– Education and training accounted for 0.2% (103) of the animals used.

Toxicological and other Safety Evaluations

– No animals were used in the testing of cosmetic products.

– Toxicological and other safety evaluations accounted for 9% (4,538) of animals used. All of these tests were conducted to comply with legislation.

– 95% of the animals used in toxicological and other safety evaluations were mice.

– 1,300 mice were used in LD_{50} and LC_{50} testing.

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 (*Mus musculus*)	16790	12990	3569	138	93	
1.b. Rats (*Rattus norvegicus*)	8282	7332	890	60		
1.c. Guinea-Pigs (*Cavia porcellus*)	35	35				
1.d. Hamsters (*Mesocricetus*)	6	6				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	130	66	64			
1.g. Cats (*Felis catus*)	46	46				
1.h. Dogs (*Canis familiaris*)	195	165	20		10	
1.i. Ferrets (*Mustela putorius furo*)	21	21				
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	19					
1.l. Pigs (*Sus*)	65					
1.m. Goats (*Capra*)	2					
1.n. Sheep (*Ovis)*	1656					
1.o. Cattle (*Bos*)	3778					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	0					
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)	132					
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)						
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)	21046					
1.z. TOTAL	52203					

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	11279	264			4328	169	15	735	16790
2.b. Rats	7489	793							8282
2.c. Guinea-Pigs	35								35
2.d. Hamsters	6								6
2.e. Other Rodents									0
2.f. Rabbits	122							8	130
2.g. Cats					46				46
2.h. Dogs	1	20			164			10	195
2.i. Ferrets						21			21
2.j. Other Carnivores									0
2.k. Horses, donkeys and cross breds				12			7		19
2.l. Pigs	15	21		6		3		20	65
2.m. Goats						2			2
2.n. Sheep		21		38		1597			1656
2.o. Cattle	1361	2029		197			81	110	3778
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	100	32							132
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish	46							21000	21046
2.z. TOTAL	20454	3180	0	253	4538	1792	103	21883	52203

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice									4328	4328
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	46									46
3.h. Dogs	164									164
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										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	210	0	0	0	0	0	0	0	4328	4538

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	442	2464	2345	6072	389	11712
4.b. Rats	591	5685	134	1825	47	8282
4.c. Guinea-Pigs		35				35
4.d. Hamsters					6	6
4.e. Other Rodents						0
4.f. Rabbits				102	20	122
4.g. Cats						0
4.h. Dogs				1	20	21
4.i. Ferrets					21	21
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	12		9	15	3	39
4.m. Goats					2	2
4.n. Sheep	1				1617	1618
4.o. Cattle					3390	3390
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys						0
4.s. Apes						0
4.t. Other Mammals					132	132
4.u. Quail						0
4.v. Other birds						0
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish		46				46
4.z. TOTAL	1046	8230	2488	8015	5647	25426

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 breds		12					12
5.l. Pigs		6					6
5.m. Goats							0
5.n. Sheep		36				2	38
5.o. Cattle		172				25	197
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	226	0	0	0	27	253

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice		1300			3028		4328
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	46						46
6.h. Dogs	164						164
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							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	210	1300	0	0	3028	0	4538

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	1300												3028	4328
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												46		46
7.h. Dogs													164	164
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	1300	0	0	0	0	0	0	0	0	0	0	46	3192	4538

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													3238	3238
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														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	1300													1300
8.j. TOTAL	1300	0	0	0	0	0	0	0	0	0	0	0	3238	4538

ITALY

Statistical data submitted

The statistical data have been submitted by the "*Ministero della Salute, Dipartimento della Prevenzione e della Comunicazione - Direzione Generale della Sanità Veterinaria e degli Alimenti – Ufficio X°* " (Ministry of Health – Prevention and Communication Department, Directorate-General for Veterinary Health and for Food, Office X).

Comments of Italian authorities

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

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

95.63% of the animal species used were rodents and rabbits.

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

32.62% of the animals were used in biological studies.

50.37% of the animals were used in the research, development, production and quality control of products and devices for human medicine, dentistry and veterinary medicine.

9.64% of the animals were used in toxicological studies.

7.37% of the animals were used for diagnosis of disease, education and other purposes.

97.79% of the animals were used to study human diseases, while the remaining **2.21%** were used to study animal diseases.

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

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

All in all, this means that horses, non-human primates, cats and dogs together account for **0.16%** of all animals used.

The use of cats in experiments in Italy is gradually being abandoned, with the result that only 10 cats were used in 2002.

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 (*Mus musculus*)	466640	449446	3742	481	12971	
1.b. Rats (*Rattus norvegicus*)	377573	373899	2665	30	979	
1.c. Guinea-Pigs (*Cavia porcellus*)	18722	10738	2100	5884	0	
1.d. Hamsters (*Mesocricetus*)	3854	3599	0	0	255	
1.e. Other Rodents (other *Rodentia*)	5252					
1.f. Rabbits (*Oryctolagus cuniculus*)	12481	11373	308	0	800	555
1.g. Cats (*Felis catus*)	10	0	10	0	0	0
1.h. Dogs (*Canis familiaris*)	1061	782	24	152	103	63
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0					
1.k. Horses, donkeys and cross breds (*Equidae*)	33					
1.l. Pigs (*Sus*)	2397					
1.m. Goats (*Capra*)	54					
1.n. Sheep (*Ovis)*	798					
1.o. Cattle (*Bos*)	489					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	18	0	18	0	0	51
1.r. Old World Monkeys (*Cercopithecoidea*)	402	1	123	0	278	33
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	11					
1.u. Quail (*Coturnix coturnix)*	201	201	0	0	0	
1.v. Other birds (other *Aves*)	28691					
1.w. Reptiles (*Reptilia*)	694					
1.x. Amphibians (*Amphibia*)	2517					
1.y. Fish (*Pisces*)	2991					
1.z. TOTAL	924889					

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	210488	117541	47567	2871	46924	34980	175	6094	466640
2.b. Rats	72469	117503	141404	8175	31860	773	2055	3334	377573
2.c. Guinea-Pigs	2679	5915	6426	0	2390	428	38	846	18722
2.d. Hamsters	1330	1375	0	20	271	225	0	633	3854
2.e. Other Rodents	617	4037	0	0	0	598	0	0	5252
2.f. Rabbits	2670	3291	4605	159	1337	237	5	177	12481
2.g. Cats	0	10	0	0	0	0	0	0	10
2.h. Dogs	21	117	0	0	923	0	0	0	1061
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	1	13	1	0	0	0	0	18	33
2.l. Pigs	1184	262	40	147	8	6	172	578	2397
2.m. Goats	28	24	0	0	0	0	0	2	54
2.n. Sheep	267	176	0	183	0	5	2	165	798
2.o. Cattle	401	47	0	0	0	1	6	34	489
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	17	0	47	0	338	0	0	0	402
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	11	0	0	0	0	0	0	0	11
2.u. Quail	60	0	0	0	0	0	0	141	201
2.v. Other birds	4113	127	118	3664	4167	1592	0	14910	28691
2.w. Reptiles	686	0	8	0	0	0	0	0	694
2.x. Amphibians	2427	0	0	0	90	0	0	0	2517
2.y. Fish	2143	0	0	0	848	0	0	0	2991
2.z. TOTAL	301612	250456	200216	15219	89156	38845	2453	26932	924889

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	32450	350	0	1515	0	5216	56	0	7337	46924
3.b. Rats	20070	442	847	160	60	640	0	8828	813	31860
3.c. Guinea-Pigs	510	0	1796	0	0	0	0	0	84	2390
3.d. Hamsters	271	0	0	0	0	0	0	0	0	271
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	1252	0	64	12	0	0	0	0	9	1337
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	923	0	0	0	0	0	0	0	0	923
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 breds	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	8	0	0	0	0	0	0	0	0	8
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	338	0	0	0	0	0	0	0	0	338
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	4167	0	0	0	0	0	0	0	0	4167
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	90	0	0	0	0	0	0	0	0	90
3.y. Fish	420	0	340	0	0	0	0	88	0	848
3.z. TOTAL	60499	792	3047	1687	60	5856	56	8916	8243	89156

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	8903	36683	83205	107914	5893	242598
4.b. Rats	13529	48527	8576	47445	124	118201
4.c. Guinea-Pigs	736	733	0	5770	260	7499
4.d. Hamsters	355	132	2	968	1233	2690
4.e. Other Rodents	0	4097	0	36	598	4731
4.f. Rabbits	514	281	321	3073	176	4365
4.g. Cats	0	0	0	10	0	10
4.h. Dogs	37	342	144	217	0	740
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 breds	0	0	0	0	0	0
4.l. Pigs	40	9	0	116	6	171
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	26	0	0	73	128	227
4.o. Cattle	0	0	0	3	0	3
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	3	160	60	0	223
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	225	0	101	40	366
4.w. Reptiles	0	0	0	11	0	11
4.x. Amphibians	0	95	45	360	0	500
4.y. Fish	0	42	50	99	0	191
4.z. TOTAL	24140	91187	92503	166256	8458	382544

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	8762	9352	0	0	21960	10364	50438
5.b. Rats	0	55711	0	0	91532	2336	149579
5.c. Guinea-Pigs	65	615	0	0	5746	0	6426
5.d. Hamsters	20	0	0	0	0	0	20
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	969	2584	0	0	1211	0	4764
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 breds	1	0	0	0	0	0	1
5.l. Pigs	104	83	0	0	0	0	187
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	183	0	0	0	0	183
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	47	0	47
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	1457	2325	0	0	0	0	3782
5.w. Reptiles	6	2	0	0	0	0	8
5.x. Amphibians	0	0	0	0	0	0	0
5.y. Fish	0	0	0	0	0	0	0
5.z. TOTAL	11384	70855	0	0	120496	12700	215435

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	19929	5098	0	199	15211	6487	46924
6.b. Rats	11066	2375	0	0	18417	2	31860
6.c. Guinea-Pigs	316	1880	0	0	112	82	2390
6.d. Hamsters	0	34	0	0	237	0	271
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	114	290	0	0	838	95	1337
6.g. Cats	0	0	0	0	0	0	0
6.h. Dogs	118	32	0	0	773	0	923
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 breds	0	0	0	0	0	0	0
6.l. Pigs	0	8	0	0	0	0	8
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	338	0	338
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	122	4045	0	0	0	0	4167
6.w. Reptiles	0	0	0	0	0	0	0
6.x. Amphibians	0	0	0	0	90	0	90
6.y. Fish	0	340	0	0	100	408	848
6.z. TOTAL	31665	14102	0	199	36116	7074	89156

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	3180	5746	10370	50	0	50	5035	1437	575	920	288	0	19273	46924
7.b. Rats	492	1174	6293	20	0	158	7190	8896	1516	484	1459	0	4178	31860
7.c. Guinea-Pigs	147	24	295	0	1914	0	6	0	0	0	0	0	4	2390
7.d. Hamsters	0	0	34	0	0	0	237	0	0	0	0	0	0	271
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	10	0	310	162	12	188	34	0	491	0	40	0	90	1337
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	5	407	0	4	0	501	0	0	0	0	0	6	923
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	8	8
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	111	0	0	0	220	0	0	0	0	0	7	338
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	8	4045	0	0	0	0	0	0	0	0	0	114	4167
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	90	0	0	0	0	90
7.y. Fish	340	0	320	0	0	0	0	0	100	0	0	88	0	848
7.z. TOTAL	4169	6957	22185	232	1930	396	13223	10333	2772	1404	1787	88	23680	89156

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	3659	6403	21581	166	134	368	12312	1505	2507	1088	1787	0	11013	62523
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	360	0	265	81	0	0	414	1120
8.c. Products/substances used or intended to be used mainly in industry	340	448	164	38	1796	26	0	0	0	235	0	0	87	3134
8.d. Products/substances used or intended to be used mainly in the household	140	50	250	22	0	0	10	0	0	0	0	0	1556	2028
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	60	0	0	0	0	0	0	60
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	30	0	190	6	0	2	481	0	0	0	0	0	10610	11319
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	56	0	0	0	0	0	0	0	0	0	0	0	56
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	8828	0	0	0	88	0	8916
8.i. Other toxicological or safety evaluations	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.j. TOTAL	4169	6957	22185	232	1930	396	13223	10333	2772	1404	1787	88	23680	89156

LUXEMBOURG

Statistical data submitted

The statistical data have been submitted by the "*Ministère de l'Agriculture, Administration des Services Vétérinaires*" (Ministry of Agriculture, Administration of Veterinary Services)

Comments of Luxembourg authorities

Single experimentation project registered in Luxembourg in 2002.

In comparison with 2000 there has been an increase in the number of laboratory animals used (2 200 rats as against 20 in 2000).

Responsibility for supervising animal welfare rests with a veterinary inspector who carries out at least two checks a year.

Detection infrastructure and the handling of laboratory animals comply with animal welfare requirements.

The purpose of the experiments is to carry out an immunological study of the protective efficiency and the antigenicity of antigens to improve vaccination strategies and diagnostic procedures for specific diseases.

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

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (*Mus musculus*)	3000	3000				
1.b. Rats (*Rattus norvegicus*)	2200	2200				
1.c. Guinea-Pigs (*Cavia porcellus*)	100	100				
1.d. Hamsters (*Mesocricetus*)	0					
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	20	20				
1.g. Cats (*Felis catus*)	0					
1.h. Dogs (*Canis familiaris*)	0					
1.i. Ferrets (*Mustela putorius furo*)	0					
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)						
1.l. Pigs (*Sus*)						
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis)*						
1.o. Cattle (*Bos*)						
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	0					
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*	0					
1.v. Other birds (other *Aves*)						
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)						
1.y. Fish (*Pisces*)						
1.z. TOTAL	5320					

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		3000							3000
2.b. Rats		2200							2200
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 breds									0
2.l. Pigs									0
2.m. Goats									0
2.n. Sheep									0
2.o. Cattle									0
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals									0
2.u. Quail									0
2.v. Other birds									0
2.w. Reptiles									0
2.x. Amphibians									0
2.y. Fish									0
2.z. TOTAL	0	5320	0	0	0	0	0	0	5320

THE NETHERLANDS

Statistical data submitted

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

Comments of Netherlands authorities

On 5 February 1997, the revised version of the **Experiments on Animals Act** (1977) entered into force. This act presents a comprehensive system for regulation of animal experimentation and only covers vertebrate animals. However, also invertebrate species to be designated by Order in Council can be brought under the scope of this act.

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. Due to differences in legal interpretation, articles 11 and 22(1) of Dir. 86/609/EEC had to be implemented in a different way. This process is almost finished now.

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

- animal experiments using LD_{50}/LC_{50} 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.

- 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 employ 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 26 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 Inspectorate for Health Protection and Veterinary Public Health of 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*. Tuning of these three types of evaluation needs due consideration.

The Inspectorate for Health Protection and Veterinary Public Health of the Food and Consumer Product Safety Authority / is in charge of the supervision of these licences to create genetically modified animals.

In 2002, for the creation of transgenic animals, 28,185 animals (28,102 mice and 83 rats) were used.

Collection of data

81 establishments (with 336 sub-units) completed the 2002 registration form.

These establishments can be categorized as follows:

a) Universities and university hospitals 15

b) Other hospitals, regional public health laboratories 3

c) Public health research institutes 9

d) Agricultural and veterinary research institutes 8

e) Other research institutes 4

f) Industries 30

g).Schools for vocational training 9

h) Miscellaneous 3

The killing of an animal without any previous intervention

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 2002, 63,235 animals were killed without previous intervention.

Total number of animals used

In 2002, according to the EU Tables, the total number of animals used was 640,303.

This is 1.6% (10,060) more than the number of animals used in 2001 (630,243), but 2,8% less than the number of animals used in 2000 (658,543).

The total number of genetically modified animals that was used (108,075) was substantially higher than the number of genetically animals used in 2001 (70,856). When split up into species, the numbers of genetically modified animals used are: 103,358 mice, 73 rats, 337 rabbits, 3,118 amphibians and 1,189 fish.

In 2002 20,487 animals were re-used.

In 2002 the number of animals used for toxicological and other safety evaluation was decreased with 23,1% compared to the number used in 2001.

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.

Discomfort is defined as a state including impairment of the animal's health, or as appreciable pain, injury or other grave distress caused to the animal. For assessment of the degree of discomfort no objective criteria are available. However, respondents are advised to attend to the effect of interferences on the behaviour and/or on the bodily functioning of the animal.

At meetings of animal welfare officers information is exchanged and discussed to promote consensus of opinion.

As a consequence of the animal experiments performed in 2002:

- 239,003 (37,3%) animals experienced minor discomfort;
- 175,468 (27,4%) animals experienced minor/moderate discomfort;
- 129,239 (20,2%) animals experienced moderate discomfort;
- 57,701 (9,0%) animals experienced moderate/severe discomfort;
- 37,880 (5,9%) animals experienced severe discomfort and
- 1,639 (0,2%) 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 (*Mus musculus*)	288706	266936	19674		2096	
1.b. Rats (*Rattus norvegicus*)	128975	118122	9451		1402	
1.c. Guinea-Pigs (*Cavia porcellus*)	8752	6733	1700		319	
1.d. Hamsters (*Mesocricetus*)	6306	5786	520			
1.e. Other Rodents (other *Rodentia*)	1482					
1.f. Rabbits (*Oryctolagus cuniculus*)	8093	6324	780		989	845
1.g. Cats (*Felis catus*)	342	280	6		56	44
1.h. Dogs (*Canis familiaris*)	1045	518	58		469	180
1.i. Ferrets (*Mustela putorius furo*)	84	16			68	40
1.j. Other Carnivores (other *Carnivora*)	497					
1.k. Horses, donkeys and cross breds (*Equidae*)	1918					
1.l. Pigs (*Sus*)	7892					
1.m. Goats (*Capra*)	1032					
1.n. Sheep (*Ovis)*	3425					
1.o. Cattle (*Bos*)	6494					
1.p. Prosimians (*Prosimia*)						
1.q. New World Monkeys (*Ceboidea*)	61	29	8		24	27
1.r. Old World Monkeys (*Cercopithecoidea*)	209	193			16	264
1.s. Apes (*Hominoidea*)						
1.t. Other Mammals (other *Mammalia*)	91					
1.u. Quail (*Coturnix coturnix)*	4801				4801	
1.v. Other birds (other *Aves*)	138299					
1.w. Reptiles (*Reptilia*)	217					
1.x. Amphibians (*Amphibia*)	5377					
1.y. Fish (*Pisces*)	26832					
1.z. TOTAL	640930					

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	203180	46402	18776	10520	7231	710	1887		288706
2.b. Rats	44070	19796	31277	3248	27896	62	2626		128975
2.c. Guinea-Pigs	576	1920	808	2703	2658	4	83		8752
2.d. Hamsters	763	3123	90	2241	75	9	5		6306
2.e. Other Rodents	564	866					52		1482
2.f. Rabbits	1013	3288	119	611	2932	5	125		8093
2.g. Cats	113	70		85			74		342
2.h. Dogs	183	252		29	557		24		1045
2.i. Ferrets	16	20					48		84
2.j. Other Carnivores	497								497
2.k. Horses, donkeys and cross breds		213	1590	94			21		1918
2.l. Pigs	3901	2554	31	1111	134		161		7892
2.m. Goats	923	14	59			4	32		1032
2.n. Sheep	828	332	2115	14		17	119		3425
2.o. Cattle	5042	744	116	262	44	0	286		6494
2.p. Prosimians									0
2.q. New World Monkeys	24	37							61
2.r. Old World Monkeys	59	150							209
2.s. Apes									0
2.t. Other Mammals	81	10							91
2.u. Quail					4801				4801
2.v. Other birds	66435	39441	133	29239	1349	26	1676		138299
2.w. Reptiles	1						216		217
2.x. Amphibians	5260				20		97		5377
2.y. Fish	7908	2932		1180	14162		650		26832
2.z. TOTAL	341437	122164	55114	51337	61859	837	8182	0	640930

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	5051	444	1507			144		85		7231
3.b. Rats	7332	685	16715	42		1230	1246	556	90	27896
3.c. Guinea-Pigs	700	566	1358	34						2658
3.d. Hamsters	75									75
3.e. Other Rodents	0									0
3.f. Rabbits	2254	112	548	18						2932
3.g. Cats	0									0
3.h. Dogs	477	80								557
3.i. Ferrets	0									0
3.j. Other Carnivores	0									0
3.k. Horses, donkeys and cross breds	0									0
3.l. Pigs	14						120			134
3.m. Goats	0									0
3.n. Sheep	0									0
3.o. Cattle	44									44
3.p. Prosimians	0									0
3.q. New World Monkeys	0									0
3.r. Old World Monkeys	0									0
3.s. Apes	0									0
3.t. Other Mammals	0									0
3.u. Quail	0	4801								4801
3.v. Other birds	74		1275							1349
3.w. Reptiles	0									0
3.x. Amphibians	0							20		20
3.y. Fish	0		202					13960		14162
3.z. TOTAL	16021	6688	21605	94	0	1374	1366	14621	90	61859

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	18728	4843	116384	74681	12148	226784
4.b. Rats	6061	11109	5910	29898	227	53205
4.c. Guinea-Pigs		107	18	1049	1107	2281
4.d. Hamsters	70	81	60	376	3115	3702
4.e. Other Rodents				985		985
4.f. Rabbits	277		31	2133	1445	3886
4.g. Cats		18	4	10	132	164
4.h. Dogs	113			141	178	432
4.i. Ferrets				16	20	36
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds					213	213
4.l. Pigs	407	22	18	453	2332	3232
4.m. Goats	178			54	300	532
4.n. Sheep				286	305	591
4.o. Cattle	25			19	4928	4972
4.p. Prosimians						0
4.q. New World Monkeys				37		37
4.r. Old World Monkeys		4	6	189		199
4.s. Apes						0
4.t. Other Mammals					66	66
4.u. Quail						0
4.v. Other birds			38	131	46342	46511
4.w. Reptiles						0
4.x. Amphibians						0
4.y. Fish					3384	3384
4.z. TOTAL	25859	16184	122469	110458	76242	351212

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	20116		304	6486	2385	29296
5.b. Rats	108	820		72	32665	860	34525
5.c. Guinea-Pigs		1308		20	1490	693	3511
5.d. Hamsters					2241	90	2331
5.e. Other Rodents		0					0
5.f. Rabbits		51			601	78	730
5.g. Cats					61	24	85
5.h. Dogs	5				24		29
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds	18				62	1604	1684
5.l. Pigs	69	225			639	209	1142
5.m. Goats						59	59
5.n. Sheep					14	2115	2129
5.o. Cattle		15		4	72	287	378
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	185	576			21555	7056	29372
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish					188	992	1180
5.z. TOTAL	390	23111	0	400	66098	16452	106451

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	90	110		144	4087	2800	7231
6.b. Rats	40	80		1481	25543	752	27896
6.c. Guinea-Pigs	28				2615	15	2658
6.d. Hamsters					75		75
6.e. Other Rodents							0
6.f. Rabbits	10	12			2910		2932
6.g. Cats							0
6.h. Dogs					557		557
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs	72	62					134
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle		12			32		44
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					4801		4801
6.v. Other birds		60			1285	4	1349
6.w. Reptiles							0
6.x. Amphibians						20	20
6.y. Fish	2424				7576	4162	14162
6.z. TOTAL	2664	336	0	1625	49481	7753	61859

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		2612	1070		600			690		1606			653	7231
7.b. Rats	30	1334	4227	510			2848	580	9916	580	6080		1791	27896
7.c. Guinea-Pigs			32		2459								167	2658
7.d. Hamsters													75	75
7.e. Other Rodents														0
7.f. Rabbits		3	6	362		366	118				1148		1047	3050
7.g. Cats														0
7.h. Dogs			236										203	439
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs													134	134
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle			44											44
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	82								4719					4801
7.v. Other birds			4						1275	10		0	60	1349
7.w. Reptiles														0
7.x. Amphibians													20	20
7.y. Fish	4588	2424	484				216		3834			2616		14162
7.z. TOTAL	4700	6373	6103	872	3059	366	3182	1270	19744	2196	7228	2616	4150	61859

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	18	2831	3452	48	737	18	535	850	512	396	3269		3355	16021
8.b. Products/substances used or intended to be used mainly in agriculture	82	272	16	207	590	58	304	420	4719				20	6688
8.c. Products/substances used or intended to be used mainly in industry	202	818	1641	604	1698	275			10679	1689	3364		635	21605
8.d. Products/substances used or intended to be used mainly in the household	0	6		13	34	15				26				94
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	12	12	430				780				140			1374
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption							791				455		120	1366
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	4386	2424	484				772		3834	85		2616	20	14621
8.i. Other toxicological or safety evaluations		10	80											90
8.j. TOTAL	4700	6373	6103	872	3059	366	3182	1270	19744	2196	7228	2616	4150	61859

AUSTRIA

Statistical data submitted

The statistical data have been submitted by the "*Bundesministerien für Gesundheit und Frauen- Land und Forstwirtshaft, 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 of Austrian authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Austria are regulated by the Animal Experiments Act (***Tierversuchsgesetz***) (Federal Act of 27 September 1989 on experiments on live animals, Federal Law Gazette (BGBl.) 501/1989, as amended in BGBl. I-169/1999). The Federal Minister for Health and Women, the Federal Minister for Economic Affairs and Labour, the Federal Minister for Agriculture, Forestry, the Environment and Water Management and the Federal Minister for Education, Science and Culture are responsible for enforcing the Act.

Under the Animal Experiments Act, **animal experiments may be carried out only if they are imperative for one of the following purposes**:

a) research and development;

b) professional training;

c) medical diagnosis and treatment;

d) investigating and testing natural or synthetically produced substances, preparations or products;

e) identification of environmental hazards;

f) extraction of substances.

Animal experiments may be carried out for these purposes only if:

1. there is a justified interest in the experiments

a) to prevent, detect or cure diseases in humans and animals;

b) to detect or influence physiological conditions or functions in humans or animals;

c) to acquire scientific knowledge;

d) to provide professional training; or

e) to prevent environmental hazards; **and**

2. the purposes for which the experiments are to be carried out cannot be fulfilled by other methods and procedures (substitute methods) or, with regard to professional training, cannot be achieved through different teaching techniques, in particular through film and other audiovisual media.

Animal experiments are inadmissible in any of the following cases:

a) if the findings of a similar experiment are factually and legally accessible and there are no justified doubts as to their accuracy and validity;

b) if it is not likely that the experiment will produce additional or new information;

c) if the experiment is not required to check earlier findings; or

d) if factually and legally accessible findings of animal experiments carried out in Austria or abroad are available for which there is no justified reason to doubt their accuracy and validity and if these are formally recognised in Austria on the basis of the relevant legislation.

Animal experiments to develop or test cosmetic products are completely prohibited.

The Animal Experiments Act also lays down **"guiding principles"** that are binding on all scientists and experimenters involved in animal experiments and also on the authorities. Accordingly:

> animal experiments must comply with the principles of scientific research and the assumption to be verified and the procedure chosen must be meaningful in the light of the current state of scientific knowledge. In carrying out animal experiments, the aim should be to acquire an optimum gain in knowledge;
>
> the validity and applicability of animal experiment models should be continuously monitored with a view to **reducing the number of experiments and using substitute methods** and adapted to the current state of scientific knowledge. Account must be taken of knowledge from behaviour research and laboratory animal science and the development of measurement and laboratory techniques in order to **minimise stress on the animals used in experiments;**
>
> all persons involved in carrying out animal experiments have an ethical and scientific responsibility within the framework of the tasks assigned to them. All scientists have the duty to personally ascertain the need for and the appropriateness of the animal experiment planned, led or to be carried out by them and to weigh these up against the stress caused to the animals.

The Austrian Animal Experiments Act thus not only explicitly supports the **"3 Rs"** (**R**eduction, **R**efinement, **R**eplacement), but enshrines them in law as a guiding principle for animal experimentation in Austria.

Promotion of substitute methods as a statutory obligation

The Federal Ministers responsible for enforcing the Animal Experiments Act (see above) are required to promote the development of other methods and procedures (substitute methods; see also above) in accordance with the relevant Federal Finance Act, taking account of the current state of scientific knowledge. The aim is to develop scientifically valid substitute methods that make it possible to reduce the number of experiments on animals or the stress imposed on them or to completely obviate the need for animal experiments, so here, too, direct pursuit of the "3 Rs" principle is made a part of the Animal Experiments Act. In the past decade, more than €2.3 million has been spent on research and development of substitute methods, in particular by the Federal Ministry for Education, Science and Culture. Wherever possible, Austria supports the development, validation and application of substitute and alternative methods to animal experimentation also at the international level, in particular in the EU and OECD contexts.

It will be recalled that in November 1998, during Austria's presidency of the EU Council, the Austrian Science Ministry organised a symposium in collaboration with the Commission on the subject of "Implementation of the 3 Rs – Objectives for the EU and for science and industry", widely reported at the time. This symposium, which was intended to promote and advance the implementation of the 3 Rs also at EU level, was attended by representatives from all EU Member States and for the first time also representatives from countries about to join the EU. A resolution adopted at the symposium and the associated recommendations were subsequently transmitted to the EU Council of Ministers and the European Commission for further action.

Through the Animal Experiments Regulation (Regulation of the Federal Minister for Education, Science and Culture on the keeping, housing and care of experimental animals, breeding and supply facilities, and the tagging of experimental animals; BGBl. II-198/2000), the guidelines of Annex II to Article 5 of Directive 86/609/EEC were made mandatory, with stricter and improved provisions on animal husbandry and protection standards.

ANIMAL EXPERIMENTATION STATISTICS

In Austria, statistics on the use of animals for experiments, compiled in compliance with Article 13 of Directive 86/609/EEC, are based on Article 16 of the Animal Experiments Act and on the Animal Experiments Statistics Regulation (BGBl. II-199/2000) under which the compilation of standardised statistics under EU provisions is made mandatory. The person responsible for the establishment where animal experiments are carried out must inform the competent Federal Minister by 1 March of each year of the animals used in experiments in the preceding calendar year, specifying the following:

a) number and species of all laboratory animals used, broken down by origin;

b) number and species of laboratory animals used, broken down by type and purpose of experiment;

c) number and species of laboratory animals used in toxicological and other safety evaluations;

d) number and species of laboratory animals used in experiments concerning human and animal diseases;

e) number and species of laboratory animals used in production and quality control of products and apparatus for human medicine and dentistry and for veterinary medicine, including any references to relevant legislation;

f) number and species of laboratory animals used in toxicological and other safety evaluations, including any references to relevant legislation, and the type of experiment (method) and products or substances (types of products or substances).

The competent Federal Ministers must compile statistics on the species and numbers of laboratory animals used, with the breakdown indicated above. By 30 June each year, these statistics, relating to the preceding calendar year, must be published as joint statistics in the *Amtsblatt zur Wiener Zeitung* [Official Gazette].

ANIMAL EXPERIMENTATION STATISTICS 2002

Still considerably fewer animal experiments and laboratory animals in Austria than in other countries

The animal experimentation statistics for 2002 published in the Official Gazette (26 June 2003) show that in 2002 a total of **192 062** laboratory animals were used in experiments. While compared with 2001 this is about 12 050 animals – predominantly rats and mice – more (2001: 180 012), the total is clearly below the figures of previous years, e.g. 1996 (203 694), 1993 (272 371) and 1992 (308 308). **Compared with 1991 (when statistics were first compiled), the number of animals used is down to less than 40%; at that time the total number used was 482 166, so over the past decade more than 60% fewer have been used.**

Mainly rats and mice used in animal experiments, and no apes

Of the total of 192 062 laboratory animals used in Austria in 2002, 166 209 were rats and mice, 7 566 guinea pigs, 15 560 rabbits, 536 farm animals (sheep, goats, pigs, cattle, etc.), 417 birds, 882 fish, 294 amphibians, 108 dogs and 280 cats. It is particularly pleasing to note that in 2002 once again no apes were used for experimental purposes in Austria. This is in line with a general EU requirement to limit such experiments as much as possible.

The statistics break down as follows by area of ministerial responsibility:

Health (ministry responsible: Federal Ministry of Health and Women; mainly for pharmaceutical research and development and in accordance with the Medicinal Products Act and in the veterinary field), with 149 480 animals used, is ahead of science (ministry responsible: Federal Ministry of Education, Science and Culture) with 36 501, environmental protection (ministry responsible: Federal Ministry of Agriculture, Forestry, the Environment and Water Management; mainly for research

into hazardous substances and environmental pollution) with 3 762 animals and trade and industry (ministry responsible: Federal Ministry of Economic Affairs and Labour) with 2 319.

Comprehensive statistics and all tables on animal experiments compiled by the federal ministries responsible for implementation of the Animal Experiments Act (Federal Ministry of Health and Women, Federal Ministry of Economic Affairs and Labour, Federal Ministry of Agriculture, Forestry, the Environment and Water Management and Federal Ministry of Education, Science and Culture) can be accessed at the website of the Federal Ministry of Education, Science and Culture at **http://www.bmbwk.gv.at/tierversuche/statistik2002**.

Animal experiments for humans and animals

The fact that over the past two years the number of animal experiments – mainly on mice and rats – has again slightly risen is due to the increase in biomedical research undertaken by companies carrying out biomedical, bioscientific and pharmaceutical research (in particular in Vienna) in the fight against major diseases, in particular cancer, leukaemia, cardiovascular disease and AIDS. In cancer research, one of the aims is to develop better, more effective treatments that are less stressful to patients.

Other factors underlying the slight increase in the number of animal experiments using rats and mice are, in particular in the health sector (ministry responsible: Federal Ministry of Health and Women), the increase in the number of tests for (mandatory) quality control and the introduction of a new standard in developing medicines and new research projects such as the development of human vaccines and therapeutics for haematological disorders. Even with the targeted use of substitute methods, the increased development of medicines and pharmaceuticals makes it absolutely essential to carry out tests on animals as a preliminary to, and a prerequisite for, clinical trials on humans in the interest of human **and** animal health and safety.

COMPARED INTERNATIONALLY: LOW FIGURES FOR ANIMAL EXPERIMENTS

"These internationally low figures for animals used in experiments - more than a 60% reduction since 1991 – can be attributed to at least two interrelated lines of development in animal experimentation":

1. "3 Rs"

First of all the 3 Rs: "Reduction" (reducing animal experiments and the number of animals used to the absolute minimum necessary), "Refinement" (refining methods to minimise stress, pain, suffering and damage to the animals used) and "Replacement" (replacing laboratory animals by *in vitro* tests). Scientists, researchers and science workers strive to translate this approach into practice and make maximum use of alternative testing methods, as required by the Austrian Animal Experiments Act.

2. Restrictive approach and promotion of alternative methods

Moreover, all competent authorities have adopted a restrictive approach in issuing licences for animal experiments as required under the strict provisions of the Animal Experiments Act. The provisions were further tightened in 1999/2000 and now allow animal experiments only under highly restrictive conditions. Proof must also be provided that the purpose of the experiment cannot be achieved through other methods or procedures (substitute methods).

Finally, mention should also be made, of the government's proactive policy under which calls for tenders are issued for research projects to develop alternative methods, and its efforts to promote the use of substitute methods (both in Austria and abroad). These initiatives have raised awareness among scientists and researchers about their responsibility in this domain. In the past two years, the Science Ministry has made more than €2.3 million available for commissioning research into the development of substitute procedures to replace animal experiments.

Publication

of the Federal Ministry of Health and Women

(No 20.903/2-VI/A/1/03),

the Federal Ministry of Agriculture, Forestry, the Environment and Water Management

(No 52 4650/1-V/2/03),

the Federal Ministry of Economic Affairs and Labour

(No 30.581/5-I/9/03) and

the Federal Ministry of Education, Science and Culture

(No 5.436/3-BrS/03)

in accordance with Article 16(2) of the Animal Experiments Act, BGBl. 501/1989, as amended in BGBl. I-169/1999

In accordance with Article 16(2) of the Animal Experiments Act, BGBl. 501/1989, as amended in BGBl. I-169/1999, the competent Federal Ministers must compile statistics on the species and numbers of laboratory animals used, in accordance with the breakdown provided for in Article 16(1) of the Animal Experiments Act, which is as follows:

a) number and species of all laboratory animals used, broken down by origin;

b) number and species of laboratory animals used, broken down by type and purpose of experiment;

c) number and species of laboratory animals used in toxicological and other safety evaluations;

d) number and species of laboratory animals used in experiments concerning human and animal diseases;

e) number and species of laboratory animals used in production and quality control of products and apparatus for human medicine and dentistry and for veterinary medicine, including any references to relevant legislation;

f) number and species of laboratory animals used in toxicological and other safety evaluations, including any references to relevant legislation, and the type of experiment (method) and products or substances (types of products or substances).

By 30 June of each year, these statistics relating to the preceding calendar year must be published as joint statistics in the Official Gazette *(Amtsblatt zur Wiener Zeitung*).

In accordance with Article 16(2) of the Animal Experiments Act, BGBl. 501/1989, as amended in BGBl. I-169/1999, the following statistics on the use of laboratory animals in 2002 are published on the basis of the data reported:

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 (*Mus musculus*)	153034	26507	124600	538	1389	45
1.b. Rats (*Rattus norvegicus*)	13175	5214	7961	0	0	0
1.c. Guinea-Pigs (*Cavia porcellus*)	7566	1034	6532	0	0	0
1.d. Hamsters (*Mesocricetus*)	63	9	54	0	0	0
1.e. Other Rodents (other *Rodentia*)	69	36	0	33	0	0
1.f. Rabbits (*Oryctolagus cuniculus*)	15560	3786	11686	0	88	0
1.g. Cats (*Felis catus*)	280	0	250	0	30	0
1.h. Dogs (*Canis familiaris*)	108	4	0	0	104	14
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breds (*Equidae*)	34	3	13	0	18	18
1.l. Pigs (*Sus*)	324	280	44	0	0	0
1.m. Goats (*Capra*)	18	10	1	0	7	8
1.n. Sheep (*Ovis)*	110	48	40	0	22	7
1.o. Cattle (*Bos*)	50	41	0	0	9	5
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	0
1.r. Old World Monkeys (*Cercopithecoidea*)	78	78	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	0	0	0	0	0	0
1.u. Quail (*Coturnix coturnix)*	0	0	0	0	0	0
1.v. Other birds (other *Aves*)	417	179	200	0	38	17
1.w. Reptiles (*Reptilia*)	0	0	0	0	0	0
1.x. Amphibians (*Amphibia*)	294	96	198	0	0	0
1.y. Fish (*Pisces*)	882	60	0	0	822	0
1.z. TOTAL	192062	37385	151579	571	2527	114

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	21135	69339	51515	0	3600	3517	109	3819	153034
2.b. Rats	6300	2468	1572	0	2713	0	122	0	13175
2.c. Guinea-Pigs	160	283	5680	0	1295	0	0	148	7566
2.d. Hamsters	54	9	0	0	0	0	0	0	63
2.e. Other Rodents	41	0	0	0	0	28	0	0	69
2.f. Rabbits	614	507	13615	8	594	7	47	168	15560
2.g. Cats	0	0	0	0	0	280	0	0	280
2.h. Dogs	0	0	0	0	0	90	18	0	108
2.i. Ferrets	0	0	0	0	0	0	0	0	0
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	10	0	0	0	4	6	14	0	34
2.l. Pigs	75	127	0	0	0	0	122	0	324
2.m. Goats	0	5	3	0	0	0	10	0	18
2.n. Sheep	45	31	1	13	0	0	20	0	110
2.o. Cattle	2	7	0	0	0	0	40	1	50
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	78	0	0	0	0	0	0	78
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	0	0	0
2.v. Other birds	358	0	8	0	0	30	21	0	417
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	278	0	0	0	0	0	16	0	294
2.y. Fish	135	0	0	0	552	0	0	195	882
2.z. TOTAL	29207	72854	72394	21	8758	3958	539	4331	192062

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	2771	0	434	0	0	0	0	0	395	3600
3.b. Rats	1047	0	1146	0	0	0	0	0	520	2713
3.c. Guinea-Pigs	205	0	1090	0	0	0	0	0	0	1295
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	426	0	168	0	0	0	0	0	0	594
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 breds	4	0	0	0	0	0	0	0	0	4
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	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	321	0	0	0	0	231	0	552
3.z. TOTAL	4453	0	3159	0	0	0	0	231	915	8758

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	1391	1763	9514	52252	834	65754
4.b. Rats	474	1384	999	3722	0	6579
4.c. Guinea-Pigs	0	0	0	443	0	443
4.d. Hamsters	9	0	0	0	0	9
4.e. Other Rodents	0	0	0	28	0	28
4.f. Rabbits	138	34	205	505	0	882
4.g. Cats	0	0	0	0	30	30
4.h. Dogs	0	0	0	0	90	90
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 breds	0	0	0	0	6	6
4.l. Pigs	80	0	0	69	0	149
4.m. Goats	0	0	0	5	0	5
4.n. Sheep	5	0	0	53	18	76
4.o. Cattle	0	0	0	0	1	1
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	78	0	78
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	106	0	0	32	0	138
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	14	0	0	0	0	14
4.y. Fish	0	0	0	0	0	0
4.z. TOTAL	2217	3181	10718	57187	979	74282

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	50	10851	0	0	40614	0	51515
5.b. Rats	709	0	0	863	0	0	1572
5.c. Guinea-Pigs	0	3518	0	906	1256	0	5680
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	13003	0	612	0	8	13623
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 breds	0	0	0	0	0	0	0
5.l. Pigs	0	0	0	0	0	0	0
5.m. Goats	3	0	0	0	0	0	3
5.n. Sheep	1	0	0	0	0	13	14
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	8	0	0	0	0	0	8
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	771	27372	0	2381	41870	21	72415

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	86	2475	0	0	820	219	3600
6.b. Rats	0	75	0	0	2058	580	2713
6.c. Guinea-Pigs	0	156	0	0	1139	0	1295
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	18	396	0	0	180	0	594
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 breds	4	0	0	0	0	0	4
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	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	0	0	0	0	552	0	552
6.z. TOTAL	108	3102	0	0	4749	799	8758

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	0	152	2055	0	0	0	549	0	0	424	0	0	420	3600
7.b. Rats	0	272	514	0	0	0	1282	0	0	80	0	0	565	2713
7.c. Guinea-Pigs	0	0	156	0	1139	0	0	0	0	0	0	0	0	1295
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	38	96	0	72	0	0	0	0	0	0	388	594
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 breds	0	0	4	0	0	0	0	0	0	0	0	0	0	4
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	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	552	0	552
7.z. TOTAL	0	424	2767	96	1139	72	1831	0	0	504	0	552	1373	8758

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	198	1928	0	49	0	1417	0	0	8	0	0	853	4453
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	226	444	96	1090	72	414	0	0	496	0	321	0	3159
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	231	0	231
8.i. Other toxicological or safety evaluations	0	0	395	0	0	0	0	0	0	0	0	0	520	915
8.j. TOTAL	0	424	2767	96	1139	72	1831	0	0	504	0	552	1373	8758

PORTUGAL

Statistical data submitted

The statistical data have been submitted by the "*Ministério da Agricultura, Desenvolvimentos Rural e das Pescas - Direcção Geral Veterinária*" (Ministry of Agriculture, Rural Development and Fisheries-Directorate-General for Veterinary Matters, Directorate for Animal Health Protection, Welfare and Feed)

Comments of Portuguese authorities

1) General Direction of Veterinary redelivered guidelines through establishments conducting experiments on animals, in order to improve the completion of the statistical tables.

2) Some conferences and workshops related to the use of animals in research happened in Portugal and CA took part on them talking about the implementation of legislation.

3) We are preparing a draft revision of our national legislation on the protection of animals used for experimental and other scientific purposes. The noteworthy topics to change are:

   To add a more precise classification of the level of suffering inflicted to any animal;

   To make compulsory the existence of an ethical committee at a research center level.

4) In 2002, compared to the previous year, there was a growth in the total number of animals used which was due to the increasing of biological studies of a fundamental nature. The species of animals that more contributed to that growth were mice, rats and fish.

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 (*Mus musculus*)	27616	19715	7709		192	
1.b. Rats (*Rattus norvegicus*)	12302	7098	5084		120	
1.c. Guinea-Pigs (*Cavia porcellus*)	633	599	28		6	
1.d. Hamsters (*Mesocricetus*)	93	93				
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	908	908				
1.g. Cats (*Felis catus*)						
1.h. Dogs (*Canis familiaris*)	34	28	6			20
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	6					
1.l. Pigs (*Sus*)	250					
1.m. Goats (*Capra*)	65					
1.n. Sheep (*Ovis)*	55					
1.o. Cattle (*Bos*)	18					
1.p. Prosimians (*Prosimia*)						
1.q. New World Monkeys (*Ceboidea*)						
1.r. Old World Monkeys (*Cercopithecoidea*)						
1.s. Apes (*Hominoidea*)						
1.t. Other Mammals (other *Mammalia*)						
1.u. Quail (*Coturnix coturnix)*	30	30				
1.v. Other birds (other *Aves*)	168					
1.w. Reptiles (*Reptilia*)	30					
1.x. Amphibians (*Amphibia*)	113					
1.y. Fish (*Pisces*)	2256					
1.z. TOTAL	44577					

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	17990	1738	280	2590	532	3243	638	655	27666
2.b. Rats	9339	1082			680	66	925	160	12252
2.c. Guinea-Pigs	69	31	6	256		44	61	166	633
2.d. Hamsters	47					40	6		93
2.e. Other Rodents									
2.f. Rabbits	262	9	70	332	85	28	45	77	908
2.g. Cats									
2.h. Dogs	14						20		34
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							6		6
2.l. Pigs	98					4	148		250
2.m. Goats	50				4	1	10		65
2.n. Sheep	30					1	12	12	55
2.o. Cattle	3						15		18
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals									
2.u. Quail							30		30
2.v. Other birds				114		54			168
2.w. Reptiles	28							2	30
2.x. Amphibians							110	3	113
2.y. Fish	650	1500					106		2256
2.z. TOTAL	28580	4360	356	3292	1301	3481	2132	1075	44577

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	140							162	230	532
3.b. Rats	40								640	680
3.c. Guinea-Pigs										
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits	85									85
3.g. Cats										
3.h. Dogs										
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breds										
3.l. Pigs										
3.m. Goats	4									4
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	269							162	870	1301

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	535	877	120	7093	140	8765
4.b. Rats	1190	2504		930		4624
4.c. Guinea-Pigs	27			20		47
4.d. Hamsters	8			71		79
4.e. Other Rodents						
4.f. Rabbits	182			106		288
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs					30	30
4.m. Goats					1	1
4.n. Sheep					1	1
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					1750	1750
4.z. TOTAL	1942	3381	120	8220	1922	15585

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	2440	150				280	2870
5.b. Rats							
5.c. Guinea-Pigs	250	6			6		262
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits	322	10			70		402
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breds							
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	114						114
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL	3126	166			76	280	3648

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State **1)**	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation **2)**	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice					200	332	532
6.b. Rats	640	40					680
6.c. Guinea-Pigs							
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits		85					85
6.g. Cats							
6.h. Dogs							
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breds							
6.l. Pigs							
6.m. Goats		4					4
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	640	129			200	332	1301

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	110	25	52					15		100			230	532
7.b. Rats									417		223		40	680
7.c. Guinea-Pigs														
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits						85								85
7.g. Cats														
7.h. Dogs														
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breds														
7.l.. Pigs														
7.m. Goats													4	4
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	110	25	52			85		15	417	100	223		274	1301

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	30	10				85				100			44	269
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	40	55	52					15						162
8.i. Other toxicological or safety evaluations	230								417		223			870
8.j. TOTAL	300	65	52			85		15	417	100	223		44	1301

FINLAND

Statistical data submitted

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

Comments of Finnish authorities

Numbers of animals used

The total number of animals used for experimental and other scientific purposes in year 2002 was unchanged from the previous year. The use of rodents increased totally with 4%, but the use of carnivores decreased with 43%. Changes were observed also in the use of horses (+31%) and pigs (+34%), as well as in birds (-12%) and amphibia (-44%). The large number of fish used (78 % of total use) was due to one large project. The total number of used animals was 645 000, with 143 000 animals other than fish.

Animals used for selected purposes

Most animals were used for biological studies of fundamental nature and research and development of products and devices for human medicine and dentistry and for veterinary medicine. Animals for veterinary medical research purposes comprised 68 %, mainly due to one large project using fish, and for human medical research purposes 8 % of the total number. Only 0.2 % of the total animal number was used for toxicological and other safety evaluations, which was less than half of the previous year.

Other activities

The Ministry of Agriculture and Forestry funded in the year 2002 studies on methods to change over from *in vivo* to *alternative methods* in research with 34 000 € for 6 projects in Finland. The ministry has also nominated a working group on national and international coordination and cooperation of the use of alternative methods. The Ministry continues preparations on revision of animal welfare legislation on animals used for experimental and scientific 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 (*Mus musculus*)	98078	77554	19603	21	900	
1.b. Rats (*Rattus norvegicus*)	27563	15704	11777	46	36	
1.c. Guinea-Pigs (*Cavia porcellus*)	757	64	693			
1.d. Hamsters (*Mesocricetus*)	0					
1.e. Other Rodents (other *Rodentia*)	3822					
1.f. Rabbits (*Oryctolagus cuniculus*)	1235	614	621			21
1.g. Cats (*Felis catus*)	0					
1.h. Dogs (*Canis familiaris*)	59	22	37			
1.i. Ferrets (*Mustela putorius furo*)	25	25				
1.j. Other Carnivores (other *Carnivora*)	410					
1.k. Horses, donkeys and cross breds (*Equidae*)	98					
1.l. Pigs (*Sus*)	2286					
1.m. Goats (*Capra*)	0					
1.n. Sheep (*Ovis)*	437					
1.o. Cattle (*Bos*)	148					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	0					
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)	690					
1.u. Quail (*Coturnix coturnix)*	50	50				
1.v. Other birds (other *Aves*)	6822					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	165					
1.y. Fish (*Pisces*)	502235					
1.z. TOTAL	644880	94033	32731	67	936	21

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	76832	16366	1033	240	874	1081	1600	52	98078
2.b. Rats	14722	11210	83		428	24	1096		27563
2.c. Guinea-Pigs	6	591	79		49		8	24	757
2.d. Hamsters									0
2.e. Other Rodents	3810	8					4		3822
2.f. Rabbits	234	809	54		79	20	7	32	1235
2.g. Cats									0
2.h. Dogs	14	37			8				59
2.i. Ferrets	25								25
2.j. Other Carnivores	410								410
2.k. Horses, donkeys and cross breds	81	3						14	98
2.l. Pigs	1912	202	108			2	52	10	2286
2.m. Goats									0
2.n. Sheep	50		387						437
2.o. Cattle	142	6							148
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys									0
2.s. Apes									0
2.t. Other Mammals	690								690
2.u. Quail	27						23		50
2.v. Other birds	3343	30		3400			49		6822
2.w. Reptiles									0
2.x. Amphibians	65	16					84		165
2.y. Fish	97163	400240		3480		512	840		502235
2.z. TOTAL	199526	429518	1744	7120	1438	1639	3763	132	644880

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	280							529	65	874
3.b. Rats	264		40						124	428
3.c. Guinea-Pigs			49							49
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	67		12							79
3.g. Cats										0
3.h. Dogs	8									8
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										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	619	0	101	0	0	0	0	529	189	1438

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	2417	7475	8761	15224	603	34480
4.b. Rats	3035	7527	1314	4529		16405
4.c. Guinea-Pigs	469			112		581
4.d. Hamsters						0
4.e. Other Rodents		8				8
4.f. Rabbits	447			425		872
4.g. Cats						0
4.h. Dogs		21		8		29
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	273			62	65	400
4.m. Goats						0
4.n. Sheep				21	22	43
4.o. Cattle					6	6
4.p. Prosimians						0
4.q. New World Monkeys						0
4.r. Old World Monkeys				4		4
4.s. Apes						0
4.t. Other Mammals					8	8
4.u. Quail						0
4.v. Other birds					30	30
4.w. Reptiles						0
4.x. Amphibians				21		21
4.y. Fish					400844	400844
4.z. TOTAL	6641	15031	10075	20406	401578	453731

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	423	760	90				1273
5.b. Rats	83						83
5.c. Guinea-Pigs	79						79
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits						54	54
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs					108		108
5.m. Goats							0
5.n. Sheep					387		387
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					3400		3400
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish					3480		3480
5.z. TOTAL	585	760	90	0	7375	54	8864

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	8	280			57	529	874
6.b. Rats	174	130			124		428
6.c. Guinea-Pigs	49						49
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	12	7				60	79
6.g. Cats							0
6.h. Dogs		8					8
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							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	243	425	0	0	181	589	1438

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice		130					150						594	874
7.b. Rats		130	150	24			93						31	428
7.c. Guinea-Pigs					49									49
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits			60	6		6	7							79
7.g. Cats														0
7.h. Dogs							8							8
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish														0
7.z. TOTAL	0	260	210	30	49	6	258	0	0	0	0	0	625	1438

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		260	194				258						88	800
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			40	6	49	6								101
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													529	529
8.i. Other toxicological or safety evaluations													8	8
8.j. TOTAL	0	260	234	6	49	6	258	0	0	0	0	0	625	1438

SWEDEN

Statistical data submitted

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

Comments of Swedish authorities

The deadline for submitting the statistical records covering the use of laboratory animals during 2002 to the EU commission was in June 2003. Most university researchers were prompt and submitted their reports in March, although some were as late as May- June despite several reminders from the Swedish National Board for Laboratory Animals (CFN).

86/609/EEC Directive

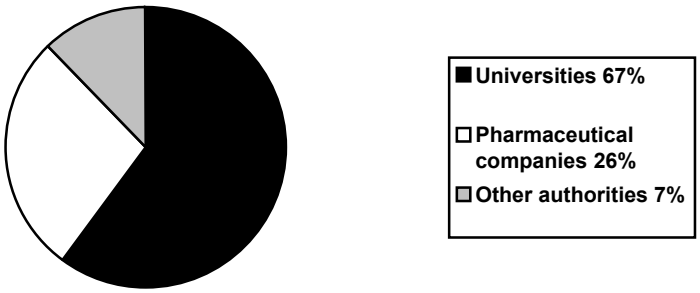
According to the EU definition (directive 86/609/EEC) the number of laboratory animals used during 2002 in Sweden reached about 281 000. This is approx. a 4 % increase (about 11 000 animals) compared to 2001. The increase were mainly found in the universities, the reason for this can possibly be explained by the fact that two new animal facilities were under construction during the year 2000-2001 and were in full operation first during 2002.

The Swedish statistical records show that throughout the 1990s, three kinds of animals were predominately used in animal experimentation, the mice, the rats and fish. Indeed, these three groups comprised about 90 % of all laboratory animals used during 2002.

Whereas, a clear decrease can be seen in the use of guinea pig and rabbits throughout the 1990s, this may be due to new techniques of producing antibodies, using *in vitro* production instead of whole animals. In 1999 CFN was active, when providing a Swedish researcher with grants to swift his antibody production from whole animals to *in vitro* techniques

Diagram 1.

Illustrating the use of laboratory animals in Sweden during 2002 according to the EU directive. Sorted in different reporting categories.



Specific use of animals

As in previous years most laboratory animals were used in either fundamental biological research (57%) or in development of product/devices (29%) used in human or veterinary medicine. During 2002, 5% of the animals were used in toxicological research, and finally, less than 1 % of the total numbers of laboratory animals were used for diagnosing diseases. The most common animals used in toxicological research are mice, rats and fish and to lesser extent dogs and rabbits. Mammals were mostly used in experiments concerning products/substances or devices relating to human medicine, dentistry and veterinary medicine, fish are mainly used in the evaluation of hazardous environmental substances.

Reused animals

During 2002, 168 animals were reused in experiments according to the EU directive. This is a slight decrease compared to 2001 when 298 animals were reused. Of the animals reused approx. 90 % were dogs (152 animals). To a much lesser extent old world monkeys and cats were reused, 8 and 8 respectively.

Tendencies in Sweden

From 1990 until 2002 the mean number of laboratory animals used in Sweden was about 315 000 with the highest number 1994 (approx. 351 000) and the lowest 1997 (267 000). The reasons behind these fluctuations are hard to speculate about. It may just be due to natural fluctuations and/or reflect the status of high or low economy in Sweden. However, one clear tendency is the decrease of rats throughout the 90ths. In 1990 approx. 160 000 rats were used according to the EU directive. Whereas, during the year 2001 the number of rats in experiments is down to 69 000, a more than 50 % decrease. On the other hand, the use of mice as laboratory animals has increased throughout the 90ths; this rise is probably due to the increased use of transgenic technique(s).

Swedish definition

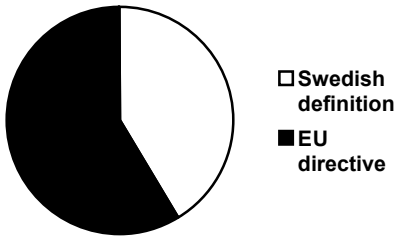
Apart from the information, Sweden also collects its own statistical data on other use of laboratory animals. According to Swedish legislation all use of animals, which have a scientific purpose, should be recorded. Therefore, this statistical data includes all animals used in behaviour studies, feeding trials or animals being euthanized for the use of their tissues and organs. During 2002 about 200 000 animals were reported

according to this definition. The dominating animals were, bird, mice, rats, fish and pigs. This is an increase with nearly 30 000 animals compared with the figures in the year 2001 and is mainly due to increased use of birds. During 2001 54 000 birds were used according to the Swedish definition whereas the figures for this species in 2002 is approx. 100 000 birds. The large increase in the use of birds can be explained by the fact that the pharmaceutical company, Pharmacia, used roosters, i.e. comb from roosters for the production of hyaloronic acids and that one Swedish university performed a large study on birds feeding behaviour.

Diagram 2. The use of laboratory animals in Sweden according

to 86/609/EEC directive 58 %(approx. 281 000) and the

Swedish definition 42 % (approx.200 000)



Transgenic animals

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

Conclusions

The overall impression is that the use of laboratory animals according to the EU directive shows a slight increase when comparing the year 2002 with the numbers used during 2001. The effect(s) is most obviously when comparing the use of animals by the universities. This is probably due to the fact that the new animal facilities where ready and in full operation during 2002. During the same period the Swedish pharmaceutical industries show a slight decrease in the use of laboratory animals (approx: 2000 animals). The overall decrease that is found in the pharmaceutical industries during the last three years is probably due to the merging between Astra and Zeneca and the fact that Pharmacia has moved all research outside Sweden. It would be of major interest to study EU: s total statistics to be able to see if the decreasing numbers in animals in Sweden could be due to an increase in number by the pharmaceutical companies elsewhere.

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 (*Mus musculus*)	163041	115327	45493	55	2166	
1.b. Rats (*Rattus norvegicus*)	73862	42879	33215	0	46	
1.c. Guinea-Pigs (*Cavia porcellus*)	2738	2062	676	0	0	
1.d. Hamsters (*Mesocricetus*)	479	257	222	0	0	
1.e. Other Rodents (other *Rodentia*)	804					
1.f. Rabbits (*Oryctolagus cuniculus*)	2165	1891	274	0	0	0
1.g. Cats (*Felis catus*)	182	174	8	0	0	8
1.h. Dogs (*Canis familiaris*)	646	462	0	18	166	152
1.i. Ferrets (*Mustela putorius furo*)	151	151	0	0	0	17
1.j. Other Carnivores (other *Carnivora*)	70					
1.k. Horses, donkeys and cross breds (*Equidae*)	178					
1.l. Pigs (*Sus*)	2341					
1.m. Goats (*Capra*)	156					
1.n. Sheep (*Ovis)*	43					
1.o. Cattle (*Bos*)	704					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	12	12	0	0	0	0
1.r. Old World Monkeys (*Cercopithecoidea*)	79	30	0	0	49	8
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	97					
1.u. Quail (*Coturnix coturnix)*	38	38	0	0	0	
1.v. Other birds (other *Aves*)	14015					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	1692					
1.y. Fish (*Pisces*)	17691					
1.z. TOTAL	281184					

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	98357	54987	3465	18	1857	773	1890	1694	163041
2.b. Rats	42271	24089	1846	0	3962	10	1607	77	73862
2.c. Guinea-Pigs	397	1065	1229	0	0	20	4	23	2738
2.d. Hamsters	446	33	0	0	0		0	0	479
2.e. Other Rodents	303	420	0	0	0	63	18	0	804
2.f. Rabbits	942	499	374	0	166	0	27	157	2165
2.g. Cats	80	55	0	0	0	47	0	0	182
2.h. Dogs	22	137	0	0	339	0	23	125	646
2.i. Ferrets	151	0	0	0	0	0	0	0	151
2.j. Other Carnivores	70	0	0	0	0	0	0	0	70
2.k. Horses, donkeys and cross breds	40	0	0	0	0	0	129	9	178
2.l. Pigs	1723	251	0	0	0	35	332	0	2341
2.m. Goats	23	0	9	0	0	0	11	0	43
2.n. Sheep	126	25	0	0	0	0	2	3	156
2.o. Cattle	112	384	0	0	0	0	197	11	704
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	4	8	0	0	0	0	0	0	12
2.r. Old World Monkeys	30	49	0	0	0	0	0	0	79
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	97	0	0	0	0	0	0	0	97
2.u. Quail	38	0	0	0	0	0	0	0	38
2.v. Other birds	4026	0	0	9745	0	0	0	244	14015
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	1603	88	0	0	0	0	0	1	1692
2.y. Fish	10348	0	0	0	7253	90	0	0	17691
2.z. TOTAL	161209	82090	6923	9763	13577	1038	4240	2344	281184

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	1683							84	90	1857
3.b. Rats	3926								36	3962
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	166									166
3.g. Cats										0
3.h. Dogs	339									339
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										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			620	730				5903		7253
3.z. TOTAL	6114	0	620	730	0	0	0	5987	126	13577

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	12085	32031	28786	57997	1768	132667
4.b. Rats	6218	28565	3606	26797	416	65602
4.c. Guinea-Pigs	324	208	0	2069	45	2646
4.d. Hamsters	45	0	0	433	0	478
4.e. Other Rodents	0	22	0	764	0	786
4.f. Rabbits	269	62	42	1158	8	1539
4.g. Cats	47	38	0	0	19	104
4.h. Dogs	57	6	0	72	26	161
4.i. Ferrets	0	45	0	35	0	80
4.j. Other Carnivores	0	0	0	0	0	0
4.k. Horses, donkeys and cross breds	0	0	0	0	40	40
4.l. Pigs	487	31	1	510	226	1255
4.m. Goats	0	0	9	0	23	32
4.n. Sheep	0	0	0	0	0	0
4.o. Cattle	0	0	0	0	431	431
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	4	0	8	0	12
4.r. Old World Monkeys	0	30	0	49	0	79
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	439	800	1239
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	88	0	0	600	0	688
4.y. Fish	0	0	0	500	533	1033
4.z. TOTAL	19620	61042	32444	91431	4335	208872

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		750		2705		28	3483
5.b. Rats					1846		1846
5.c. Guinea-Pigs		1190				39	1229
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		358				16	374
5.g. Cats							0
5.h. Dogs							0
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds							0
5.l. Pigs							0
5.m. Goats	9						9
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						9745	9745
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	9	2298	0	2705	1846	9828	16686

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	1058				461	338	1857
6.b. Rats	3777					185	3962
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits	166						166
6.g. Cats							0
6.h. Dogs	339						339
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							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	5360				1100	793	7253
6.z. TOTAL	10700	0	0	0	1561	1316	13577

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

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a.		806	426		30		511			84				1857
7.b. Rats		399	1937				633		221	103	345		324	3962
7.c. Guinea-Pigs														0
7.d. Hamsters														
7.e. Other Rodents														0
7.f. Rabbits									128		21		17	166
7.g. Cats														0
7.h. Dogs		221	84										34	339
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs														0
7.m. Goats														0
7.n. Sheep														0
7.o. Cattle														0
7.p. Prosimians														0
7.q. New World Monkeys														0
7.r. Old World Monkeys														0
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail														0
7.v. Other birds														0
7.w. Reptiles														0
7.x. Amphibians														0
7.y. Fish	1100						250		720		4640	543		7253
7.z. TOTAL	1100	1426	2447	0	30	0	1394	0	1069	187	5006	543	375	13577

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		1426	2351				1144		349	103	366		375	6114
8.b. Products/substances used or intended to be used mainly in agriculture	500						120							
8.c. Products/substances used or intended to be used mainly in industry	600						130							730
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									720	84	4640	543		5987
8.i. Other toxicological or safety evaluations			96		30									126
8.j. TOTAL	1100	1426	2447	0	30	0	1394	0	1069	187	5006	543	375	13577

UNITED KINGDOM

Statistical data submitted

The statistical data have been prepared and submitted by the "Home Office".

Comments of United Kingdom authorities

The statistical data for the United Kingdom were published in the UK in two separate reports - one for Great Britain (GB) and the other for Northern Ireland (NI). These largely report on research as numbers of procedures rather than numbers of animals. The figures here have been compiled to show numbers of animals only for the purposes of the EU tables submitted. It should also be noted that the UK counts the breeding of animals for the maintenance of genetically modified or harmful mutant animals, which accounts for the apparent discrepancy in figures between the GB and NI publications and this EU submission.

Overall, there was an increase in the animals used for the first time in procedures regulated in the UK compared with use in 2001.

Just over 1.8 million animals were used for the first time in procedures started in 2002.

Mice and rats accounted for 76% of the animals used - 1,388,080 animals.

Cold-blooded animals (fish and amphibians) represented 9% of the animals used - 165,717 animals.

Dogs, cats, horses and non-human primates are accorded special protection in the UK and collectively accounted for 0.5% of the animals used - 9945 animals.

Non-human primates accounted for just under 0.2% of the animals used - 3173 animals.

For the species which should be obtained from registered breeding or supplying establishments within the UK, Over 99% of animals listed were so sourced and less than 0.5% were sourced outside of EC or Council of Europe member countries.

Biological studies of a fundamental nature, together with research and development of products and devices for human medicine and dentistry and for veterinary medicine accounted for the use of just under one million animals - 54% of the total animal use.

18% of the animals used - 321,947 animals, were used for toxicological or other safety evaluation. The majority of that use (85%) was to fulfil European or other regulatory requirements.

Nearly 9% of the animals used - 155,742 animals, were used for production and quality control of products and devices for human medicine, dentistry or veterinary medicine.

About 40% of the animals used were given some form of anaesthesia to alleviate the severity of the interventions. For most of the remaining animals, the use of anaesthesia would have increased the severity of the procedure.

No animals were used in 2002 for the purpose of evaluating the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2002 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 (*Mus musculus*)	914795	905273	2724	119	6679	
1.b. Rats (*Rattus norvegicus*)	473285	471411	907	-	967	
1.c. Guinea-Pigs (*Cavia porcellus*)	43779	42722	996	-	61	
1.d. Hamsters (*Mesocricetus*)	5947	5947	-	-	-	
1.e. Other Rodents (other *Rodentia*)	7873					
1.f. Rabbits (*Oryctolagus cuniculus*)	20574	20396	82	-	96	2612
1.g. Cats (*Felis catus*)	616	335	281	-	-	551
1.h. Dogs (*Canis familiaris*)	5734	4634	76	-	1024	912
1.i. Ferrets (*Mustela putorius furo*)	1021	990	-	-	31	-
1.j. Other Carnivores (other *Carnivora*)	1328					
1.k. Horses, donkeys and cross breds (*Equidae*)	422					
1.l. Pigs (*Sus*)	9254					
1.m. Goats (*Capra*)	325					
1.n. Sheep (*Ovis)*	14887					
1.o. Cattle (*Bos*)	7121					
1.p. Prosimians (*Prosimia*)	0	-	-	-	-	-
1.q. New World Monkeys (*Ceboidea*)	613	613	-	-	-	85
1.r. Old World Monkeys (*Cercopithecoidea*)	2560	682	-	-	1878	257
1.s. Apes (*Hominoidea*)	0	-	-	-	-	-
1.t. Other Mammals (other *Mammalia*)	1384					
1.u. Quail (*Coturnix coturnix)*	195	195	-	-	-	
1.v. Other birds (other *Aves*)	139834					
1.w. Reptiles (*Reptilia*)	221					
1.x. Amphibians (*Amphibia*)	8521					
1.y. Fish (*Pisces*)	157196					
1.z. TOTAL	**1817485**					

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	424676	104404	91190	15054	86227	7019	1621	184604	914795
2.b. Rats	132863	158665	14781	-	146299	34	1971	18672	473285
2.c. Guinea-Pigs	4397	14254	7057	1422	14730	62	125	1732	43779
2.d. Hamsters	2550	472	-	462	546	7	-	1910	5947
2.e. Other Rodents	3941	3068	-	-	129	10	11	714	7873
2.f. Rabbits	3255	1592	611	617	9442	4305	92	660	20574
2.g. Cats	266	149	-	16	43	-	-	142	616
2.h. Dogs	149	815	30	30	4602	17	-	91	5734
2.i. Ferrets	231	400	328	-	-	32	12	18	1021
2.j. Other Carnivores	949	-	-	-	6	-	-	373	1328
2.k. Horses, donkeys and cross breds	48	50	-	106	72	95	12	39	422
2.l. Pigs	5848	200	-	343	500	1852	-	511	9254
2.m. Goats	106	-	4	-	9	27	-	179	325
2.n. Sheep	8163	203	75	113	180	1023	8	5122	14887
2.o. Cattle	5280	249	-	761	341	72	-	418	7121
2.p. Prosimians	-	-	-	-	-	-	-	-	-
2.q. New World Monkeys	306	76	22	-	173	32	-	4	613
2.r. Old World Monkeys	141	167	57	-	2159	2	-	34	2560
2.s. Apes	-	-	-	-	-	-	-	-	-
2.t. Other Mammals	728	-	-	-	-	-	-	656	1384
2.u. Quail	195	-	-	-	-	-	-	-	195
2.v. Other birds	28753	2210	117	7555	3572	3103	113	94411	139834
2.w. Reptiles	206	-	-	-	15	-	-	-	221
2.x. Amphibians	6487	-	-	-	1090	-	731	213	8521
2.y. Fish	69112	462	-	14991	51812	750	-	20069	157196
2.z. TOTAL	698650	287436	114272	41470	321947	18442	4696	330572	1817485

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 inteded to be used mainly in industry	3.5 Products/ substances used or intended to be used mainly in the household	3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7 Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9 Potential or actual contami-nents in the general envi-ronment which do not appear in other columns	3.10 Other toxico-logical or safety evaluations	3.11 Total
3.a. Mice	44895	6168	4943	112	-	526	-	127	29456	86227
3.b. Rats	66692	39867	21246	277	-	4509	-	281	13427	146299
3.c. Guinea-Pigs	3722	2904	7306	359	-	107	-	21	311	14730
3.d. Hamsters	308	179	-	-	-	-	-	-	59	546
3.e. Other Rodents	-	-	-	-	-	-	-	64	65	129
3.f. Rabbits	5234	1127	2419	210	-	31	-	12	409	9442
3.g. Cats	36	-	-	-	-	-	-	-	7	43
3.h. Dogs	3985	440	40	-	-	54	-	-	83	4602
3.i. Ferrets	-	-	-	-	-	-	-	-	-	-
3.j. Other Carnivores	-	-	-	-	-	-	-	-	6	6
3.k. Horses, donkeys and cross breds	40	31	-	-	-	-	-	-	1	72
3.l. Pigs	419	37	-	-	-	-	-	-	44	500
3.m. Goats	4	5	-	-	-	-	-	-	-	9
3.n. Sheep	174	6	-	-	-	-	-	-	-	180
3.o. Cattle	157	184	-	-	-	-	-	-	-	341
3.p. Prosimians	-	-	-	-	-	-	-	-	-	-
3.q. New World Monkeys	173	-	-	-	-	-	-	-	-	173
3.r. Old World Monkeys	2058	-	-	-	-	-	-	-	101	2159
3.s. Apes	-	-	-	-	-	-	-	-	-	-
3.t. Other Mammals	-	-	-	-	-	-	-	-	-	-
3.u. Quail	-	-	-	-	-	-	-	-	-	-
3.v. Other birds	2930	642	-	-	-	-	-	-	-	3572
3.w. Reptiles	-	-	-	-	-	-	-	-	15	15
3.x. Amphibians	-	-	-	-	-	-	-	1090	-	1090
3.y. Fish	2424	6196	6312	74	-	-	-	36806	-	51812
3.z. TOTAL	133251	57786	42266	1032	-	5227	-	38401	43984	321947

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	22841	139117	104135	516282	19787	802162
4.b. Rats	24888	151817	7004	202369	3068	389146
4.c. Guinea-Pigs	726	5887	20	24215	1696	32544
4.d. Hamsters	311	948	8	2113	2332	5712
4.e. Other Rodents	37	4050	91	2841	688	7707
4.f. Rabbits	1640	529	79	13140	1179	16567
4.g. Cats	0	186	-	80	350	616
4.h. Dogs	480	58	22	4200	148	4908
4.i. Ferrets	97	246	-	666	-	1009
4.j. Other Carnivores	-	-	-	949	297	1246
4.k. Horses, donkeys and cross breds	-	-	-	143	267	410
4.l. Pigs	504	99	8	7598	1025	9234
4.m. Goats	6	-	-	156	158	320
4.n. Sheep	48	991	-	8605	5162	14806
4.o. Cattle	56	240	-	5059	1632	6987
4.p. Prosimians	-	-	-	-	-	-
4.q. New World Monkeys	11	197	22	383	-	613
4.r. Old World Monkeys	47	416	-	2054	-	2517
4.s. Apes	-	-	-	-	-	-
4.t. Other Mammals	-	164	-	564	21	749
4.u. Quail	-	195	-	-	-	195
4.v. Other birds	2104	5142	-	25007	103492	135745
4.w. Reptiles	-	35	-	186	-	221
4.x. Amphibians	228	174	453	5632	-	6487
4.y. Fish	88	393	-	69987	33032	103500
4.z. TOTAL	54112	310884	111842	892229	174334	1543401

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	4768	9048	-	323	64191	27914	106244
5.b.	Rats	-	1983	1	192	3437	9168	14781
5.c.	Guinea-Pigs	3930	2067	-	34	1165	1283	8479
5.d.	Hamsters	-	410	-	-	-	52	462
5.e.	Other Rodents	-	-	-	-	-	-	-
5.f.	Rabbits	193	-	-	79	687	269	1228
5.g.	Cats	-	-	-	-	-	16	16
5.h.	Dogs	-	-	-	-	-	60	60
5.i.	Ferrets	-	-	-	-	10	318	328
5.j.	Other Carnivores	-	-	-	-	-	-	-
5.k.	Horses, donkeys and cross breds	-	-	-	-	16	90	106
5.l.	Pigs	-	83	209	-	36	15	343
5.m.	Goats	-	-	-	-	-	4	4
5.n.	Sheep	-	51	-	-	48	89	188
5.o.	Cattle	53	213	21	-	355	119	761
5.p.	Prosimians	-	-	-	-	-	-	-
5.q.	New World Monkeys	-	-	-	-	-	22	22
5.r.	Old World Monkeys	-	-	-	12	18	27	57
5.s.	Apes	-	-	-	-	-	-	-
5.t.	Other Mammals	-	-	-	-	-	-	-
5.u.	Quail	-	-	-	-	-	-	-
5.v.	Other birds	163	1758	-	105	5499	147	7672
5.w.	Reptiles	-	-	-	-	-	-	-
5.x.	Amphibians	-	-	-	-	-	-	-
5.y.	Fish	-	11930	-	-	3061	-	14991
5.z.	TOTAL	9107	27543	231	745	78523	39593	155742

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

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

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

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

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

Regulatory requirements versus species

6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a. Mice	2078	11636	141	2025	49913	20434	86227
6.b. Rats	1189	5872	1774	18203	105830	13431	146299
6.c. Guinea-Pigs	1200	2052	-	3952	7301	225	14730
6.d. Hamsters	-	-	-	-	430	116	546
6.e. Other Rodents	-	-	-	-	65	64	129
6.f. Rabbits	439	2231	72	1579	4712	409	9442
6.g. Cats	-	18	-	18	7	-	43
6.h. Dogs	26	26	10	42	4450	48	4602
6.i. Ferrets	-	-	-	-	-	-	-
6.j. Other Carnivores	-	-	-	-	-	6	6
6.k. Horses, donkeys and cross breds	-	41	-	-	31	-	72
6.l. Pigs	1	85	-	21	326	67	500
6.m. Goats	4	-	-	-	5	-	9
6.n. Sheep	-	105	-	-	65	10	180
6.o. Cattle	12	195	3	-	131	-	341
6.p. Prosimians	-	-	-	-	-	-	-
6.q. New World Monkeys	-	-	-	-	173	-	173
6.r. Old World Monkeys	-	362	16	-	1777	4	2159
6.s. Apes	-	-	-	-	-	-	-
6.t. Other Mammals	-	-	-	-	-	-	-
6.u. Quail	-	-	-	-	-	-	-
6.v. Other birds	206	619	-	60	2687	-	3572
6.w. Reptiles	15	-	-	-	-	-	15
6.x. Amphibians	-	-	-	-	-	1090	1090
6.y. Fish	6170	10992	1464	3499	18069	11618	51812
6.z. TOTAL	11340	34234	3480	29399	195972	47522	321947

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

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

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

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

Types of tests versus species

7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisation	7.5 Eye irritation	7.6 Sub-chronic and chronic toxicity	7.7 Carcino-genicity	7.8 Develop-mental toxicity	7.9 Muta-genicity	7.10 Repro-ductive toxicity	7.11 Toxicity to aquatic vertebra-tes not included in other columns	7.12 Other	7.13 Total
	7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods											
7.a. Mice	19371	1088	11760	246	2120	-	3175	8260	282	4029	425	-	35471	86227
7.b. Rats	1897	3509	36868	-	-	-	13464	10849	3574	5128	35570	-	35440	146299
7.c. Guinea-Pigs	-	113	97	197	12138	-	-	-	-	-	-	-	2185	14730
7.d. Hamsters	-	-	172	-	-	-	-	-	-	-	-	-	374	546
7.e. Other Rodents	65	-	-	-	-	-	-	-	-	-	-	-	64	129
7.f. Rabbits	-	70	298	1903	-	1185	152	-	3312	-	135	-	2387	9442
7.g. Cats	-	-	-	-	-	-	-	-	-	-	-	-	43	43
7.h. Dogs	-	4	2346	-	-	-	1667	-	-	-	-	-	585	4602
7.i. Ferrets	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.j. Other Carnivores	-	-	-	-	-	-	-	-	-	-	-	-	6	6
7.k. Horses, donkeys and cross breds	-	-	-	-	-	-	-	-	-	-	-	-	72	72
7.l.. Pigs	-	-	70	13	-	-	48	-	23	-	-	-	346	500
7.m. Goats	-	-	-	-	-	-	-	-	-	-	-	-	9	9
7.n. Sheep	-	-	44	-	-	-	-	-	-	-	-	-	136	180
7.o. Cattle	-	-	8	-	-	-	-	-	-	-	-	-	333	341
7.p. Prosimians	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.q. New World Monkeys	-	-	120	-	-	-	16	-	-	-	-	-	37	173
7.r. Old World Monkeys	-	-	994	-	-	-	641	-	-	-	-	-	524	2159
7.s. Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.t. Other Mammals	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.u. Quail	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.v. Other birds	180	148	658	-	-	-	-	-	-	-	120	-	2466	3572
7.w. Reptiles	-	-	-	-	-	-	-	-	-	-	-	-	15	15
7.x. Amphibians	-	-	1080	-	-	-	-	-	-	-	-	-	10	1090
7.y. Fish	16285	10883	7015	-	-	-	359	-	-	80	9931	-	7259	51812
7.z. TOTAL	37798	15815	61530	2359	14258	1185	19522	19109	7191	9237	46181	-	87762	321947

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	8438	811	38205	669	1375	24	13324	10662	5121	6062	12623	-	35937	133251
8.b. Products/substances used or intended to be used mainly in agriculture	1812	2356	4256	296	2945	265	4144	3881	1252	1146	17546	-	17887	57786
8.c. Products/substances used or intended to be used mainly in industry	5359	2540	10854	1258	9201	788	1564	400	746	1883	5627	-	2046	42266
8.d. Products/substances used or intended to be used mainly in the household	-	154	229	121	359	89	-	-	-	-	-	-	80	1032
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	10536	9293	6355	-	-	-	-	-	-	80	9931	-	2019	38214
8.i. Other toxicological or safety evaluations	11653	661	1631	15	378	19	490	4166	72	66	454	-	29793	49398
8.j. TOTAL	37798	15815	61530	2359	14258	1185	19522	19109	7191	9237	46181	-	87762	321947

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