COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

THIRD REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT ON THE STATISTICS ON THE NUMBER OF ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES IN THE MEMBER STATES OF THE EUROPEAN UNION

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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 [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, COM (94) 195 final, published in 1994, covered data on animals used for experimental purposes in 1991 in the Member States of the Community.

The second Report, COM (1999) 191 final, was published 1999 and covered data from the Member States from 1996[2].

At the end of 1997, the Commission services reached an agreement with the 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. Because the data had already been collected for 1996, only a few Member States were able to submit data in the new agreed format for the second Report.

For the third Report, Member States agreed to submit the data from 1999, as far as possible, in the format of the above mentioned eight harmonized statistical tables. In this report these tables will be referred to as EU Tables. Apart from Germany, due to an amendment, which was needed in the existing federal law, fourteen Member States submitted data in accordance with the EU Tables.

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1 OJ L 358, 18.12.1986, p.1.

2 including 1997 data from France

II. STATISTICS

II.1. General

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 1999.

Council Resolution 86/C331/02[3] 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 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 this Resolution in the report.

The aim of this report is to provide a comprehensive overview on the numbers of animals used in various experimental purposes in the Community in 1999. Because previous reports have been compiled on the basis on non-harmonized data it was only possible to make very limited comparison with the results of the previous reports.

The purpose of the report is not to draw conclusions or to interpret individual data submitted by the Member States but rather to give a general picture of the situation regarding animals used for experimental purposes at the Community level. Comments and interpretations from the Member States can be found in the second part of the report.

The main difference with the previous reports is that the data submitted by the Member States now covers a much wider range of procedures and purposes. This is due to the introduction of the harmonised tables. 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 much more precise and comprehensive picture to be drawn at the EU level for the first time.

The use of the harmonised EU Tables is intended to simplify and increase the coherence and the subsequent statistical analysis. However, it must also be recognised that because the system is put into practice for the first time, many reporting laboratories had some difficulties in adapting to the new situation. Nevertheless, it is expected that in the coming years some shortcomings will be overcome and the system will operate on a more routinely basis.

The estimated total number of animals used for experimental and other scientific purposes in 1999 is 9,8 millions. The total number of animals reported in 1996[4] was 11,6 millions. Even though it is not possible make statistically correct estimate of the reduction of the number of animals used since the report of 1996, it can nevertheless be seen that in 1999 the total number has passed below the 10 millions mark, which indicates a significant reduction trend.

As with the previous results, by far the biggest group of animals was rodents and rabbits. 6,6% of animals used are cold-blooded animals. The readers are invited to further examine the distribution between the different groups of species in Chapter III.1.2.

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

[4] including 1997 data from France

II.2. Data submitted by the Member States

Before examining further the statistical data, it is necessary to draw the attention of the readers to the difficulties which have arisen from the collection of data in the format of the eight EU Tables.

After the preliminary compilation of the data, some discrepancies were noted. The relationship between some of the tables and their totals provided a tool for a quality control. These relationships have clearly not been understood in some cases.

The first of these relationships is the total number of animals used by species, column 1.2 of the EU Table 1, which is broken down into purposes of experiments in EU Table 2. Thus, the totals of the Tables 1 and 2 must 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.

For the total number of animals used in the EU, Tables 1 and 2, it was decided to apply a conservative rule, namely to make the calculations on the highest number of animals reported by species. This method allowed drawing a relative error on the total number of animals used in the 15 Member States of no more than 0.085%. This reassuring result shows a very high consistency of the data submitted by the Member States on the total numbers of animals used for experimental purposes in the EU in 1999.

For the reason that “animals used for toxicological and other safety evaluation”, column 2.6 of EU Table 2, is broken down in several EU Tables addressing non comparable parameters, it was not possible to apply the above conservative rule between EU Table 2 and Tables 3, 6 and 7. The differences in totals have been used to calculate a relative error, which amounts to an acceptable 0.39 %. It must be born in mind, however, that the number of animals used for toxicological and other safety evaluation represents only 10% of all animals used for experimental purposes.

The different values reported by some Member States in the case of the third relationship resulted in a much higher relative error of 3.3%. Consequently it was decided not to interpret further the data of EU Table 5.

In conclusion, considering that a new protocol of data submission was applied for the first time, there is a good consistency of the data submitted by the Member States.

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 submitted by the Member States for 1999.

A consolidated Table has been computed on the basis of the data submitted by the Member States for each EU Table and is appearing in the beginning of each sub-chapter.

B The data submitted by the Member States with a summary of the comments provided by the Member States.

The reader is invited to take note that the numbering of tables and figures of 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.

PART A: COMPILATION AND OVERVIEW OF THE DATA OF 1999

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

III.1.1. The data

Fourteen Member States reported the total number of animals used by species for experimental purposes in the format of the EU Table 1. One Member State reported data in accordance with the format of the statistical table from the Council of Europe.

The different species of animals used for experimental purposes or other safety evaluation reported in Table 1 of the Council of Europe are similar to those of EU Table 1. The difference lies in the fact that the table of the Council of Europe presents the following four grouped species:

- Golden hamsters + other rodents
- New world +old world monkeys
- Goats and sheep
- Quails + other birds

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.

The estimated total number of animals used in 1999 is 9,814,171.

III.1.2. Treatment and interpretation of the data

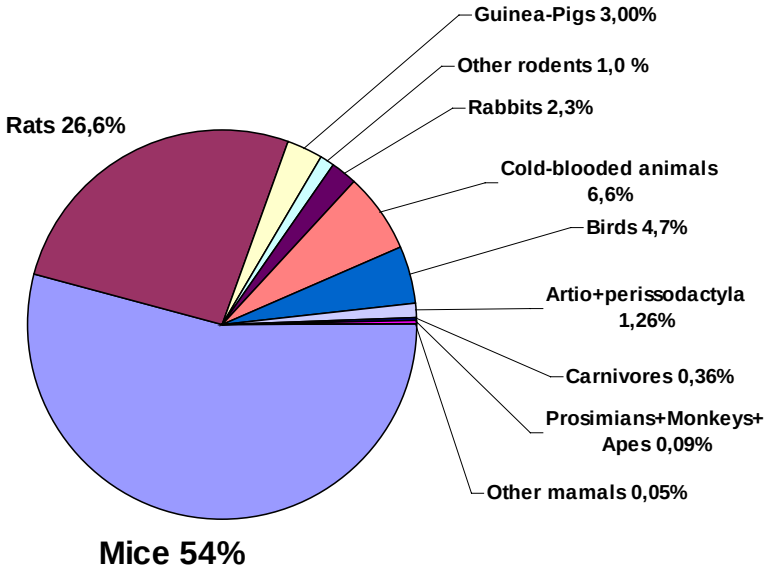
In order to include the data in the format of the Council of Europe, submitted by one Member State, into the overall evaluation and subsequent graphical analysis of the number of animals used by the 14 other Member States, it was first necessary to create the same grouping as listed above in the data of these Member States.

In a second step, for a better graphical presentation of the results of the data, species were grouped further into classes of animals.

Table 1.2 represents classes of animals used for experimental purposes.

Figure 1.1 shows the percentages of animals per class of animals.

Figure 1.1
Class of animals



Mice and rats are by far the most used species. Rodents together with rabbits represent the majority of animals with some 86,9%.

There is a significant reduction in the use of cold-blooded animals compared to the previous report (12,9%); however, it still amounts to 6,6% of all the species used.

Artio and Perissodactyla group horses, donkeys and cross-breds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla). This group represents only 1,25% of the total number of animals used.

Carnivores represent 0,36 % of the total number of animals used and primates represent less than 0,1% of the animals used in 1999.

Table 1.3: Comparison between results of 1996 and 1999

	Report 1996	Data of 1999	Comments
Number of animals used	11,646,130 (*)	9,814,171	Clear decreasing trend
% Rodents-rabbits	81,3 %	86,9 %	
% Cold-blooded animals	12,9 %	6,6 %	50% reduction

(*) 14 countries reporting for 1996, one country reporting for 1997

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

Data of 1999

Species		B	DK	D	EL	E	F	IRL	I(*)	L	NL	A	P(*)	FIN	S	UK	Total
1.a.	Mice (Mus musculus)	446677	163680	775932	3566	261301	1552330	31251	410788	3000	277774	91194	23669	89959	184230	990162	5305513
1.b.	Rats (Rattus norvegicus)	169662	96864	403227	1900	134070	460407	14484	500625	20	159758	12699	9836	32519	84374	526904	2607349
1.c.	Guinea-Pigs (Cavia porcellus)	37397	10431	42891	240	13892	77021	1041	18474	20	10246	7367	1452	1737	9355	61308	292872
1.d.	Hamsters (Mesocricetus)	4074	773			674	16200	133	3595	0	4661	208	1182	100	315	10186	42101
1.e.	Other Rodents (other Rodentia)	15567	537			553	9405	0	2428	0	606	188	29	1663	235	8662	39873
1.f.	Rabbits (Oryctolagus cuniculus)	20968	6543	50623	632	19496	49836	915	19030	20	9222	15056	730	1686	5031	27578	227366
1.g.	Cats (Felis catus)	104	44	1124		1080	1855	129	86	0	222	24		0	155	683	5506
1.h.	Dogs (Canis familiaris)	1453	143	6031	2	725	5203	312	745	0	803	68	94	104	412	5938	22033
1.i.	Ferrets (Mustela putorius furo)	0	20			26	190	0	16	0	64	0		90	132	1115	1653
1.j.	Other Carnivores (other Carnivora)	0	1151	376		0	169	0	0	0	64	0		1650	75	2896	6381
1.k.	Horses, donkeys and cross breds (Equidae)	104	85	657	6	6	440	192	20	0	219	21	3	93	71	519	2436
1.l.	Pigs (Sus)	6511	7192	10494	65	3292	8897	844	2049	0	12299	366	546	1163	3278	9135	66131
1.m.	Goats (Capra)	104	111			100	1839	0	64	0	334	23	138	38	6	419	3176
1.n.	Sheep (Ovis)	1014	140		1146	677	4455	1472	620	0	3121	142	700	439	104	14462	28492
1.o.	Cattle (Bos)	1141	1476	4018	209	106	3104	1862	542	0	1457	118	365	614	706	4841	20559
1.p.	Prosimians (Prosimia)	0	0	271		0	455	0	0	0	0	0		0	0	0	726
1.q.	New World Monkeys (Ceboidea)	21	0			96	53	0	62	0	42	0		0	6	1073	1353
1.r.	Old World Monkeys (Cercopithecoidea)	469	0			0	1814	0	450	0	272	7		9	60	2118	5199
1.s.	Apes (Hominoidea)	0	0	0		0	0	0	0	0	6	0		0	0	0	6
1.t.	Other Mammals (other Mammalia)	0	11	660		0	272	13	25	0	45	0	301	2148	353	937	4765
1.u.	Quail (Coturnix coturnix)	915	0		60	318	442	0	226	0	4738	50		62	0	0	6811
1.v.	Other birds (other Aves)	18811	5225		20	18709	86168	1229	19931	0	88085	1317	267	5166	6920	105931	357779
1.w.	Reptiles (Reptilia)	147	10	21		0	50	0	1410	0	34	0	110	182	10	56	2030
1.x.	Amphibians (Amphibia)	2143	267	5915	1840	255	6187	0	2940	0	3186	709	79	246	1585	9254	34606
1.y.	Fish (Pisces)	62807	28741	173933		20350	22805	20052	3645	0	44208	738	350	88666	26654	121285	614234
	sub-total	790089	323444		9686	475726	2309597	73929	987771	3060	621466	130295	39851	228334	324067	1905462	9698950
Golden hamsters + other rodents				18020													18020
New world + old world monkeys				1813													1813
goats + sheeps				2596													2596
quails + other birds				92792													92792
				1591394													9814171
1.z.	TOTAL	790089	323444	1591394	9686	475726	2309597	73929	987771	3060	621466	130295	39851	228334	324067	1905462	**9814171**

* The highest number of animals between column 1.2 and 2.10

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

Data of 1999

Species	B	DK	D	EL	E	F	IRL	I(*)	L	NL	A	P(*)	FIN	S	UK	Total
Mice	446677	163680	775932	3566	261301	1552330	31251	410788	3000	277774	91194	23669	89959	184230	990162	5305513
Rats	169662	96864	403227	1900	134070	460407	14484	500625	20	159758	12699	9836	32519	84374	526904	2607349
Guinea-Pigs	37397	10431	42891	240	13892	77021	1041	18474	20	10246	7367	1452	1737	9355	61308	292872
Golden hamsters + other rodents	19641	1310	18020	0	1227	25605	133	6023	0	5267	396	1211	1763	550	18848	99994
Rabbits	20968	6543	50623	632	19496	49836	915	19030	20	9222	15056	730	1686	5031	27578	227366
Cold-blooded animals (1)	65097	29018	179869	1840	20605	29042	20052	7995	0	47428	1447	539	89094	28249	130595	650870
birds (2)	19726	5225	92792	80	19027	86610	1229	20157	0	92823	1367	267	5228	6920	105931	457382
Artio + Perissodactyla (3)	8874	9004	17765	1426	4181	18735	4370	3295	0	17430	670	1752	2347	4165	29376	123390
Carnivores (4)	1557	1358	7531	2	1831	7417	441	847	0	1153	92	94	1844	774	10632	35573
Prosimians + monkeys + apes	490	0	2084	0	96	2322	0	512	0	320	7	0	9	66	3191	9097
Other Mammals	0	11	660		0	272	13	25	0	45	0	301	2148	353	937	4765
																9814171
Total	790089	323444	1591394	9686	475726	2309597	73929	987771	3060	621466	130295	39851	228334	324067	1905462	**9814171**

Species % total	B	DK	D	EL	E	F	IRL	I	L	NL	A	P	FIN	S	UK	Mean
Mice	56,54	50,61	48,76	36,82	54,93	67,21	42,27	41,59	98,04	44,70	69,99	59,39	39,40	56,85	51,96	54,06
Rats	21,47	29,95	25,34	19,62	28,18	19,93	19,59	50,68	0,65	25,71	9,75	24,68	14,24	26,04	27,65	26,57
Guinea-Pigs	4,73	3,22	2,70	2,48	2,92	3,33	1,41	1,87	0,65	1,65	5,65	3,64	0,76	2,89	3,22	2,98
Golden hamsters + other rodents	2,49	0,41	1,13	0,00	0,26	1,11	0,18	0,61	0,00	0,85	0,30	3,04	0,77	0,17	0,99	1,02
Rabbits	2,65	2,02	3,18	6,52	4,10	2,16	1,24	1,93	0,65	1,48	11,56	1,83	0,74	1,55	1,45	2,32
Cold-blooded animals (1)	8,24	8,97	11,30	19,00	4,33	1,26	27,12	0,81	0,00	7,63	1,11	1,35	39,02	8,72	6,85	6,63
birds (2)	2,50	1,62	5,83	0,83	4,00	3,75	1,66	2,04	0,00	14,94	1,05	0,67	2,29	2,14	5,56	4,66
Artio + Perissodactyla (3)	1,12	2,78	1,12	14,72	0,88	0,81	5,91	0,33	0,00	2,80	0,51	4,40	1,03	1,29	1,54	1,26
Carnivores (4)	0,20	0,42	0,47	0,02	0,38	0,32	0,60	0,09	0,00	0,19	0,07	0,24	0,81	0,24	0,56	0,36
Prosimians + monkeys + apes	0,06	0,00	0,13	0,00	0,02	0,10	0,00	0,05	0,00	0,05	0,01	0,00	0,00	0,02	0,17	0,09
Other Mammals	0,00	0,00	0,04	0,00	0,00	0,01	0,02	0,00	0,00	0,01	0,00	0,76	0,94	0,11	0,05	0,05
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

* The highest number of animals between column 1.2 and 2.10 (see also table 1.1)

(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

EU Table 1 is not only providing the total number of animals used in the Member States, it also requires reporting the origin of some experimental animals. EU Table 1 requires also that Member States report the number of animals re-used in experimental purposes.

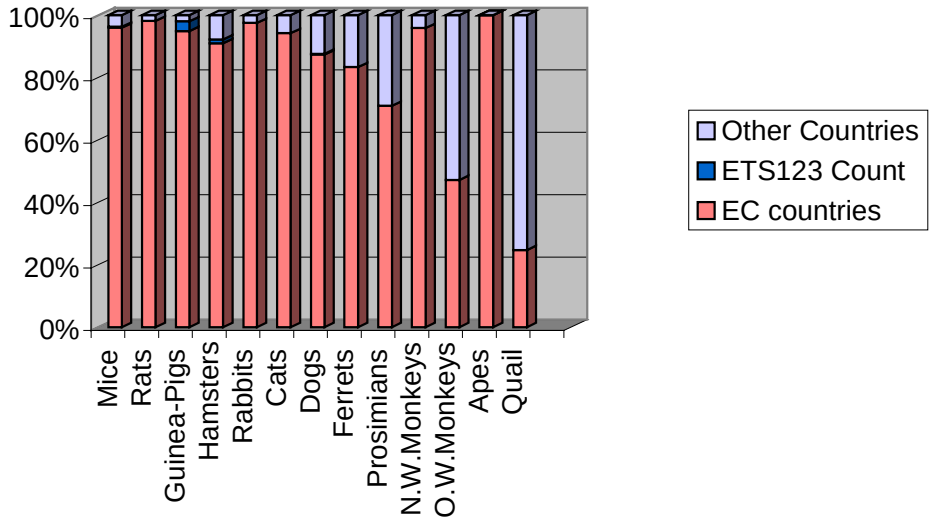
The consolidated results of EU Table 1 on the origin of some species used for experimental purposes in the 14 Member States are reported in table 1.4 of the present report.

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

Figure 1.2
Origin of species
Data of 1999



It appears that the majority of common species originated from the Community. However, for certain species shown on the right side of the graph there is clear shift towards non-European origin. It is important to underline that the bar for apes represents only 6 animals. All the other bars range between 10^2 to 10^6 animals.

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

Data of 1999

1.1 Spieces		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)	4529581	4049813	300463	12353	166952	
1.b.	Rats (Rattus norvegicus)	2204122	2032257	133002	234	38629	
1.c.	Guinea-Pigs (Cavia porcellus)	249937	192984	44213	7785	4955	
1.d.	Hamsters (Mesocricetus)	40488	33511	3335	510	3132	
1.f.	Rabbits (Oryctolagus cuniculus)	176743	151164	21266	0	4307	6610
1.g.	Cats (Felis catus)	4382	3479	651	0	252	583
1.h.	Dogs (Canis familiaris)	15998	12179	1797	54	1968	2318
1.i.	Ferrets (Mustela putorius furo)	1653	1363	0	0	274	20
1.p.	Prosimians (Prosimia)	455	323	0	0	132	0
1.q.	New World Monkeys (Ceboidea)	1353	1169	46	0	56	364
1.r.	Old World Monkeys (Cercopithecoidea)	5199	2274	181	0	2736	595
1.s.	Apes (Hominoidea)	6	6	0	0	0	1
1.u.	Quail (Coturnix coturnix)	6811	1633	0	0	5128	
1.z.	TOTAL	7236728	6482155	504954	20936	228521	

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 procedures***

III.3.1. The data

Fourteen Member States reported the purposes of the procedures in the format of the EU Table 2. One Member State reported data in accordance with the format of the statistical table from the Council of Europe.

The consolidated results for 14 Member States are presented in table 2.1 of this report.

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 14 Member States in 1999. For the sake of a better presentation of results some species were grouped.

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

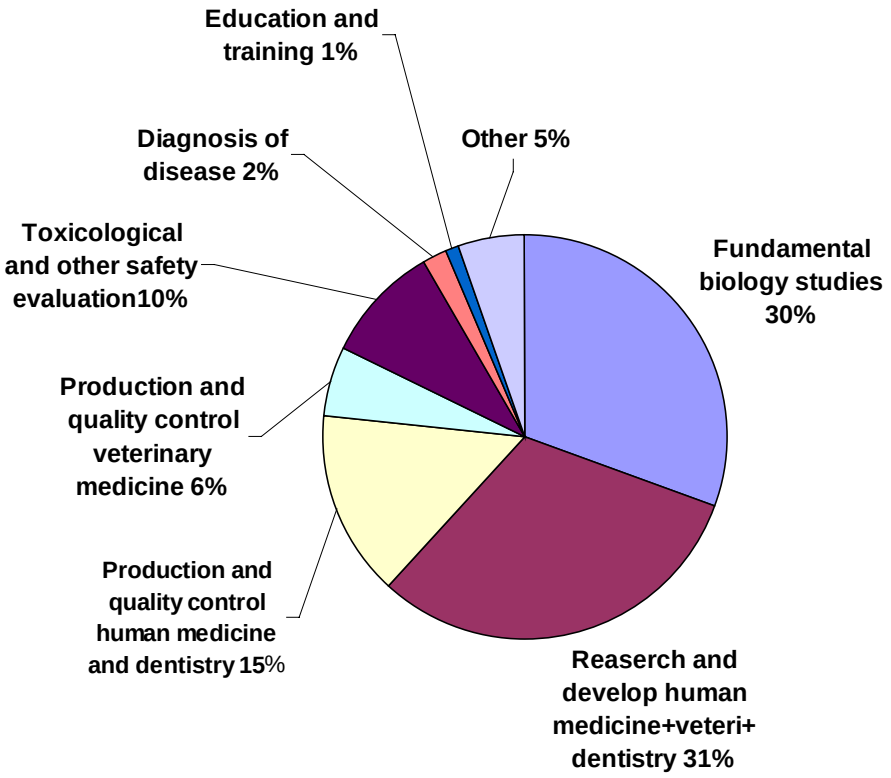
Species	Biological studies of a fundamental nature	Research, development and quality control of products and devices for human medicine and dentistry and for veterinary medicine	Toxicological and other safety evaluations (including safety evaluation of products)	Diagnosis of disease	Education and training	Other	Total
Mice	1452583	2347842	285132	93218	27719	219937	4426431
Rats	567904	1265125	284940	4837	36157	24959	2183922
Other rodents	40631	215796	51397	3618	1571	11897	324910
Rabbits	22701	84159	30104	9108	3316	9850	159238
Carnivores	6930	8963	9190	221	594	1995	27893
Artio+perissodactyla	45687	34135	3584	3573	4824	13129	104932
Prosimians+monkeys+apes	1279	1796	3687	22	4	206	6994
Other mammals	3430	312	274	0	0	89	4105
Birds	101487	165879	18571	4107	1707	71472	363223
Cold-blooded animals	215412	56186	82113	21317	11300	82470	468798
1.z. TOTAL	2458044	4180193	768992	140021	87192	436004	8070446

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

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)	1452583	1358524	685184	304134	285132	93218	27719	219937	4426431
1.b.	Rats (Rattus norvegicus)	567904	866719	391208	7198	284940	4837	36157	24959	2183922
1.c.	Guinea-Pigs (Cavia porcellus)	16639	56837	81243	31485	47427	1604	1147	6950	243332
1.d.	Hamsters (Mesocricetus)	14346	9422	1380	6900	3786	1649	154	4256	41893
1.e.	Other Rodents (other Rodentia)	9646	28514	15	0	184	365	270	691	39685
1.f.	Rabbits (Oryctolagus cuniculus)	22701	42303	35132	6724	30104	9108	3316	9850	159238
1.g.	Cats (Felis catus)	721	1545	64	422	282	51	41	1175	4301
1.h.	Dogs (Canis familiaris)	898	4791	95	602	8898	42	529	79	15934
1.i.	Ferrets (Mustela putorius furo)	720	752	40	6	10	11	24	90	1653
1.j.	Other Carnivores (other Carnivora)	4591	54	0	592	0	117	0	651	6005
1.k.	Horses, donkeys and cross breds (Equidae)	534	453	95	142	129	96	243	66	1758
1.l.	Pigs (Sus)	21078	13462	399	8585	2284	1500	2480	5483	55271
1.m.	Goats (Capra)	1351	53	21	0	3	214	220	1268	3130
1.n.	Sheep (Ovis)	15614	4328	557	1335	780	1503	783	3450	28350
1.o.	Cattle (Bos)	7110	2850	0	1855	388	260	1098	2862	16423
1.p.	Prosimians (Prosimia)	455	0	0	0	0	0	0	0	455
1.q.	New World Monkeys (Ceboidea)	355	410	0	0	568	0	0	8	1341
1.r.	Old World Monkeys (Cercopithecoidea)	469	483	895	2	3119	22	4	198	5192
1.s.	Apes (Hominoidea)	0	6	0	0	0	0	0	0	6
1.t.	Other Mammals (other Mammalia)	3430	312	0	0	274	0	0	89	4105
1.u.	Quail (Coturnix coturnix)	1738	0	30	160	4738	0	83	12	6761
1.v.	Other birds (other Aves)	99749	76894	10809	77986	13833	4107	1624	71460	356462
1.w.	Reptiles (Reptilia)	1925	0	0	0	0	0	84	0	2009
1.x.	Amphibians (Amphibia)	17285	67	0	0	845	0	8778	251	27226
1.y.	Fish (Pisces)	196202	44299	0	11820	81268	21317	2438	82219	439563
1.z.	TOTAL	2458044	2513078	1207167	459948	768992	140021	87192	436004	8070446

Figure 2.1
purposes of experiments



More than 60 % of animals have been 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 21 % of the total number of animals reported in 1999.

Toxicological and other safety evaluation represents the third important group of experimental purposes with 10% of animals used.

Table 2.3: Comparison between results of 1996 and 1999

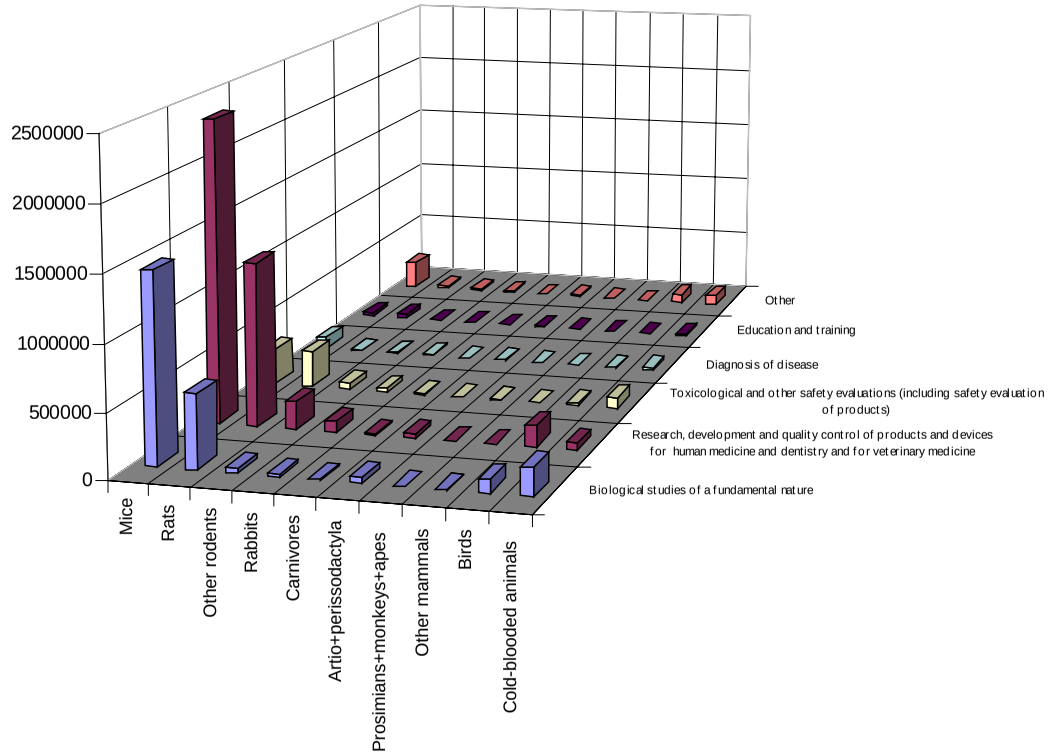
Purpose	1996 Report*	Data 1999	Comment
Research development and quality control in human medicine, veterinary medicine and dentistry	44%	52%	
Fundamental biology studies	25%	30%	
Toxicological and safety evaluation	9%	10%	Status quo

* 13 Member States reported purposes of experiments

Since the introduction of EU Tables has improved the resolution of the data for the different purposes of experiments in the Member States, it is worth noting that purpose “other” has decreased from 17% to 5%.

The 3D figure 2.2 presents the number of animals used for selected purposes by species. In comparison to the data of 1996 a more detailed graph could be drawn regarding species used. The general pattern of uses has not changed significantly for rodents and rabbits (except for details by species). For the group of cold-blooded animals including fish however, it is observed that this group has been more used in fundamental biological studies than in 1996.

Figure 2.2
Species and purposes



III.3.3. Diagnosis of disease

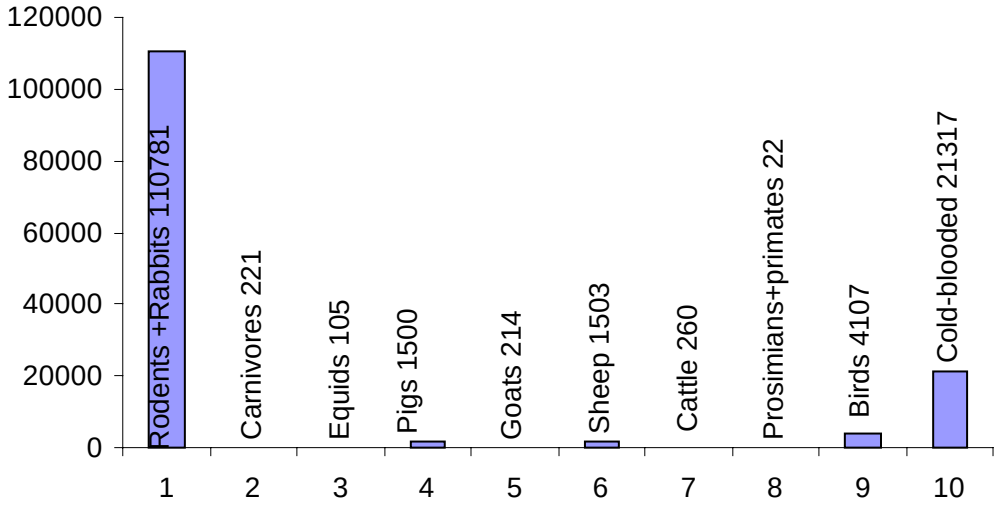
Column 2.7 of EU Table 2 presents a parameter, which could be important in the future in the light of new emerging epidemic in the Community. Table 2.4 shows the number of animals used in the 14 Member States by groups of species.

Table 2.4: Classes of animals used in the diagnosis of disease

Rodents +rabbits	110781
Carnivores	221
Horses, donkeys and cross bred (Equidae)	96
Pigs (Sus)	1500
Goats (Capra)	214
Sheep (Ovis)	1503
Cattle (Bos)	260
Prosimians +primates	22
Birds (Aves)	4107
Cold blooded animals	21317

Cold-blooded animals represent 15,2 % of the total number of animals used for diagnosis of disease.

Figure 2.3
Diagnosis of disease



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

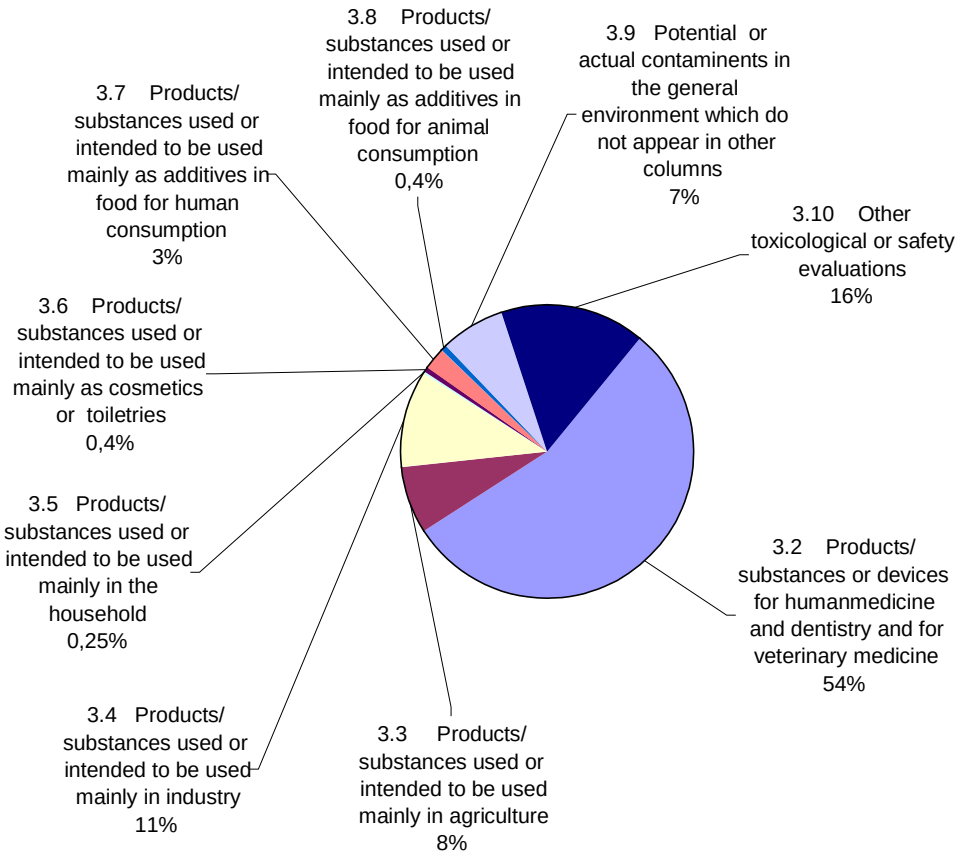
III.4.1. The data

Fourteen Member States reported data on animals used in toxicological or other safety evaluation for products or other endpoints.

The consolidated table of results on animals used in toxicological and other safety evaluation (EU Table 3) in 14 Member States is presented in table 3.1 of this report.

III.4.2. Treatment and interpretation of the data

Figure 3.1
Animals used in toxicological or other safety evaluations
products
1999 Data



For the first time the statistical report can give a representative outlook of the number of animals used in toxicological or other safety evaluation experiments in the 14 Member States when broken down into type of products for which the tests were required.

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

The number of animals used for toxicological evaluation of products/substances for animal feed, for additives for human food consumption, for cosmetics and for household are very small (4%) when compared to the other products or endpoints.

Products or devices used for human medicine, veterinary medicine and dentistry occupy 54% of the chart surface.

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, is responsible for the use of 19 % of animals.

Another important group is the “other” toxicological evaluations (16%).

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)	178484	4360	10677	931	1621	14758	486	1782	91728	305587
1.b.	Rats (Rattus norvegicus)	181155	29470	45040	563	237	5779	942	2161	25773	292597
1.c.	Guinea-Pigs (Cavia porcellus)	22953	5120	15351	39	27	120	30	74	4270	48422
1.d.	Hamsters (Mesocricetus)	2588	871	0	0	0	115	0	0	212	3786
1.e.	Other Rodents (other Rodentia)	0	0	0	0	0	0	26	158	0	184
1.f.	Rabbits (Oryctolagus cuniculus)	21175	1504	5520	438	1447	57	0	203	1037	31573
1.g.	Cats (Felis catus)	274	0	0	0	0	0	0	0	16	290
1.h.	Dogs (Canis familiaris)	8373	357	3	0	0	0	0	0	165	8898
1.i.	Ferrets (Mustela putorius furo)	10	0	0	0	0	0	0	0	0	10
1.j.	Other Carnivores (other Carnivora)	10	0	0	0	0	0	0	0	0	10
1.k.	Horses, donkeys and cross breds (Equidae)	129	0	0	0	0	0	0	0	0	129
1.l.	Pigs (Sus)	2165	48	0	0	0	0	0	14	120	2347
1.m.	Goats (Capra)	4	23	0	0	0	0	0	0	0	27
1.n.	Sheep (Ovis)	613	97	0	0	0	0	0	24	46	780
1.o.	Cattle (Bos)	319	57	0	0	0	6	5	0	4	391
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	496	0	0	0	0	0	0	0	72	568
1.r.	Old World Monkeys (Cercopithecoidea)	3078	0	10	0	0	0	0	0	30	3119
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0	270	0	0	0	0	0	4	0	274
1.u.	Quail (Coturnix coturnix)	0	4738	0	0	0	0	0	0	0	4738
1.v.	Other birds (other Aves)	8150	5788	0	0	0	0	0	0	112	14050
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0
1.x.	Amphibians (Amphibia)	0	0	0	0	0	0	0	845	0	845
1.y.	Fish (Pisces)	3702	8274	9991	70	15	30	1820	52047	5862	82163
1.z.	TOTAL	433678	60977	86592	2041	3347	20865	3309	57312	129447	800788

III.4.3 Species versus type of products

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

The 3D Figure 3.2 shows the number of animals used per class of animals versus the type of products/endpoints.

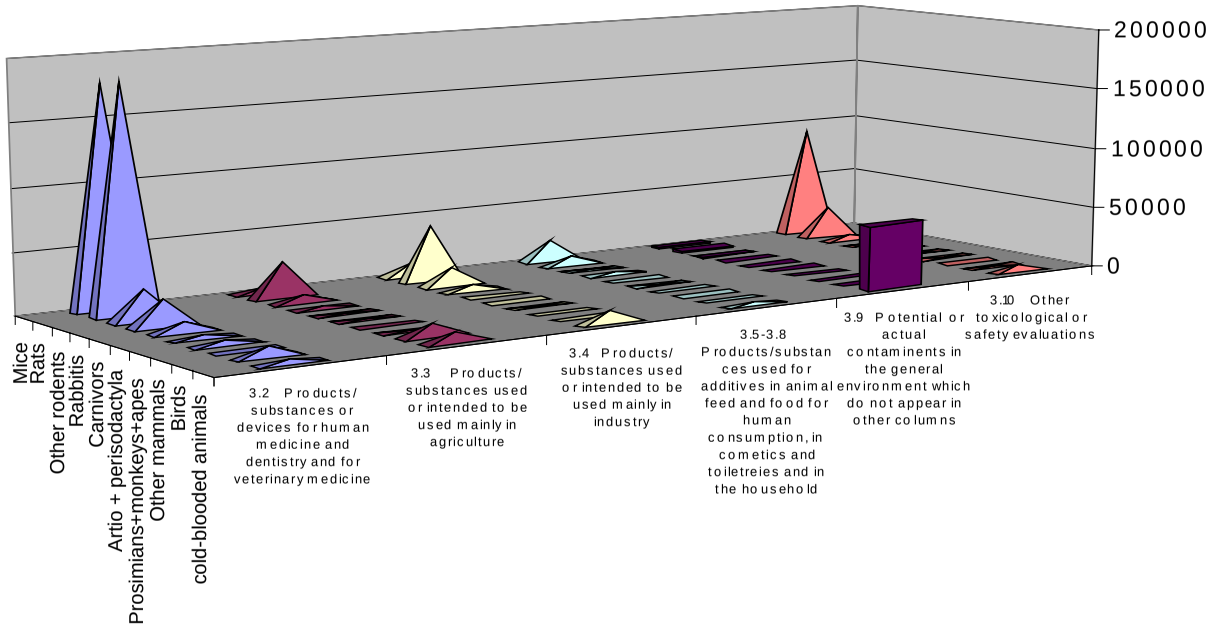
An interesting feature of the “potential or actual contaminants in the general environment” is a characteristic tendency towards the use of environmental representative species such as the fish and amphibians.

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	178484	4360	10677	17796	1782	91728	305587
Rats	181155	29470	45040	7521	2161	25773	292597
Other rodents	25541	5991	15351	357	232	4482	52392
Rabbits	21175	1504	5520	1942	203	1037	31573
Carnivores	8667	357	3	0	0	181	9208
Artio + perisodactyla	3230	225	0	11	38	170	3674
Prosimians+monkeys+apes	3574	0	10	0	0	102	3687
Other mammals	0	270	0	0	4	0	274
Birds	8150	10526	0	0	0	112	18788
cold-blooded animals	3702	8274	9991	1935	52892	5862	83008
1.z. TOTAL	433678	60977	86592	29562	57312	129447	800788

Figure 3.2

Species versus type of products/endpoints



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

III.5.1. The data

Fourteen Member States reported data on animals used in procedures for studies of human and animal diseases compared to nine in 1996-1997.

The consolidated table of results (EU Table 4) for 14 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 relative percentage of animals used in studies per type of diseases.

The number of animals used for studies of diseases represents 50,4% of the total number of animals used for experimental purposes.

In 1999 the pattern of uses is similar to that observed in 1996 except for a decrease of animals used for studying human cancer.

Figure 4.1
Number of animals used in studies of diseases
Data of 1999

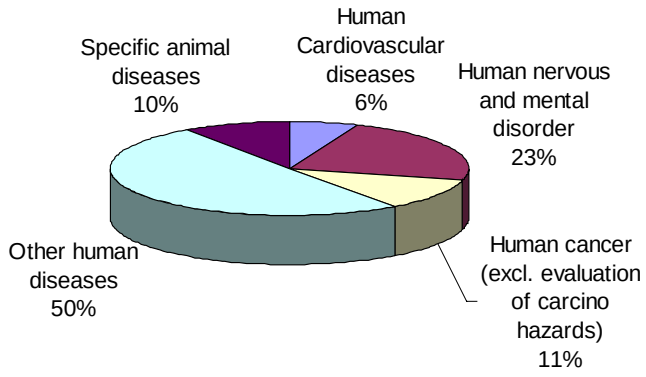


Table 4.1: Number of animals used in experiments for studies on human and animal diseases

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)	125795	557955	483527	1619102	176115	2962494
1.b.	Rats (Rattus norvegicus)	140217	528076	50931	591762	12545	1323531
1.c.	Guinea-Pigs (Cavia porcellus)	7507	10683	1324	75658	5818	100990
1.d.	Hamsters (Mesocricetus)	3226	2281	424	14268	6445	26644
1.e.	Other Rodents (other Rodentia)	744	26761	0	7779	1005	36289
1.f.	Rabbits (Oryctolagus cuniculus)	14037	1610	1583	34847	5803	57880
1.g.	Cats (Felis catus)	83	401	3	433	1640	2560
1.h.	Dogs (Canis familiaris)	2085	192	158	6039	1352	9826
1.i.	Ferrets (Mustela putorius furo)	159	611	12	705	23	1510
1.j.	Other Carnivores (other Carnivora)	0	28	0	2999	322	3349
1.k.	Horses, donkeys and cross breds (Equidae)	16	0	0	588	434	1038
1.l.	Pigs (Sus)	4485	283	125	9518	13393	27804
1.m.	Goats (Capra)	133	0	3	970	90	1196
1.n.	Sheep (Ovis)	614	525	48	15405	6666	23258
1.o.	Cattle (Bos)	147	0	0	3665	5639	9451
1.p.	Prosimians (Prosimia)	0	0	0	455	0	455
1.q.	New World Monkeys (Ceboidea)	37	274	5	922	0	1238
1.r.	Old World Monkeys (Cercopithecoidea)	84	469	176	2528	0	3257
1.s.	Apes (Hominoidea)	0	0	0	6	0	6
1.t.	Other Mammals (other Mammalia)	68	22	0	764	144	998
1.u.	Quail (Coturnix coturnix)	0	160	0	270	0	430
1.v.	Other birds (other Aves)	2053	8322	211	33738	148908	193232
1.w.	Reptiles (Reptilia)	0	24	0	242	114	380
1.x.	Amphibians (Amphibia)	550	436	500	9018	250	10754
1.y.	Fish (Pisces)	153	935	0	57996	89612	148696
1.z.	TOTAL	302193	1140048	539030	2489677	476318	4947266

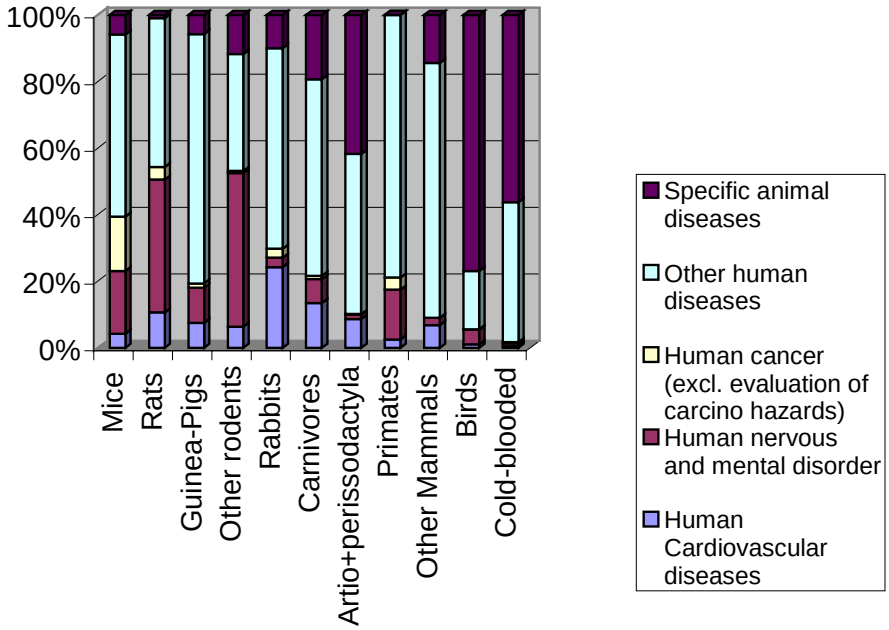
Table 4.2: Animals used in studies of diseases by classes of animals

Species	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	125795	557955	483527	1619102	176115	2962494
Rats	140217	528076	50931	591762	12545	1323531
Guinea-Pigs	7507	10683	1324	75658	5818	100990
Other rodents	3970	29042	424	22047	7450	62933
Rabbits	14037	1610	1583	34847	5803	57880
Carnivores	2327	1232	173	10176	3337	17245
Artio+Perissodactyla	5395	808	176	30146	26222	62747
Primates	121	743	181	3911	0	4956
Other Mammals	68	22	0	764	144	998
Birds	2053	8482	211	34008	148908	193662
Cold-blooded animals	703	1395	500	67256	89976	159830
TOTAL	302193	1140048	539030	2489677	476318	4947266

Species %	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	4,25	18,83	16,32	54,65	5,94	100,00
Rats	10,59	39,90	3,85	44,71	0,95	100,00
Guinea-Pigs	7,43	10,58	1,31	74,92	5,76	100,00
Other rodents	6,31	46,15	0,67	35,03	11,84	100,00
Rabbits	24,25	2,78	2,73	60,21	10,03	100,00
Carnivores	13,49	7,14	1,00	59,01	19,35	100,00
Artio+perissodactyla	8,60	1,29	0,28	48,04	41,79	100,00
Primates	2,44	14,99	3,65	78,91	0,00	100,00
Other Mammals	6,81	2,20	0,00	76,55	14,43	100,00
Birds	1,06	4,38	0,11	17,56	76,89	100,00
Cold-blooded animals	0,44	0,87	0,31	42,08	56,29	100,00

Species of Table 4.1 were grouped by 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 for studies of diseases
Data of 1999



The top of the stack shows the relative percentage of animals used for studies on animal diseases. Two groups of animals i.e. birds and cold-blooded animals are significant. It was reported at the National experts meeting that a lot of vaccines are tested on these groups of animals.

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

Fourteen Member States reported data on animals used in production and quality control of products for human medicine and dentistry and veterinary medicine.

The number of animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine represents 14% of the total number of animals used for experimental purposes.

The consolidated table for the 14 Member States reporting these data (EU Table 5) is presented in table 5.1 of this report.

Owing to variations in the data submitted by some Member States, the data of table 5.1 will not be interpreted further.

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)	34884	478819	27	24506	380716	69798	988750
1.b.	Rats (Rattus norvegicus)	5243	14758	150	4874	81349	18277	124651
1.c.	Guinea-Pigs (Cavia porcellus)	10460	50807	39	4512	43998	2649	112465
1.d.	Hamsters (Mesocricetus)	1249	6330	376	21	198	189	8363
1.e.	Other Rodents (other Rodentia)	15	0	0	0	0	0	15
1.f.	Rabbits (Oryctolagus cuniculus)	1193	28251	224	487	15884	5438	51477
1.g.	Cats (Felis catus)	68	427	0	16	25	11	547
1.h.	Dogs (Canis familiaris)	0	508	0	0	76	180	764
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	30	104	134
1.j.	Other Carnivores (other Carnivora)	0	582	0	0	0	10	592
1.k.	Horses, donkeys and cross breds (Equidae)	70	122	0	0	7	102	301
1.l.	Pigs (Sus)	605	3072	5	0	1885	3217	8784
1.m.	Goats (Capra)	2	0	0	0	16	1	19
1.n.	Sheep (Ovis)	292	832	0	0	517	464	2105
1.o.	Cattle (Bos)	283	1077	55	0	281	184	1880
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	0	0	0	0	35	35
1.r.	Old World Monkeys (Cercopithecoidea)	0	519	0	12	276	37	844
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)	160	30	0	0	0	0	190
1.v.	Other birds (other Aves)	1140	70492	48	1248	8747	4198	85873
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0
1.x.	Amphibians (Amphibia)	70	0	0	0	0	0	70
1.y.	Fish (Pisces)	0	2850	4690	0	4280	0	11820
1.z.	TOTAL	55734	659476	5614	35676	538285	104894	1399679

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.

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

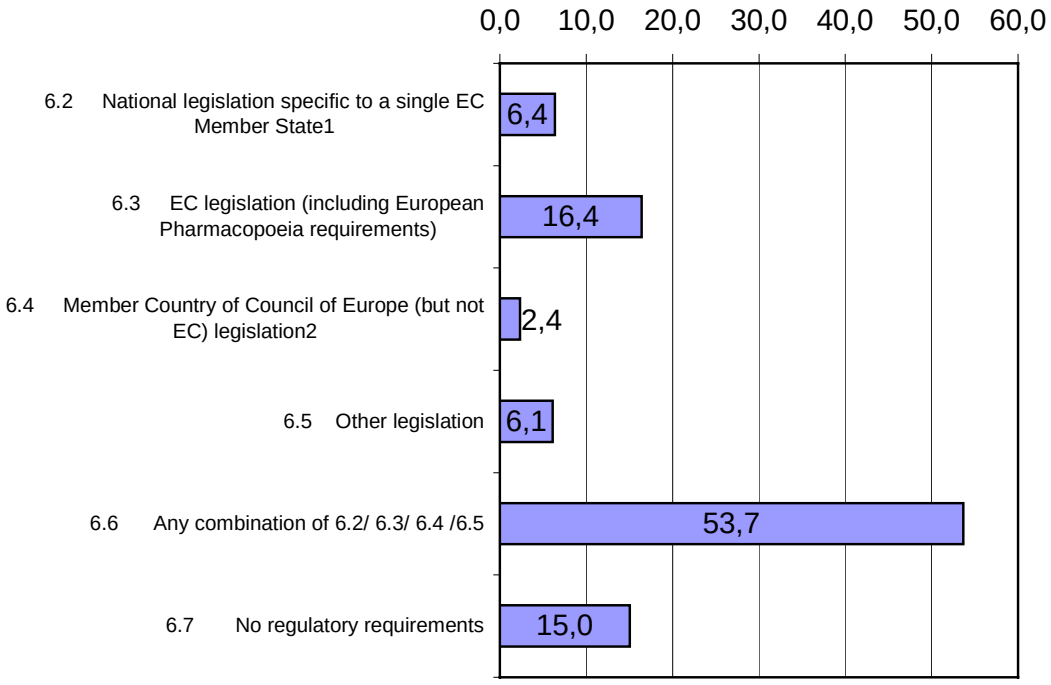
Fourteen Member States reported data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations.

The consolidated table for the 14 Member States reporting these data (EU Table 6) is presented in table 6.1 of this report.

III.7.2. Treatment and interpretation of the data

Figure 6.1

Percentage of animals used versus regulatory requirements for toxicological or other safety evaluations



It is observed that sum of percentages of individual requirements such as in columns 6.2 to 6.5 represent a much lower number of animals used (31,3%) than for combined requirements (53,7%).

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)	13840	64353	2049	13467	137089	51000	281798
1.b.	Rats (Rattus norvegicus)	9629	30571	8550	18462	190880	25287	283379
1.c.	Guinea-Pigs (Cavia porcellus)	5098	8410	662	4196	26421	3618	48405
1.d.	Hamsters (Mesocricetus)	247	26	500	0	2767	246	3786
1.e.	Other Rodents (other Rodentia)	0	0	0	0	32	158	190
1.f.	Rabbits (Oryctolagus cuniculus)	1799	6098	894	4626	16438	576	30431
1.g.	Cats (Felis catus)	17	40	0	0	229	1	287
1.h.	Dogs (Canis familiaris)	119	437	1284	92	6678	256	8866
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	10	0	10
1.j.	Other Carnivores (other Carnivora)	0	0	0	0	0	0	0
1.k.	Horses, donkeys and cross breds (Equidae)	0	126	0	0	3	0	129
1.l.	Pigs (Sus)	190	508	18	14	1198	356	2284
1.m.	Goats (Capra)	0	0	0	0	3	0	3
1.n.	Sheep (Ovis)	45	279	0	0	348	100	772
1.o.	Cattle (Bos)	57	256	4	0	67	7	391
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	5	192	0	358	13	568
1.r.	Old World Monkeys (Cercopithecoidea)	0	299	605	41	2083	91	3119
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0	0	0	0	0	274	274
1.u.	Quail (Coturnix coturnix)	0	0	0	0	4738	0	4738
1.v.	Other birds (other Aves)	717	4348	162	150	5077	369	10823
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0
1.x.	Amphibians (Amphibia)	0	0	0	0	0	845	845
1.y.	Fish (Pisces)	16892	9442	3120	5814	15234	31661	82163
1.z.	TOTAL	48650	125198	18040	46862	409653	114858	763261

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 anISO 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

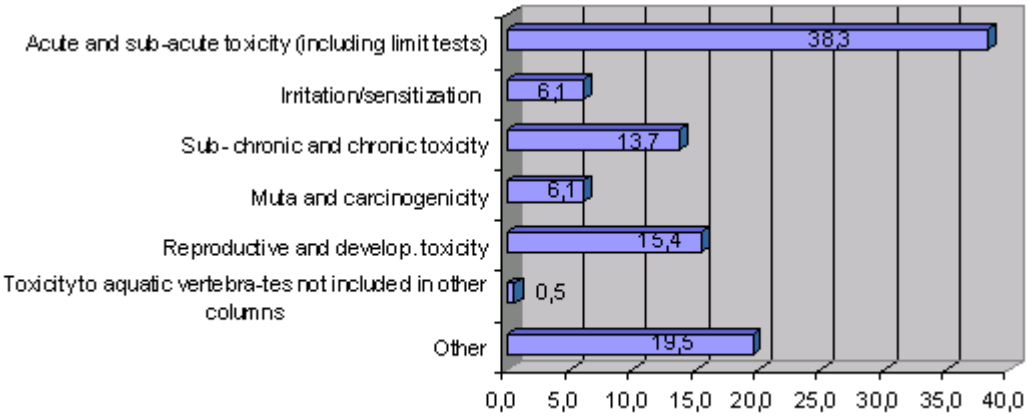
Fourteen Member States reported data on animals used in toxicity tests for the purpose of toxicological or other safety evaluations of products.

The consolidated table for the 14 Member States reporting animals used in different toxicity tests (EU Table 7) is presented in table 7.1 of this report.

III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of table 7.1 have been grouped in table 7.2 of this report. A 3D chart showing the percentage of animals used per toxicity test groups is presented in figure 7.1.

Figure 7.1
Percentage animals used in toxicity tests for toxicological or other safety evaluations



Acute and sub-acute toxicity tests on experimental animals are the most widely used tests (38%). With the addition of sub-chronic and chronic toxicity, the short and long term classical toxicity testing accounts for the use of more than half of the experimental animals in 1999 for toxicological and other safety evaluations (52 %).

Systemic effects, special effects (carcinogenicity, mutagenicity) and toxicity to reproduction represent approximately half of the above percentages of classical toxicity.

Environmental toxicity represents a low percentage.

Finally, the 19,5 % for “other tests” where no further indication is given.

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)	16992	63444	55215	20	3006	0	39255	11931	2128	14917	3180	42	77884	288994
1.b.	Rats (Rattus norvegicus)	11910	18533	64353	1064	80	0	46180	10267	14459	9449	64331	0	45231	286628
1.c.	Guinea-Pigs (Cavia porcellus)	60	812	7278	496	31225	0	2572	0	0	0	0	0	5958	48401
1.d.	Hamsters (Mesocricetus)	0	0	588	20	0	31	515	1029	0	20	0	0	1583	3786
1.e.	Other Rodents (other Rodentia)	0	26	0	0	0	0	0	0	0	0	0	0	158	184
1.f.	Rabbits (Oryctolagus cuniculus)	6	127	4209	6723	385	4331	1650	0	5251	0	4237	0	4525	31512
1.g.	Cats (Felis catus)	0	0	40	0	0	0	184	0	0	0	0	0	63	287
1.h.	Dogs (Canis familiaris)	0	19	3500	118	0	0	4085	0	0	0	0	0	1212	8970
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0	0	0	0	0	0	0	10	10
1.j.	Other Carnivores (other Carnivora)	0	0	6	0	0	0	0	0	0	0	0	0	0	6
1.k.	Horses, donkeys and cross breds (Equidae)	0	0	83	0	0	0	22	0	0	0	0	0	18	123
1.l.	Pigs (Sus)	0	185	442	12	0	0	533	0	39	0	0	0	1073	2284
1.m.	Goats (Capra)	0	0	0	0	0	0	0	0	0	0	0	0	23	23
1.n.	Sheep (Ovis)	0	0	133	0	20	0	72	0	0	0	41	0	492	758
1.o.	Cattle (Bos)	0	0	162	0	0	0	61	0	0	0	0	0	162	385
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	0	233	0	0	0	195	0	0	0	0	0	140	568
1.r.	Old World Monkeys (Cercopithecoidea)	0	8	1157	0	0	0	1567	0	0	0	0	0	427	3159
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	270	0	0	0	0	0	0	0	0	0	0	0	522	792
1.u.	Quail (Coturnix coturnix)	1566	104	114	0	0	0	120	50	4358	0	360	0	0	6672
1.v.	Other birds (other Aves)	521	4	4395	0	0	0	2545	0	2790	0	0	0	1657	11912
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.x.	Amphibians (Amphibia)	0	0	50	0	0	0	0	0	0	0	0	0	795	845
1.y.	Fish (Pisces)	20636	12744	8962	0	0	0	7273	0	8410	0	10471	4085	10201	83247
1.z.	TOTAL	51961	96137	151173	8459	34716	4371	107505	23277	37435	24386	83140	4222	152764	781866

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	Repro-ductive and develop. toxicity	Toxicity to aquatic vertebrates not included in other columns	Other	Total
1.a.	Mice (Mus musculus)	135651	3026	39255	26848	5308	42	77884	288994
1.b.	Rats (Rattus norvegicus)	94796	1144	46180	19716	78790	0	45231	286628
1.c.	Guinea-Pigs (Cavia porcellus)	8150	31721	2572	0	0	0	5958	48401
1.d.	Hamsters (Mesocricetus)	588	51	515	1049	0	0	1583	3786
1.e.	Other Rodents (other Rodentia)	26	0	0	0	0	0	158	184
1.f.	Rabbits (Oryctolagus cuniculus)	4342	11439	1650	0	9488	0	4525	31512
1.g.	Cats (Felis catus)	40	0	184	0	0	0	63	287
1.h.	Dogs (Canis familiaris)	3519	118	4085	0	0	0	1212	8970
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0	10	10
1.j.	Other Carnivores (other Carnivora)	6	0	0	0	0	0	0	6
1.k.	Horses, donkeys and cross breds (Equidae)	83	0	22	0	0	0	18	123
1.l.	Pigs (Sus)	627	12	533	0	39	0	1073	2284
1.m.	Goats (Capra)	0	0	0	0	0	0	23	23
1.n.	Sheep (Ovis)	133	20	72	0	41	0	492	758
1.o.	Cattle (Bos)	162	0	61	0	0	0	162	385
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	233	0	195	0	0	0	140	568
1.r.	Old World Monkeys (Cercopithecoidea)	1165	0	1567	0	0	0	427	3159
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	270	0	0	0	0	0	522	792
1.u.	Quail (Coturnix coturnix)	1784	0	120	50	4718	0	0	6672
1.v.	Other birds (other Aves)	4920	0	2545	0	2790	0	1657	11912
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0
1.x.	Amphibians (Amphibia)	50	0	0	0	0	0	795	845
1.y.	Fish (Pisces)	42342	0	7273	0	18881	4085	10201	83247
1.z.	TOTAL	299271	47546	107505	47663	120575	4222	152764	781866

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 14 Member States reporting (EU Table 8) is presented in table 8.1 of this report.

III.9.2. Treatment and interpretation of the data

Owing to variations in data reported it was decided not to interpret results further.

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	11115	22418	111669	1857	9682	1556	87409	20158	15424	15564	40599	0	104855	442306
8.b. Products/ substances used or intended to be used mainly in agriculture	7431	5156	10641	605	5472	570	2968	2173	7590	1001	14401	326	7666	66000
8.c. Products/ substances used or intended to be used mainly in industry	8432	9764	16216	4295	16498	1359	3545	52	2940	4535	14113	15	4951	86715
8.d. Products/ substances used or intended to be used mainly in the household	0	0	360	417	0	9	0	0	0	0	0	85	341	1212
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	1667	267	66	897	313	534	0	0	570	55	410	15	108	4902
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	367	4341	1222	103	352	81	1527	839	0	237	197	0	1291	10557
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	0	0	51	0	0	0	0	408	0	0	0	0	600	1059
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	16342	19924	19709	477	1412	329	10447	4000	7352	2008	10971	3449	8458	104878
8.i. Other toxicological or safety evaluations	8510	41455	5010	218	2399	117	4791	897	3557	2582	2323	0	14836	86695
8.j. TOTAL	47214	82143	136474	7963	33304	3897	100945	20887	33585	22664	79476	3890	135894	708336

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

BELGIUM

Comments of Belgian authorities

Statistical data submitted

The statistical data have been submitted by the "*Ministère des Classes Moyennes et de l'Agriculture*" (Ministry of Small Enterprises and Agriculture).

General comments

1. The legal basis for the collection of statistical data in Belgium is the royal decree of 14 November 1993 which states that all laboratories must send each year to the Veterinary services their statistical data on the use of animals.

2. Statistical data of 1999 were, for the first time, collected on the standardised set of statistical tables of the European Union. Prior to collection guidelines were dispatched to all laboratory directors. The purpose was to precise the way of recording re-used animals in the tables as well as to explain the links between the different tables. All the laboratories in activity in 1999 have sent their statistical data.

Specific comments

1. It is noteworthy that the total number of animals used in research or other scientific purposes, when it is ***compared with the figure of 1996***, has been reduced in 1999 in Belgium by 47,87 %.

2. More precisely comparison of data of 1999 with the figures of 1998 shows the following trends:

2.1. Rodents and rabbits still represent the most used group of animals used and mainly for "research -development and quality control of products and devices for human medicine, veterinary medicine and dentistry ".

2.2. The second group is represented by the cold-blooded animals in fundamental research, environmental toxicity evaluation and in food research.

2.3. The total number of animals used in 1999 (790,089 animals) decreased by 5.6 % when it is compared with the figure of 1998 (837,560 animals).

2.4. The number of rodents and rabbits increased by 2.11 %.

2.5. The use of sensitive carnivores shows a regular reduction: the number used in experiments has been reduced by 20.8 % for dogs and by 40.9 % for cats.

2.6. The number of pigs is increased by 7.1 % but other farm animals were less used (sheep: - 15.7 %, goats: - 7.1 %, cattle: - 4.9 %, horses and donkeys: - 11.1 %).

2.7. The number of primates is reduced by 41.7 %.

2.8. The number of birds decreased by 64.2 %.

2.9. As far as cold-blooded animals are concerned 28.2 % less have been used in 1999.

As a conclusion we can notice that two strong trends in the use of animals in experiments in Belgium are shown. The first one is a confirmed decrease of use of dogs and cats and the second trend is the reduction of use of primates. The latter reduction is due to less primates being used for some safety evaluation of pharmacological products.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (*Mus musculus*)	446677	346842	69164	8587	22084	
1.b. Rats (*Rattus norvegicus*)	169662	106913	57209	0	5540	
1.c. Guinea-Pigs (*Cavia porcellus*)	37397	11994	25145	178	80	
1.d. Hamsters (*Mesocricetus*)	4074	1448	2616	0	10	
1.e. Other Rodents (other *Rodentia*)	15567					
1.f. Rabbits (*Oryctolagus cuniculus*)	20968	15787	5063	0	118	631
1.g. Cats (*Felis catus*)	104	51	53	0	0	66
1.h. Dogs (*Canis familiaris*)	1453	618	789	28	18	554
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*)	104					
1.l. Pigs (*Sus*)	6511					
1.m. Goats (*Capra*)	104					
1.n. Sheep (*Ovis*)	1014					
1.o. Cattle (*Bos*)	1141					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	21	21	0	0	0	21
1.r. Old World Monkeys (*Cercopithecoidea*)	469	0	2	0	467	62
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	0					
1.u. Quail (*Coturnix coturnix*)	915	915	0	0	0	
1.v. Other birds (other *Aves*)	18811					
1.w. Reptiles (*Reptilia*)	147					
1.x. Amphibians (*Amphibia*)	2143					
1.y. Fish (*Pisces*)	62807					
1.z. TOTAL	790089					

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	119965	157688	110706	974	26811	25549	2001	2983	446677
2.b. Rats	28738	114431	13577	313	9686	181	1579	1157	169662
2.c. Guinea-Pigs	594	9590	21383	100	5016	161	369	184	37397
2.d. Hamsters	1123	369	1255	104	1200	9	14	0	4074
2.e. Other Rodents	617	14856	0	0	0	0	94	0	15567
2.f. Rabbits	2749	10803	5860	74	718	5	108	651	20968
2.g. Cats	35	13	3	28	0	0	25	0	104
2.h. Dogs	271	246	0	70	531	1	334	0	1453
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	24	1	2	3	0	0	67	7	104
2.l. Pigs	1536	228	0	2875	134	22	132	1584	6511
2.m. Goats	2	2	16	0	0	0	84	0	104
2.n. Sheep	292	84	0	3	0	14	23	598	1014
2.o. Cattle	184	180	0	246	31	0	45	455	1141
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	20	1	0	0	0	0	0	0	21
2.r. Old World Monkeys	3	32	272	2	160	0	0	0	469
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	915	0	0	0	0	0	0	0	915
2.v. Other birds	6340	667	0	69	63	0	411	11261	18811
2.w. Reptiles	147	0	0	0	0	0	0	0	147
2.x. Amphibians	673	0	0	0	0	0	1470	0	2143
2.y. Fish	9750	23	0	0	4666	0	368	48000	62807
2.z. TOTAL	173978	309214	153074	4861	49016	25942	7124	66880	790089

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	26187	0	0	0	0	0	0	60	376	26623
3.b. Rats	8606	0	138	22	0	0	0	0	1108	9874
3.c. Guinea-Pigs	5016	0	0	0	0	0	0	0	0	5016
3.d. Hamsters	1200	0	0	0	0	0	0	0	0	1200
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	700	0	0	18	0	0	0	0	0	718
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	531	0	0	0	0	0	0	0	0	531
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	86	48	0	0	0	0	0	0	0	134
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	31	0	0	0	0	0	0	0	0	31
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	160	0	0	0	0	0	0	0	0	160
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	63	0	0	0	0	0	0	0	0	63
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	1400	1526	1000	0	0	0	0	740	0	4666
3.z. TOTAL	43980	1574	1138	40	0	0	0	800	1484	49016

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	25812	44837	45676	204995	3064	324384
4.b. Rats	3335	47550	3089	72611	838	127423
4.c. Guinea-Pigs	894	923	0	19567	20	21404
4.d. Hamsters	627	100	67	502	104	1400
4.e. Other Rodents	155	13015	0	2104	97	15371
4.f. Rabbits	1670	70	190	1382	354	3666
4.g. Cats	0	0	0	0	0	0
4.h. Dogs	215	32	0	204	42	493
4.i. Ferrets	0	0	0	0	3	3
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	319	0	9	39	673	1040
4.m. Goats	4	0	0	0	0	4
4.n. Sheep	154	0	0	140	15	309
4.o. Cattle	0	0	0	0	347	347
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	0	0	1	0	1
4.r. Old World Monkeys	0	2	0	304	0	306
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	7	1321	1328
4.w. Reptiles	0	0	0	0	114	114
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	0	0	120	305	425
4.z. TOTAL	33185	106529	49031	301976	7303	498024

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	8563	15713	0	20755	65646	1003	111680
5.b. Rats	2938	534	0	0	9214	1204	13890
5.c. Guinea-Pigs	504	2212	0	3834	14933	0	21483
5.d. Hamsters	1249	104	0	0	0	6	1359
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	66	271	0	217	4384	996	5934
5.g. Cats	3	28	0	0	0	0	31
5.h. Dogs	0	42	0	0	28	0	70
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	5	0	5
5.l. Pigs	0	180	0	0	585	2110	2875
5.m. Goats	0	0	0	0	16	0	16
5.n. Sheep	0	3	0	0	0	0	3
5.o. Cattle	0	147	0	0	77	22	246
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	274	0	274
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	10	0	0	59	0	69
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	13323	19244	0	24806	95221	5341	157935

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	902	1540	0	262	23500	607	26811
6.b.	Rats	330	0	0	590	8114	652	9686
6.c.	Guinea-Pigs	0	256	0	272	4488	0	5016
6.d.	Hamsters	0	0	0	0	1200	0	1200
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	0	0	0	0	718	0	718
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	531	0	531
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	108	0	0	0	26	0	134
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	0	0	0	0	0	0
6.o.	Cattle	31	0	0	0	0	0	31
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	160	0	160
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	63	0	0	0	0	0	63
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	2000	526	0	0	1400	740	4666
6.z.	TOTAL	3434	2322	0	1124	40137	1999	49016

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	888	174	20625	0	0	0	920	0	0	800	86	0	3318	26811
7.b. Rats	0	138	3859	0	0	0	3320	0	986	32	468	0	883	9686
7.c. Guinea-Pigs	0	0	4579	0	186	0	0	0	0	0	0	0	251	5016
7.d. Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	1200	1200
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	0	305	49	0	9	112	0	243	0	0	0	0	718
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	210	0	0	0	321	0	0	0	0	0	0	531
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	26	0	0	0	0	0	0	0	0	0	108	134
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	31	31
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	160	0	0	0	0	0	0	0	0	0	0	160
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	63	63
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	1015	500	0	0	0	0	0	0	0	0	900	851	1400	4666
7.z. TOTAL	1903	812	29764	49	186	9	4673	0	1229	832	1454	851	7254	49016

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	700	0	29744	43	186	9	4072	0	1229	832	494	0	6675	43984
8.b. Products/substances used or intended to be used mainly in agriculture	750	200	150	0	0	0	0	0	0	0	0	326	48	1474
8.c. Products/substances used or intended to be used mainly in industry	50	138	150	0	0	0	0	0	0	0	900	0	0	1238
8.d. Products/substances used or intended to be used mainly in the household	0	0	18	15	0	3	0	0	0	0	0	0	0	36
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	215	0	0	0	0	0	0	0	0	0	60	525	0	800
8.i. Other toxicological or safety evaluations	188	174	0	0	0	0	590	0	0	0	0	0	532	1484
8.j. TOTAL	1903	512	30062	58	186	12	4662	0	1229	832	1454	851	7255	49016

DENMARK

Statistical data submitted

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

Comments of Danish authorities

An animal is included in the statistics when it is first used for experimental purposes. However, animals that have been used for experimental purposes over a period dating back to before 1 January 1999 are not included in the statistics for the reporting year.

As the following pages indicate, the total number of experimental animals used in 1999 was 323 444 (of which 29 018 were "other vertebrate animals", mainly fish). For many years the number of animals used for experimental purposes has remained constant at around 350 000 with only a few fluctuations, as, for example, in 1998, when the number fell to 290 590. This sudden reduction could be regarded as a random fluctuation, and this is borne out by the figures for 1997 and 1999 (380 322 and 323 444 animals, respectively).

In contrast to the situation in Denmark, the number of animals used in several other European countries has fallen significantly over the last two decades. According to the Animal Experiments Inspectorate (Dyreforsøgstilsynet), this difference is attributable to the fact that the Danish pharmaceuticals industry has stepped up its activities significantly in recent years, due in part to the launching of new companies. However, this increase in activity has not been accompanied by a corresponding increase in the number of animals used for experimental purposes. For instance, one large Danish pharmaceuticals company has informed the Animal Experiments Inspectorate that, over recent years, it has been able to conduct a substantial part of its development research through the use of newly developed, refined (alternative) methods, which significantly reduce the need for experimental animals. In the year 2000 the company expects to use about 70 000 experimental animals for development research. If the company had been forced to rely solely on the methods available in 1990, the number of experimental animals required in 2000 by this one company alone would have come to about 1 million.

In terms of numbers, the most significant fluctuation is in the use of mice and rats, which in 1999 stands at 260 544 animals, i.e. 81 %. Guinea-pigs and rabbits account for 16 974 animals in total (5%). The number of fish, totalling 28 741 (9%), is higher than in the two preceding years.

The numbers for animal species such as cats, dogs and monkeys have never been lower than in 1999 (44, 143 and 0 respectively, i.e. 0.6 per thousand collectively).

Apart from the total numbers involved, there are not many differences in the patterns of use of experimental animals compared with previous years. Changes in pattern that are worthy of special mention are the following. There has been a marked decline in basic biological tests involving experimental animals, from just under 100 000 to

66 797. At the same time, the use of experimental animals for research and development involving medical, odontological and veterinary products and articles has increased significantly from 102 823 in 1998 to 153 671 in 1999, although this latter figure reflects levels of use in previous years. Similarly, the use of experimental animals for toxicological and other safety assessments has risen from 14 573 in 1998 to 17 696 in 1999, which again is in line with patterns of use in previous years.

The number of animals used in experiments relating to diseases in humans and animals has risen significantly compared with previous years, involving a total of 195 666 animals, i.e. 60%. While levels of use in cases involving human cardiovascular diseases have more than halved, the use of experimental animals in the context of human nervous and mental disorders has risen sharply, and this is reflected in the case of other human diseases.

In the area of toxicology, it is worth pointing out that the number of animals used in connection with “other lethal methods” is continuing to decline. Similarly, the number of animals used in skin irritation and skin sensitisation tests is constantly falling. In 1999, 21 rodents were used in acute or subacute toxicity tests involving cosmetics or toiletries.

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*)	163680	161674	1527	118	361	
1.b. Rats (*Rattus norvegicus*)	96864	91881	4340	0	643	
1.c. Guinea-Pigs (*Cavia porcellus*)	10431	9148	1044	239	0	
1.d. Hamsters (*Mesocricetus*)	773	701	62	10	0	
1.e. Other Rodents (other *Rodentia*)	537					
1.f. Rabbits (*Oryctolagus cuniculus*)	6543	6049	494	0	0	435
1.g. Cats (*Felis catus*)	44	16	28	0	0	3
1.h. Dogs (*Canis familiaris*)	143	7	108	10	18	16
1.i. Ferrets (*Mustela putorius furo*)	20	20	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	1151					
1.k. Horses, donkeys and cross breds (*Equidae*)	85					
1.l. Pigs (*Sus*)	7192					
1.m. Goats (*Capra*)	111					
1.n. Sheep (*Ovis*)	140					
1.o. Cattle (*Bos*)	1476					
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*)	0	0	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	11					
1.u. Quail (*Coturnix coturnix*)	0	0	0	0	0	
1.v. Other birds (other *Aves*)	5225					
1.w. Reptiles (*Reptilia*)	10					
1.x. Amphibians (*Amphibia*)	267					
1.y. Fish (*Pisces*)	28741					
1.z. TOTAL	323444					

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	36250	84530	25432	315	7098	1507	868	7680	163680
2.b. Rats	17889	55990	8138	0	6510	6	1550	6781	96864
2.c. Guinea-Pigs	45	2317	3931	1003	2365	12	92	666	10431
2.d. Hamsters	100	653	0	0	10	0	10	0	773
2.e. Other Rodents	0	511	0	0	26	0	0	0	537
2.f. Rabbits	928	1153	1442	0	512	2093	163	252	6543
2.g. Cats	7	12	17	0	0	0	8	0	44
2.h. Dogs	14	47	3	0	69	0	0	10	143
2.i. Ferrets	20	0	0	0	0	0	0	0	20
2.j. Other Carnivores	521	29	0	582	0	19	0	0	1151
2.k. Horses, donkeys and cross breds	39	0	0	2	0	5	39	0	85
2.l. Pigs	3847	1742	16	368	557	9	541	112	7192
2.m. Goats	1	11	0	0	0	99	0	0	111
2.n. Sheep	139	0	0	1	0	0	0	0	140
2.o. Cattle	1164	52	0	40	0	12	63	145	1476
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	11	0	0	0	0	0	0	0	11
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	5019	44	23	10	0	91	0	38	5225
2.w. Reptiles	10	0	0	0	0	0	0	0	10
2.x. Amphibians	75	0	0	0	0	0	192	0	267
2.y. Fish	718	6580	0	0	549	0	172	20722	28741
2.z. TOTAL	66797	153671	39002	2321	17696	3853	3698	36406	323444

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	4643	0	1920	0	0	207	58	0	270	7098
3.b. Rats	2955	0	1120	0	14	892	755	0	774	6510
3.c. Guinea-Pigs	1991	0	200	23	0	0	0	0	151	2365
3.d. Hamsters	10	0	0	0	0	0	0	0	0	10
3.e. Other Rodents	0	0	0	0	0	0	26	0	0	26
3.f. Rabbits	420	0	33	3	0	0	0	0	56	512
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	69	0	0	0	0	0	0	0	0	69
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	553	0	0	0	0	0	0	0	4	557
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	0	0
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	0	0	0	0	0	549	0	549
3.z. TOTAL	10641	0	3273	26	14	1099	839	549	1255	17696

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	537	50006	18038	43260	5262	117103
4.b. Rats	680	38568	1325	20115	303	60991
4.c. Guinea-Pigs	0	961	0	1128	16	2105
4.d. Hamsters	0	0	0	704	0	704
4.e. Other Rodents	0	511	0	0	0	511
4.f. Rabbits	262	245	0	864	171	1542
4.g. Cats	0	19	0	0	0	19
4.h. Dogs	0	18	1	34	0	53
4.i. Ferrets	0	0	0	0	20	20
4.j. Other Carnivores	0	0	0	0	297	297
4.k. Horses, donkeys and cross breds	0	0	0	5	0	5
4.l. Pigs	285	170	4	683	2049	3191
4.m. Goats	2	0	0	9	0	11
4.n. Sheep	0	0	0	0	134	134
4.o. Cattle	0	0	0	0	99	99
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	44	1711	1755
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	46	0	46
4.y. Fish	0	0	0	500	6580	7080
4.z. TOTAL	1766	90498	19368	67392	16642	195666

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	162	75	0	0	24304	1206	25747
5.b. Rats	0	501	0	0	6564	1073	8138
5.c. Guinea-Pigs	1003	0	0	0	3931	0	4934
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	13	0	0	0	1115	314	1442
5.g. Cats	0	3	0	0	7	7	17
5.h. Dogs	0	0	0	0	0	3	3
5.i. Ferrets	0	0	0	0	0	0	0
5.j. Other Carnivores	0	582	0	0	0	0	582
5.k. Horses, donkeys and cross breds	0	0	0	0	2	0	2
5.l. Pigs	337	0	0	0	15	32	384
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	1	0	1
5.o. Cattle	36	0	0	0	4	0	40
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	21	0	0	12	0	33
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	1551	1182	0	0	35955	2635	41323

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	194	0	0	2586	4318	7098
6.b.	Rats	88	140	0	0	4387	1895	6510
6.c.	Guinea-Pigs	0	0	0	0	2253	112	2365
6.d.	Hamsters	0	0	0	0	10	0	10
6.e.	Other Rodents	0	0	0	0	26	0	26
6.f.	Rabbits	0	40	0	0	410	62	512
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	69	0	69
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	531	26	557
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	0	549	549
6.z.	TOTAL	88	374	0	0	10272	6962	17696

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	714	2992	0	0	0	410	143	0	145	452	0	2242	7098
7.b. Rats	0	704	962	0	0	0	1653	972	446	0	1507	0	266	6510
7.c. Guinea-Pigs	0	0	623	56	1600	0	0	0	0	0	0	0	86	2365
7.d. Hamsters	0	0	10	0	0	0	0	0	0	0	0	0	0	10
7.e. Other Rodents	0	26	0	0	0	0	0	0	0	0	0	0	0	26
7.f. Rabbits	0	0	49	57	0	18	126	0	0	0	134	0	128	512
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	6	0	0	0	54	0	0	0	0	0	9	69
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	194	6	0	0	335	0	0	0	0	0	22	557
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	549	0	549
7.z. TOTAL	0	1444	4836	119	1600	18	2578	1115	446	145	2093	549	2753	17696

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	656	3585	91	1345	0	1928	554	30	104	1230	0	1122	10645
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.c. Products/substances used or intended to be used mainly in industry	0	0	866	28	190	15	190	52	328	41	142	0	1414	3266
8.d. Products/substances used or intended to be used mainly in the household	0	0	23	0	0	3	0	0	0	0	0	0	0	26
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	21	0	0	0	0	0	0	0	0	0	0	21
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	270	0	0	0	320	509	0	0	0	0	0	1099
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	51	0	0	0	0	0	0	0	0	0	0	51
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	549	0	549
8.i. Other toxicological or safety evaluations	0	788	20	0	65	0	140	0	88	0	721	0	217	2039
8.j. TOTAL	0	1444	4836	119	1600	18	2578	1115	446	145	2093	549	2753	17696

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 official figures at the time of drafting this report refer to the year 1999. In this reporting period the number of the experimental animals increased by 58,822 animals to 1.591 million compared with the previous year. This means an increase of 3.8% vis-a-vis 1998. The rise is due in particular to the basic research as well as the development of diagnostics etc. Although it is difficult to draw detailed conclusions on the basis of the statistics, it is expected that the development of new diagnostics and gene-technological procedures could be a cause of the rise. The rise in the animal numbers could also be attributed to the increasing importance of the basic research. On the other hand, it has to be pointed out, that in the field of product-testing, for example for development of medicine products, the number of animals used continue to decrease since years.

The trends in animal use are different in individual categories; the largest decreases in 1999 with regard to the previous year concern guinea pigs (-7,8 %) and rabbits (21.7 %). In contrast to this, the experimental animal numbers have risen in particular for fish (29.6 %), birds (23 %) and mouse (1.8 %). The number of monkeys and pro-simians rose compared with the previous year by 21.8%. Also the number of dogs and cats rose in the reporting period. With regard to these numbers, it is to be born in mind, however, that in view of the small absolute numbers, a single large project can cause a significant increase. Great apes have no longer been used in Germany since 1991.

The numbers, kinds and sources of animals used in procedures during 1999 in Germany

	Total	From [1] breeding or user establ. registered within the Party	From [1] other Parties to the Convention	From [1] other sources	Re-used
Mice	775.932				
Rats	403.227				
Guinea pigs	42.891				
Golden hamsters [2]					
Other rodents	18.020				
Rabbits	50.623				428
Prosimians	271				0
New World Monkeys [3]					
Old World Monkeys [3]	1.813				123
Apes	0				
Dogs	6.031				213
Cats	1.124				31
Other carnivores	376				
Horses, donkeys and cross breds	657				
Pigs	10.494				
Goats and sheep	2.596				
Cattle	4.018				
Other mammals	660				
Quails [4]					
Other birds	92.792				
Reptiles	21				
Amphibians	5.915				
Fish	173.933				
Total	1.591.394				

[1] The Order of 1 August 1988 on the notification of vertebrates used in experiments does not provide the legal basis for collecting information on the sources of animals.

[2] Animals of this species are counted under "other rodents".

[3] New World and Old World Monkeys are counted together as "other simians".

[4] These Animals are not counted separately, but under "birds".

The number of animals used in procedures for selected purposes during 1999 in Germany

			Selected species		
		All species	Rodents and rabbits	Dogs and cats	Primates
1	Biological (including medical) studies of a fundamental nature	438.017	346.596	471	251
2	Research into, development and quality control (**including** safety evaluation) of products or appliances for human and veterinary medicine	643.423	620.878	4.611	1.484
3	Diagnosis of disease[1]	312.057	249.700	1.306	398
4	Protection of man, animals and the environment by toxicological or safety evaluation[2]	170.439	63.967	389	53
5	Education and training[3]				
6	Others				

[1] These data refer only to vertebrates used in procedures for research into or testing of methods of diagnosis, preventive or curative treatment.

[2] These data include - in a relatively low proportion - also animals, which have not been used for safety evaluations in the proper sense, but f. ex. for efficacy testing.

[3] The Animal Welfare Act of 1986 does not provide the legal basis to collect statistical information in this field

The number of animals used in procedures for selected purposes for the protection

of man, animals and the environment by toxicological or safety evaluationduring 1999 in Germany

(including safety evaluation of products or appliances

for human and veterinary medicine)[1]

			Selected species		
		All species	Rodents and rabbits	Dogs and cats	Primates
1	Substances used or intended to be used mainly in agriculture	46.673	31.755	233	38
2	Substances used or intended to be used mainly in households[1]	49.553	28.196	156	0
3	Substances used or intended to be used mainly as cosmetics or toiletries[1]				
4	Substances used or intended to be used mainly as additives in food for human consumption[1]				
5	Substances used or intended to be used mainly in industry which do not appear in rows 1, 2, 3 and 4 [1]				
6	Potential or actual hazards of contaminants in the general environment which do not appear in the other rows	74.213	4.016	0	15
7	Safety evaluation of products or appliances for human or veterinary medicine[1]				

[1] Information on this aspect is not collected separately.

The number of animals used in procedures

concerned with diseases and disorders[1]

during (year) in the Bundesrepublik Deutschland

			Selected species		
		All species	Rodents and rabbits	Dogs and cats	Primates
1	Human cancer (excluding evaluations of carcinogenic hazards)				
2	Cardiovascular human diseases				
3	Nervous and mental human disorders				
4	Other human diseases				
5	Animal diseases				

Note: When a procedure covers cancer under any item from 2 to 4, the cancer classification should take precedence

[1] If the type of human disease or disorder is not precisely known, the data should be entered in row 4

The number of animals used in procedures required by law

during 1999 in Germany

				Selected species		
			All species	Rodents and rabbits	Dogs and cats	Primates
1	Party only					
2	Other Parties and other States	Other Parties or member States				
		Other States				
3	Both (1 + 2): Party and other Parties/States		450.690	406.213	3.536	607
4	Total		450.690	406.213	3.536	607

Note: These data refer to statutory testing for notification or authorization of substances or products.

GREECE

Statistical data submitted

The statistical data have been submitted by the "*Ypoyrgeio Gevrgiaw, Gen. Diey/Nsh Kthniatrikhw*""" (Ministry of Agriculture, Veterinary Services).

Comments of Greek authorities

Experiments on vertebrate animals in Greece are governed by the following provisions:

(a) Law No 2015/92 (Government Gazette I 30) approving the European Convention on the Protection of Vertebrates used for Experimental and Other Scientific Purposes;

(b) Presidential Decree No 160/91 (GG I 64) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC.

In accordance with the above provisions:

- licences are issued to scientists who carry out experiments with animals (Articles 7 and 14 of Directive 86/609/EEC)

- establishments breeding and supplying animals for experiments are registered (Articles 15, 16, 19 and 21 of Directive 86/609/EEC).

1. ESTABLISHMENTS

Experiments are carried out at registered establishments, of which there are 21 in all.

These can be broken down as follows:

a)	Universities and university hospitals	7
b)	Hospitals	3
c)	Research institutes	5
d)	Pharmaceuticals companies	2
e)	Agricultural and veterinary laboratories	3
f)	Other research institutes	1

2. EXPERIMENTS

The total number of experiments conducted can be broken down as follows:

68.1% on human and animal diseases

2.1% on checking the quality of medicines, and of dental and veterinary products and equipment

1.72% on toxicological and other safety testing.

Animals are not used for the testing of cosmetics and detergents.

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*)	3566	3566				
1.b. Rats (*Rattus norvegicus*)	1900	1900				
1.c. Guinea-Pigs (*Cavia porcellus*)	240	240				
1.d. Hamsters (*Mesocricetus*)						
1.e. Other Rodents (other *Rodentia*)						
1.f. Rabbits (*Oryctolagus cuniculus*)	632	595			37	50
1.g. Cats (*Felis catus*)						
1.h. Dogs (*Canis familiaris*)	2				2	
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*)	65					
1.m. Goats (*Capra*)						
1.n. Sheep (*Ovis*)	1146					
1.o. Cattle (*Bos*)	209					
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*)	60				60	
1.v. Other birds (other *Aves*)	20					
1.w. Reptiles (*Reptilia*)						
1.x. Amphibians (*Amphibia*)	1840					
1.y. Fish (*Pisces*)						
1.z. TOTAL	9686					

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	1831	650	100			735	250		3566
2.b. Rats	450	253			148	493	556		1900
2.c. Guinea-Pigs						200	40		240
2.d. Hamsters									
2.e. Other Rodents									
2.f. Rabbits	305	8	18	17		119	165		632
2.g. Cats									
2.h. Dogs							2		2
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							6		6
2.l. Pigs						31	34		65
2.m. Goats									
2.n. Sheep	1088	19			20	15	4		1146
2.o. Cattle	139			8			62		209
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals									
2.u. Quail							60		60
2.v. Other birds						20			20
2.w. Reptiles									
2.x. Amphibians	200						1640		1840
2.y. Fish									
2.z. TOTAL	4013	930	118	25	168	1613	2819		9602

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										
3.b. Rats		72						10	66	148
3.c. Guinea-Pigs										
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits										
3.g. Cats										
3.h. Dogs										
3.i. Ferrets										
3.j. Other Carnivores										
3.k. Horses, donkeys and cross breds										
3.l. Pigs										
3.m. Goats		20								20
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		92						10	66	168

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	71	621	689	1785	50	3216
4.b. Rats	110	91	222	623	150	1196
4.c. Guinea-Pigs					240	240
4.d. Hamsters						
4.e. Other Rodents						
4.f. Rabbits	105		4	253	70	432
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs	15			16		31
4.m. Goats						
4.n. Sheep	19				1103	1122
4.o. Cattle					139	139
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					20	20
4.w. Reptiles						
4.x. Amphibians					200	200
4.y. Fish						
4.z. TOTAL	320	712	915	2677	1972	6596

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State **1)**	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation **2)**	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice							
5.b. Rats		160					160
5.c. Guinea-Pigs							
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits	10	25					35
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		8					8
5.p. Prosimians							
5.q. New World Monkeys							
5.r. Old World Monkeys							
5.s. Apes							
5.t. Other Mammals							
5.u. Quail							
5.v. Other birds							
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL	10	193					203

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							
6.b. Rats	148						148
6.c. Guinea-Pigs							
6.d. Hamsters							
6.e. Other Rodents							
6.f. Rabbits							
6.g. Cats							
6.h. Dogs							
6.i. Ferrets							
6.j. Other Carnivores							
6.k. Horses, donkeys and cross breds							
6.l. Pigs							
6.m. Goats							
6.n. Sheep		20					20
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	148	20					168

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														
7.b. Rats	84		64											148
7.c. Guinea-Pigs														
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits														
7.g. Cats														
7.h. Dogs														
7.i. Ferrets														
7.j. Other Carnivores														
7.k. Horses, donkeys and cross breds														
7.l.. Pigs														
7.m. Goats														
7.n. Sheep					20									20
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	84		64		20									168

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														
8.b. Products/substances used or intended to be used mainly in agriculture	20		52		20									92
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	54													54
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	10													10
8.i. Other toxicological or safety evaluations			12											12
8.j. TOTAL	84		64		20									168

SPAIN

Statistical data submitted

The Statistical data have been provided by the :"*Ministerio de Agricultura, Pesca y Alimentación, Subdirección General de Sanidad Animal*" (Ministry of Agriculture, Fisheries and Food, Directorate General of Livestock, Subdirectorate General of Animal Health).

Comments of Spanish authorities

No comments

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*)	261.301	187.840	70.008	985	2.468	0
1.b. Rats (*Rattus norvegicus*)	134.070	123.669	9.514	0	887	0
1.c. Guinea-Pigs (*Cavia porcellus*)	13.892	11.448	2.059	370	15	0
1.d. Hamsters (*Mesocricetus*)	674	559	40	0	75	0
1.e. Other Rodents (other *Rodentia*)	553	0	0	0	0	0
1.f. Rabbits (*Oryctolagus cuniculus*)	19.496	19.193	230	6	67	1.350
1.g. Cats (*Felis catus*)	1.080	1.080	0	0	0	7
1.h. Dogs (*Canis familiaris*)	725	522	197	0	6	83
1.i. Ferrets (*Mustela putorius furo*)	26	26	0	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breds (*Equidae*)	6	0	0	0	0	0
1.l. Pigs (*Sus*)	3.292	0	0	0	0	0
1.m. Goats (*Capra*)	100	0	0	0	0	0
1.n. Sheep (*Ovis*)	677	0	0	0	0	0
1.o. Cattle (*Bos*)	106	0	0	0	0	0
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	96	82	6	0	8	40
1.r. Old World Monkeys (*Cercopithecoidea*)	0	0	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*)	318	0	0	0	318	0
1.v. Other birds (other *Aves*)	18.709	0	0	0	0	0
1.w. Reptiles (*Reptilia*)	0	0	0	0	0	0
1.x. Amphibians (*Amphibia*)	255	0	0	0	0	0
1.y. Fish (*Pisces*)	20.350	0	0	0	0	0
1.z. TOTAL	475.726					

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	54.241	84.143	5.074	18.432	65.037	27.745	3.922	2.707	261.301
2.b. Rats	33.455	74.640	3.015	0	12.299	1.005	7.886	1.770	134.070
2.c. Guinea-Pigs	274	7.284	445	2.409	3.281	90	38	71	13.892
2.d. Hamsters	206	195	79	120	0	21	24	29	674
2.e. Other Rodents	130	106	0	0	0	0	136	181	553
2.f. Rabbits	730	4.713	454	3.744	5.066	3.375	961	453	19.496
2.g. Cats	8	43	16	7	0	0	0	1.006	1.080
2.h. Dogs	30	378	0	21	227	0	66	3	725
2.i. Ferrets	0	26	0	0	0	0	0	0	26
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	0	0	0	0	0	0	6	0	6
2.l. Pigs	319	1.468	0	584	339	62	349	171	3.292
2.m. Goats	0	0	0	0	0	100	0	0	100
2.n. Sheep	42	178	0	178	170	32	17	60	677
2.o. Cattle	0	36	0	0	49	0	21	0	106
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	31	54	0	0	11	0	0	0	96
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	0	0	0	0	0	0	0	0	0
2.u. Quail	288	0	30	0	0	0	0	0	318
2.v. Other birds	9.776	1.498	0	1.498	2.461	507	0	2.969	18.709
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	85	10	0	0	0	0	160	0	255
2.y. Fish	625	17.400	0	0	2.275	50	0	0	20.350
2.z. TOTAL	100.240	192.172	9.113	26.993	91.215	32.987	13.586	9.420	475.726

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	33.589	210	31	0	1.561	30	0	0	29.616	65.037
3.b. Rats	11.332	0	586	0	80	0	0	256	45	12.299
3.c. Guinea-Pigs	3.061	0	40	0	27	0	0	0	153	3.281
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	2.843	0	528	357	1.266	0	0	0	72	5.066
3.g. Cats	0	0	0	0	0	0	0	0	0	0
3.h. Dogs	227	0	0	0	0	0	0	0	0	227
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	339	0	0	0	0	0	0	0	0	339
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	170	0	0	0	0	0	0	0	0	170
3.o. Cattle	49	0	0	0	0	0	0	0	0	49
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	11	0	0	0	0	0	0	0	0	11
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	2.364	0	0	0	0	0	0	0	97	2.461
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	50	0	275	0	0	30	1.820	100	0	2.275
3.z. TOTAL	54.035	210	1.460	357	2.934	60	1.820	356	29.983	91.215

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	759	5.479	11.592	38.755	3.156	59.741
4.b. Rats	3.911	7.928	3.385	10.648	295	26.167
4.c. Guinea-Pigs	37	40	0	433	29	539
4.d. Hamsters	0	30	0	46	20	96
4.e. Other Rodents	0	89	0	53	100	242
4.f. Rabbits	260	2	2	365	118	747
4.g. Cats	0	8	0	0	0	8
4.h. Dogs	53	0	0	22	0	75
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	110	0	110
4.l. Pigs	153	1	0	290	428	872
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	46	22	68
4.o. Cattle	0	0	0	0	0	0
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	12	5	31	0	48
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	0	0
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	10	0	0	10
4.y. Fish	0	0	0	0	8.975	8.975
4.z. TOTAL	5.173	13.589	14.994	50.799	13.143	97.698

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	1.079	22.337	0	0	90	0	23.506
5.b. Rats	0	2.916	0	0	25	74	3.015
5.c. Guinea-Pigs	34	2.740	0	0	10	70	2.854
5.d. Hamsters	0	124	0	0	0	75	199
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	343	1.736	0	0	28	2.091	4.198
5.g. Cats	0	7	0	16	0	0	23
5.h. Dogs	0	21	0	0	0	0	21
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	122	408	0	0	0	54	584
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	166	0	0	12	0	178
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	30	0	0	0	0	30
5.v. Other birds	0	1.498	0	0	0	0	1.498
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	1.578	31.983	0	16	165	2.364	36.106

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	563	29.799	920	100	31.577	2.078	65.037
6.b.	Rats	200	10.073	34	0	1.905	87	12.299
6.c.	Guinea-Pigs	179	2.756	0	0	346	0	3.281
6.d.	Hamsters	0	0	0	0	0	0	0
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	451	3.428	0	79	886	222	5.066
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	32	50	0	0	119	26	227
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	339	0	0	0	0	339
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	49	0	0	72	49	170
6.o.	Cattle	0	0	0	0	49	0	49
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	5	0	0	0	6	11
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	2.461	0	0	0	0	2.461
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	100	150	0	0	275	1.750	2.275
6.z.	TOTAL	1.525	49.110	954	179	35.229	4.218	91.215

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	2.848	31.737	3.050	20	0	0	23.800	0	279	570	300	0	2.433	65.037
7.b. Rats	1.302	288	582	54	80	0	2.496	0	211	0	100	0	7.186	12.299
7.c. Guinea-Pigs	0	224	185	0	566	0	2.306	0	0	0	0	0	0	3.281
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	2.201	1.312	357	615	76	0	129	0	70	0	306	5.066
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	0	0	23	0	0	180	0	0	0	0	0	24	227
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	155	0	0	0	0	178	0	0	0	0	0	6	339
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	72	0	0	0	0	0	98	170
7.o. Cattle	0	0	0	0	0	0	49	0	0	0	0	0	0	49
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	11	0	0	0	0	0	0	11
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	2.461	0	0	0	0	0	0	2.461
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	425	0	0	0	0	0	0	0	0	0	0	0	1.850	2.275
7.z. TOTAL	4.575	32.404	6.018	1.409	1.003	615	31.629	0	619	570	470	0	11.903	91.215

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	2.089	3.186	5.919	74	346	160	31.532	0	508	360	470	0	9.853	54.497
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	210	0	0	0	210
8.c. Products/substances used or intended to be used mainly in industry	695	128	69	163	397	8	0	0	0	0	0	0	0	1.460
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	357	0	0	0	0	0	0	0	0	0	357
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	1.561	0	0	791	107	447	0	0	0	0	0	0	28	2.934
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	30	30
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	600	600
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	180	954	0	24	0	0	0	0	0	0	0	0	0	1.158
8.i. Other toxicological or safety evaluations	50	28.136	30	0	153	0	97	0	111	0	0	0	1.392	29.969
8.j. TOTAL	4.575	32.404	6.018	1.409	1.003	615	31.629	0	619	570	470	0	11.903	91.215

FRANCE

Statistical data submitted

The statistical data have been submitted by the "*Ministère de la Recherche*" (Ministry of Research).

Comments of the French authorities

In accordance with Articles 13 and 26 of Directive 86/609/EEC of 24 November 1986 on the protection of animals used for experimental and other scientific purposes, a statistical survey on the use of animals for experimental purposes during 1999 was made. The French statistical data, presented in standard form, has been sent to the European Commission by the Ministry for Research which is responsible for these studies.

The series of eight tables indicating the categories of information required, finalised by the Commission and the Member States' competent authorities, have been used for this purpose. It is worth recalling that these tables were used before in conducting the survey on 1997, as the French authorities were involved in testing the new harmonised structure on that occasion.

In methodological terms, an innovation compared with the preceding study was that establishments were asked to reply to the questionnaire, if they so wished, either on diskette in PC or Mac format, including tables with results formatted in an Excel software package, or by e-mail, the inbox being protected by a password. The latter system was greatly appreciated, since almost 20% of mailings (and replies) used this channel.

The analysis of these results leads to some comments.

- Between 1990 and 1999, i.e. in almost 10 years, the total number of animal vertebrates used for experiments fell by 37%, corresponding to an average decrease of 5% per annum.

- This decrease is more significant in private-sector establishments than in the public sector as regards the total number of animals used, which was 75.6% in 1997, falling to 61% in 1999.

- Rodents still provide the largest experimentation contingent. Although there was a reduction of 36% in the number used between 1990 and 1999, their weight in the total has notably increased. It was 90.8% in 1990 and reached 91.6% in 1999, with a notable net increase in the number of rodents used between 1997 and 1999 in public-sector laboratories.

- As regards rabbits, their number decreased by 56% between 1990 and 1999 but there was a significant increase in their use by public laboratories between 1997 and 1999.

- In 1999, the number of dogs used, which had fallen by 33% since 1990, rose between 1997 and 1999. Private establishments use them the most, even though public sector laboratories have significantly increased their requirements.

- The use of cats, with a decrease of 34% between 1990 and 1999, was similar as regards public sector laboratories.

- The number of primates used decreased by 26% between 1990 and 1999. After a decrease in their use of only 2% between 1993 and 1997, a further reduction in their use of 11% between 1997 and 1999 was recorded. As in 1997, no apes are used.

- The use of pigs has been decreasing steadily since 1993, with an average reduction of 11% per annum. In 1999, pigs represented 0.4% of vertebrates used, compared to 0.6% in 1993.

- The number of goats and sheep rose by 46% from 1997 to 1999. The annual average increase from 1990 to 1999 is 4%.

- The variations in the use of cows is similar to that recorded for goats and sheep. However, the increase between 1997 and 1999 is higher, reaching 90%. It rose on average by 3% between 1990 and 1999, with public sector laboratories being the largest users.

Finally, and as in the previous surveys, the Ministry for Research has deemed it necessary, to ensure transparency, to draw up a non-Community table, in order to take account of a particular category of animals, the use of which does not comply with the experiment definition in Article 2 of Directive 86/609/EEC. According to this Article, sacrificing an animal by a "humane" method (least painful method accepted by modern-day practices) with regard to removing cells, tissue or organs, does not constitute an experiment. This table shows that the number of animals put down by "humane" methods to implement *in vitro* studies remains significant: 255 089. There are clear differences between the two related types of use. Between 1997 and 1999, the use of vertebrates in "alternative methods to animal experiments" increased by 66%, whilst their use in "basic research" fell by 51%.

In a note dated 20 April 2001 our attention was drawn to the fact that some statistical survey tables on the use of laboratory animals in France in 1999 showed inconsistencies. Specifically, the totals of Tables 3, 6, 7 and 8 should have been identical to the total in column 2.6 of Table 2.

This was a known problem but, nevertheless it was decided to abide by the data supplied, in order to ensure transparency and because these data could be informative to the Commission and the competent authorities of the Member States.

There are two main reasons for these divergences:

1. In each table the respondent institutions had to indicate individual data (broken down by type of use and by species) and the corresponding totals. It was noted on a number of occasions that the sum of the individual data was different - usually lower - than the totals indicated. The basic reason seems to

be the fact that the person ordering the animals is not always the same as the person carrying out the experiments.

2. The system of checking coherence within this survey was based on exceptions. In other words, when results were recorded all tables that did not meet the coherence criteria were rejected for verification at the institutions concerned.

2.1 If upon verification at these institutions it appeared that they were unable to correct the data within an acceptable time span, the approach adopted was to respect the totals indicated. Accordingly, it is likely that the actual number of animals used is substantially lower (about 0.25%). This largely explains why the figures are slightly higher than those that should have appeared in the totals of Tables 3, 6, 7 and 8.

2.2 Moreover, if the replies came from a central animal house, the verification procedure was more complex because of the need to first identify the laboratory or laboratories using the joint service where the divergence originated and in some cases because of the difficulty of distinguishing animals ordered from animals used.

Finally, it should be noted that **the strongest margin of error noted between the dependent tables is 0.4%**. Of course it would have been preferable for this margin to be nil, but the data-collating procedure and the heterogeneity of the institutions in practice make such divergences unavoidable, however minor they may be.

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*)	1.552.330	1.469.187	5.153	953	77.037	
1.b. Rats (*Rattus norvegicus*)	460.407	452.908	729	0	6.770	
1.c. Guinea-Pigs (*Cavia porcellus*)	77.021	76.860	0	0	161	
1.d. Hamsters (*Mesocricetus*)	16.200	14.854	56	0	1.290	
1.e. Other Rodents (other *Rodentia*)	9.405					
1.f. Rabbits (*Oryctolagus cuniculus*)	49.836	48.202	1.597	0	37	1.717
1.g. Cats (*Felis catus*)	1.855	1.176	492	0	187	86
1.h. Dogs (*Canis familiaris*)	5.203	3.130	541	0	1.532	266
1.i. Ferrets (*Mustela putorius furo*)	190	76	0	0	114	0
1.j. Other Carnivores (other *Carnivora*)	169					
1.k. Horses, donkeys and cross breds (*Equidae*)	440					
1.l. Pigs (*Sus*)	8.897					
1.m. Goats (*Capra*)	1.839					
1.n. Sheep (*Ovis*)	4.455					
1.o. Cattle (*Bos*)	3.104					
1.p. Prosimians (*Prosimia*)	455	323	0	0	132	0
1.q. New World Monkeys (*Ceboidea*)	53	15	38	0	0	0
1.r. Old World Monkeys (*Cercopithecoidea*)	1.814	290	16	0	1.508	24
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	272					
1.u. Quail (*Coturnix coturnix*)	442	430	0	0	12	
1.v. Other birds (other *Aves*)	86.168					
1.w. Reptiles (*Reptilia*)	50					
1.x. Amphibians (*Amphibia*)	6.187					
1.y. Fish (*Pisces*)	22.805					
1.z. TOTAL	2.309.597					

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	366.493	541.115	318.644	250.072	38.646	3.191	14.509	19.660	1.552.330
2.b. Rats	106.582	266.242	17.028	0	55.933	320	13.174	1.128	460.407
2.c. Guinea-Pigs	1.769	13.660	30.857	23.919	6.349	53	275	139	77.021
2.d. Hamsters	3.800	2.137	0	6.102	221	0	72	3.868	16.200
2.e. Other Rodents	2.416	6.914	15	0	0	50	0	10	9.405
2.f. Rabbits	4.428	10.775	18.853	1.219	6.711	16	1.520	6.314	49.836
2.g. Cats	151	1.191	14	210	184	0	0	105	1.855
2.h. Dogs	20	2.220	0	410	2.486	0	67	0	5.203
2.i. Ferrets	20	164	0	6	0	0	0	0	190
2.j. Other Carnivores	134	25	0	10	0	0	0	0	169
2.k. Horses, donkeys and cross breds	200	85	55	42	46	0	12	0	440
2.l. Pigs	1.106	3.842	35	1.811	152	0	693	1.258	8.897
2.m. Goats	616	11	0	0	0	0	32	1.180	1.839
2.n. Sheep	3.121	502	0	217	244	0	4	367	4.455
2.o. Cattle	1.213	1.222	0	255	23	44	2	345	3.104
2.p. Prosimians	455	0	0	0	0	0	0	0	455
2.q. New World Monkeys	15	38	0	0	0	0	0	0	53
2.r. Old World Monkeys	239	72	519	0	957	0	4	23	1.814
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	2	0	0	0	270	0	0	0	272
2.u. Quail	430	0	0	0	0	0	0	12	442
2.v. Other birds	8.804	11.964	10.034	54.754	486	0	0	126	86.168
2.w. Reptiles	0	0	0	0	0	0	50	0	50
2.x. Amphibians	2.580	16	0	0	0	0	3.591	0	6.187
2.y. Fish	10.295	9.648	0	0	2.022	10	830	0	22.805
2.z. TOTAL	514.889	871.843	396.054	339.027	114.730	3.684	34.835	34.535	2.309.597

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	32.373	100	1.371	0	60	1.131	0	222	3.389	38.646
3.b. Rats	47.498	710	2.030	0	45	946	0	84	4.660	55.973
3.c. Guinea-Pigs	4.561	500	392	0	0	120	0	74	746	6.393
3.d. Hamsters	80	0	0	0	0	115	0	0	26	221
3.e. Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f. Rabbits	6.016	145	42	42	181	0	0	0	352	6.778
3.g. Cats	184	0	0	0	0	0	0	0	0	184
3.h. Dogs	2.434	0	0	0	0	0	0	0	52	2.486
3.i. Ferrets	0	0	0	0	0	0	0	0	0	0
3.j. Other Carnivores	10	0	0	0	0	0	0	0	0	10
3.k. Horses, donkeys and cross breds	46	0	0	0	0	0	0	0	0	46
3.l. Pigs	134	0	0	0	0	0	0	14	0	148
3.m. Goats	4	0	0	0	0	0	0	0	0	4
3.n. Sheep	239	20	0	0	0	0	0	5	0	264
3.o. Cattle	18	0	0	0	0	0	5	0	0	23
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	947	0	10	0	0	0	0	0	0	957
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	270	0	0	0	0	0	0	0	270
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	147	339	0	0	0	0	0	0	0	486
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	1.502	500	0	0	0	0	0	0	20	2.022
3.z. TOTAL	96.193	2.584	3.845	42	286	2.312	5	399	9.245	114.911

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	36.985	229.938	97.889	453.530	92.184	910.526
4.b. Rats	65.011	158.054	9.871	139.795	698	373.429
4.c. Guinea-Pigs	3.271	830	338	10.470	573	15.482
4.d. Hamsters	1.087	0	0	4.500	350	5.937
4.e. Other Rodents	520	6.767	0	1.593	500	9.380
4.f. Rabbits	5.898	6	95	7.502	1.714	15.215
4.g. Cats	0	19	0	186	1.137	1.342
4.h. Dogs	577	24	0	892	747	2.240
4.i. Ferrets	0	0	0	184	0	184
4.j. Other Carnivores	0	0	0	134	25	159
4.k. Horses, donkeys and cross breds	0	0	0	215	70	285
4.l. Pigs	1.338	4	11	881	2.190	4.424
4.m. Goats	0	0	0	537	90	627
4.n. Sheep	81	0	16	2.336	1.190	3.623
4.o. Cattle	0	0	0	1.512	967	2.479
4.p. Prosimians	0	0	0	455	0	455
4.q. New World Monkeys	0	50	0	3	0	53
4.r. Old World Monkeys	17	67	0	185	0	269
4.s. Apes	0	0	0	0	0	0
4.t. Other Mammals	0	0	0	2	0	2
4.u. Quail	0	160	0	270	0	430
4.v. Other birds	0	399	136	3.795	15.904	20.234
4.w. Reptiles	0	0	0	18	0	18
4.x. Amphibians	0	16	0	2.530	50	2.596
4.y. Fish	135	0	0	8.876	10.942	19.953
4.z. TOTAL	114.920	396.334	108.356	640.401	129.331	1.389.342

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	1.510	327.441	0	1.751	208.558	29.456	568.716
5.b.	Rats	0	3.219	0	4.490	7.864	1.455	17.028
5.c.	Guinea-Pigs	96	35.757	0	0	18.923	0	54.776
5.d.	Hamsters	0	6.102	0	0	0	0	6.102
5.e.	Other Rodents	15	0	0	0	0	0	15
5.f.	Rabbits	14	11.668	0	8	7932	450	20.072
5.g.	Cats	0	224	0	0	0	0	224
5.h.	Dogs	0	410	0	0	0	0	410
5.i.	Ferrets	0	0	0	0	6	0	6
5.j.	Other Carnivores	0	0	0	0	0	10	10
5.k.	Horses, donkeys and cross breds	55	42	0	0	0	0	97
5.l.	Pigs	0	1.846	0	0	0	0	1.846
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	0	217	0	0	0	0	217
5.o.	Cattle	0	255	0	0	0	0	255
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	519	0	0	0	0	519
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	64.210	0	578	0	0	64.788
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	1.690	451.910	0	6.827	243.283	31.371	735.081

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	950	3.455	0	8.582	21.107	4.512	38.606
6.b.	Rats	1.392	4.319	0	1.581	42.136	6.515	55.943
6.c.	Guinea-Pigs	0	941	0	424	3.974	1.084	6.423
6.d.	Hamsters	0	26	0	0	20	175	221
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	124	1.138	0	2.040	3.317	92	6.711
6.g.	Cats	0	24	0	0	160	0	184
6.h.	Dogs	12	20	0	3	2.348	103	2.486
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	46	0	0	0	0	46
6.l.	Pigs	4	79	0	14	55	0	152
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	57	0	0	187	0	244
6.o.	Cattle	0	23	0	0	0	0	23
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	40	877	40	957
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	270	270
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	70	134	0	0	0	282	486
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	0	20	0	500	0	1.502	2.022
6.z.	TOTAL	2.552	10.282	0	13.184	74.181	14.575	114.774

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	3.035	3.282	7.096	0	0	0	7.111	1.280	0	1.073	550	0	15.219	38.646
7.b. Rats	2.671	1.789	8.414	259	0	0	18.604	2.834	4.394	3.678	3.205	0	10.095	55.943
7.c. Guinea-Pigs	0	79	62	281	4.335	0	0	0	0	0	0	0	1.666	6.423
7.d. Hamsters	0	0	40	20	0	0	0	0	0	20	0	0	141	221
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	0	15	397	870	0	771	641	0	1.375	0	459	0	2.491	7.019
7.g. Cats	0	0	0	0	0	0	184	0	0	0	0	0	0	184
7.h. Dogs	0	0	341	95	0	0	1.699	0	0	0	0	0	351	2.486
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	6	0	0	0	0	0	0	0	0	0	0	6
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	22	0	0	0	0	0	18	40
7.l.. Pigs	0	0	8	0	0	0	20	0	39	0	0	0	85	152
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	20	20
7.n. Sheep	0	0	6	0	0	0	0	0	0	0	0	0	224	230
7.o. Cattle	0	0	0	0	0	0	12	0	0	0	0	0	5	17
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	7	49	0	0	0	901	0	0	0	0	0	40	997
7.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t. Other Mammals	270	0	0	0	0	0	0	0	0	0	0	0	0	270
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	269	0	133	0	0	0	84	0	0	0	0	0	0	486
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	1.502	112	0	0	0	100	0	100	0	100	100	40	2.054
7.z. TOTAL	6.245	6.674	16.664	1.525	4.335	771	29.378	4.114	5.908	4.771	4.314	100	30.395	115.194

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	3.542	5.158	14.733	904	2.827	567	26.338	5.754	4.026	4.225	3.359	0	25.482	96.915
8.b. Products/substances used or intended to be used mainly in agriculture	1.349	0	170	48	500	30	100	0	100	0	100	0	100	2.497
8.c. Products/substances used or intended to be used mainly in industry	172	0	0	252	142	0	1.249	0	550	56	0	0	1.424	3.845
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	42	0	0	0	0	0	0	0	0	0	42
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	60	45	100	120	81	0	0	0	0	0	0	20	426
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	288	736	179	0	0	0	260	0	0	0	0	0	729	2.192
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	38	180	0	137	0	0	274	629
8.i. Other toxicological or safety evaluations	0	720	1.500	179	746	93	1.219	0	0	0	0	0	4.119	8.576
8.j. TOTAL	5.351	6.674	16.627	1.525	4.335	771	29.204	5.934	4.676	4.418	3.459	0	32.148	115.122

IRELAND

Statistical data submitted

The 1999 statistical data for Ireland have been provided by the Department of Health and Children.

Comments of Irish authorities

General

- A total of 73,929 animals were used, this represents an increase of 7% from 1998.
- There were 456 valid licences during this period.
- 182 new licences were issued in 1999, this was a reduction of 27% in the number of licences issued the previous year.
- Rodents accounted for 63% 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, 66% (48,913) were bred in registered breeding establishments in Ireland.
- Commercial concerns accounted for 26% (19,165) of the animals used. This represents a reduction of 5% from 1998 in the commercial use of animals.
- Universities and Colleges accounted for 37% (27,507) of all animals used in scientific procedures.
- 58% of all procedures (49,922) used no anaesthesia, usually because the procedure was so minor that anaesthesia was inappropriate.
- 6% of animals (4,524) were used in procedures involving anaesthesia with permitted recovery (Certificate B).
- 691 genetically modified animals were used in experimental activity. This represents 1% of the total numbers used.

Animals Used for Selected Purposes

- 32% of animals (23,463) were involved in studies specific to animal diseases.
- 20,000 fish (over 99% of all fish used) were used in the regulatory monitoring of infection in farmed stocks.
- Of the 844 pigs used in 1999, 78% were involved in studies on animal diseases.

- 129 cats were used in total, 87% (112) of which were used in studies on feline disease.
- 312 dogs were used in 1999, of which 132 were used in studies on human disease.
- Approximately 10% of the animals were used for studies on human nervous and mental disorders.
- Education and training accounted for 2.5% 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 17% (12,347) of animals used. 97% of these tests were conducted to comply with legislation.
- 90% of the animals used in toxicological and other safety evaluations were mice.
- No animals were used to conduct LD_{50} or LC_{50} tests.

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

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (*Mus musculus*)	31251	29244	1851	0	156	
1.b. Rats (*Rattus norvegicus*)	14484	11940	2544	0	0	
1.c. Guinea-Pigs (*Cavia porcellus*)	1041	1041	0	0	0	
1.d. Hamsters (*Mesocricetus*)	133	6	108	0	19	
1.e. Other Rodents (other *Rodentia*)	0					
1.f. Rabbits (*Oryctolagus cuniculus*)	915	814	101	0	0	0
1.g. Cats (*Felis catus*)	129	129	0	0	0	12
1.h. Dogs (*Canis familiaris*)	312	304	0	8	0	93
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*)	192					
1.l. Pigs (*Sus*)	844					
1.m. Goats (*Capra*)	0					
1.n. Sheep (*Ovis*)	1472					
1.o. Cattle (*Bos*)	1862					
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*)	0	0	0	0	0	0
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	13					
1.u. Quail (*Coturnix coturnix*)	0	0	0	0	0	
1.v. Other birds (other *Aves*)	1229					
1.w. Reptiles (*Reptilia*)	0					
1.x. Amphibians (*Amphibia*)	0					
1.y. Fish (*Pisces*)	20052					
1.z. TOTAL	73929					

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	5700	2562	11142	380	11040	63	328	36	31251
2.b. Rats	6260	3158	4324	0	232	0	269	241	14484
2.c. Guinea-Pigs	0	0	388	124	484	9	36	0	1041
2.d. Hamsters	108	25	0	0	0	0	0	0	133
2.e. Other Rodents	0	0	0	0	0	0	0	0	0
2.f. Rabbits	301	15	348	120	116	2	4	9	915
2.g. Cats	20	92	0	0	17	0	0	0	129
2.h. Dogs	31	114	5	0	162	0	0	0	312
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	0	0	0	83	80	0	29	0	192
2.l. Pigs	129	16	0	6	6	539	18	130	844
2.m. Goats	0	0	0	0	0	0	0	0	0
2.n. Sheep	741	8	0	0	74	21	510	118	1472
2.o. Cattle	649	23	0	184	136	65	250	555	1862
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	0	0	0	0	0	0	0	0	0
2.r. Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	13	0	0	0	0	0	0	0	13
2.u. Quail	0	0	0	0	0	0	0	0	0
2.v. Other birds	100	320	0	12	0	12	0	785	1229
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	0	0	0	0	0	0	0	0	0
2.y. Fish	52	0	0	0	0	20000	0	0	20052
2.z. TOTAL	14104	6333	16207	909	12347	20711	1444	1874	73929

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	948	0	0	0	0	0	0	0	10092	11040
3.b. Rats	232	0	0	0	0	0	0	0	0	232
3.c. Guinea-Pigs	450	0	0	0	0	0	0	0	34	484
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	116	0	0	0	0	0	0	0	0	116
3.g. Cats	17	0	0	0	0	0	0	0	0	17
3.h. Dogs	162	0	0	0	0	0	0	0	0	162
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	80	0	0	0	0	0	0	0	0	80
3.l. Pigs	6	0	0	0	0	0	0	0	0	6
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	33	0	0	0	0	0	0	19	22	74
3.o. Cattle	136	0	0	0	0	0	0	0	0	136
3.p. Prosimians	0	0	0	0	0	0	0	0	0	0
3.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r. Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s. Apes	0	0	0	0	0	0	0	0	0	0
3.t. Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u. Quail	0	0	0	0	0	0	0	0	0	0
3.v. Other birds	0	0	0	0	0	0	0	0	0	0
3.w. Reptiles	0	0	0	0	0	0	0	0	0	0
3.x. Amphibians	0	0	0	0	0	0	0	0	0	0
3.y. Fish	0	0	0	0	0	0	0	0	0	0
3.z. TOTAL	2180	0	0	0	0	0	0	19	10148	12347

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	179	3352	1075	3082	637	8325
4.b. Rats	1024	3777	451	4097	69	9418
4.c. Guinea-Pigs	0	0	0	0	9	9
4.d. Hamsters	0	108	0	4	21	133
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	40	0	4	272	2	318
4.g. Cats	0	0	0	0	112	112
4.h. Dogs	26	0	0	106	13	145
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	0	0	0	22	662	684
4.m. Goats	0	0	0	0	0	0
4.n. Sheep	0	0	0	14	756	770
4.o. Cattle	0	0	0	0	737	737
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	13	13
4.u. Quail	0	0	0	0	0	0
4.v. Other birds	0	0	0	0	432	432
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	0	0	0	0	0	0
4.y. Fish	0	52	0	0	20000	20052
4.z. TOTAL	1269	7289	1530	7597	23463	41148

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	11522		0	0	0	11522
5.b. Rats	0	4324	0	0	0	0	4324
5.c. Guinea-Pigs	0	512	0	0	0	0	512
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	468	0	0	0	0	468
5.g. Cats	0	0	0	0	0	0	0
5.h. Dogs	0	0	0	0	0	5	5
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	80	0	0	0	3	83
5.l. Pigs	0	6	0	0	0	0	6
5.m. Goats	0	0	0	0	0	0	0
5.n. Sheep	0	0	0	0	0	0	0
5.o. Cattle	0	112	0	0	0	72	184
5.p. Prosimians	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	12	0	0	0	0	12
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	0	17036	0	0	0	80	17116

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	5522	0	8	5510	0	11040
6.b. Rats	0	0	0	0	0	232	232
6.c. Guinea-Pigs	0	450	0	0	0	34	484
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	116	0	0	0	0	116
6.g. Cats	17	0	0	0	0	0	17
6.h. Dogs	39	123	0	0	0	0	162
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	80	0	0	0	0	80
6.l. Pigs	0	6	0	0	0	0	6
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	28	24	0	0	0	22	74
6.o. Cattle	0	136	0	0	0	0	136
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	0	0	0
6.z. TOTAL	84	6457	0	8	5510	288	12347

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	10092	0	0	0	0	0	0	0	0	0	0	948	11040	
7.b. Rats	0	232	0	0	0	0	0	0	0	0	0	0	232	
7.c. Guinea-Pigs	0	0	0	450	0	0	0	0	0	0	0	34	484	
7.d. Hamsters	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	
7.f. Rabbits	0	0	0	0	0	0	0	0	0	0	0	116	116	
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	17	17	
7.h. Dogs	0	0	0	0	0	0	0	0	0	0	0	162	162	
7.i. Ferrets	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	
7.k. Horses, donkeys and cross breds	0	80	0	0	0	0	0	0	0	0	0	0	80	
7.l.. Pigs	0	6	0	0	0	0	0	0	0	0	0	0	6	
7.m. Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	
7.n. Sheep	0	9	0	0	0	0	0	0	0	41	0	24	74	
7.o. Cattle	0	112	0	0	0	0	0	0	0	0	0	24	136	
7.p. Prosimians	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	
7.r. Old World Monkeys	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	
7.t. Other Mammals	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	
7.v. Other birds	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	
7.x. Amphibians	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	0	0	
7.z. TOTAL	10092	439	0	450	0	0	0	0	0	41	0	1325	12347	

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	0	430	0	450	0	0	0	0	0	0	0	1334	2214
8.b. Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.c. Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d. Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f. Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	41	0	0	41
8.i. Other toxicological or safety evaluations	0	10092	0	0	0	0	0	0	0	0	0	0	0	10092
8.j. TOTAL	0	10092	430	0	450	0	0	0	0	0	41	0	1334	12347

ITALY

Statistical data submitted

The statistical data have been submitted by the "*Ministero della Sanita' Dipartiemento Alimenti, Nutrizione e della Sanità Pubblica Veterinaria*" (Ministry of Health, Directorate-General for Veterinary Public Health, Food and Nutrition).

Comments of Italian authorities

The collected data have been entered into the "*standard statistical tables"* agreed by the competent national authorities in the EU in 1997.

Generally speaking, they confirm the downward trend in the total number of animals used in experiments, which in 1999 fell below one million.

Species	1997	1998	1999	Diff. % 1997-1999
ALL	1 130 536	1 099 491	959 105	- 15.16 %

Details of the various species of animal:

Species	**1997**	**1998**	**1999**	**Diff. % 1997-1999**
RATS	688 145	579 479	491 966	- 28.5%
GUINEA PIGS	31 564	29 471	18 455	- 41.5%
OTHER RODENTS	2 782	5 372	2 428	
RABBITS	31 004	22 920	16 430	
CATS	263	89	29	
DOGS	897	876	745	
GOATS	45	206	41	
PROSIMIANS	--	103 (?)	--	
OTHER MAMMALS	24	70	25	
OTHER BIRDS	6 673	24 992	19 931	
REPTILES	910	1 739	1 410	

The tables also include data on animals used for in vitro studies (sacrificed for the removal of organs, tissue and cells), for teaching purposes and for diagnosis of human and animal diseases.

Mice and rats account for 92.4% of the animal species used.

Dogs, cats and simians represent 0.13% of all animals used, i.e. a fall of 26.9% since 1997. For details of the various species, see Annex 1.

88.58% of the animals are used in basic biological studies, the research and development of products and devices for human medicine, dentistry and veterinary medicine and the production and quality control of products and devices for human medicine and dentistry.

Annex I

2.1 Species	2.10 1997 Total	2.10 1999 Total	2. Percentage difference
2.a. Mice (Mus musculus)	356.887	394.310	10,49
2.b. Rats (Rattus norvegicus)	688.145	491.966	-28,51
2.c. Guinea pigs (Cavia porcellus)	31.564	18.455	-41,53
2.d. Hamsters (Mesocricetus)	2.957	3.565	20,56
2.e. Other rodents (other Rodentia)	2.782	2.428	-12,72
2.f. Rabbits (Oryctolagus cuniculus)	31.004	16.430	-47,01
2.g. Cats (Felis catus)	263	29	-88,97
2.h. Dogs (Canis familiaris)	897	745	-16,95
2.i. Ferrets (Mustela putorius furo)	8	16	100,00
2.j. Other carnivores (other Carnivora)	0	0	0,00
2.k. Horses, donkeys and cross-breds (Equidae)	31	20	-35,48
2.l. Pigs (Sus)	1.708	2.045	19,73
2.m. Goats (Capra)	45	41	-8,89
2.n. Sheep (Ovis)	415	612	47,47
2.m. Cattle (Bos)	182	542	197,80
2.p. Prosimians (Prosimia)	0	0	0,00
2.q. New World monkeys (Ceboidea)	27	50	85,19
2.r. Old World monkeys (Cercopithecoidea)	556	450	-19,06
2.s. Apes (Hominoidea)	0	0	0,00
2.t. Other mammals (other Mammalia)	24	25	4,17
2.u. Quail (Coturnix coturnix)	88	226	156,82
2.v. Other birds (other Aves)	6.673	19.931	198,68
2.w. Reptiles (Reptilia)	910	1.410	54,95
2.x. Amphibians (Amphibia)	1.725	2.164	25,45
2.y. Fish (Pisces)	3.645	3.645	0,00
2.z. TOTAL	**1.130.536**	**959.105**	**-15,16**

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*)	410788	390176	11768	773	8071	2437
1.b. Rats (*Rattus norvegicus*)	500625	491881	7356	204	1184	1527
1.c. Guinea-Pigs (*Cavia porcellus*)	18430	11388	70	6972	0	17
1.d. Hamsters (*Mesocricetus*)	2773	1639	0	0	1134	0
1.e. Other Rodents (other *Rodentia*)	629	459	160	0	10	32
1.f. Rabbits (*Oryctolagus cuniculus*)	19030	18711	10	0	309	739
1.g. Cats (*Felis catus*)	86	26	60	0	0	0
1.h. Dogs (*Canis familiaris*)	741	738	0	0	3	94
1.i. Ferrets (*Mustela putorius furo*)	16	4	12	0	0	0
1.j. Other Carnivores (other *Carnivora*)	0	0	0	0	0	0
1.k. Horses, donkeys and cross breds (*Equidae*)	20	20	0	0	0	15
1.l. Pigs (*Sus*)	1924	1691	233	0	0	6
1.m. Goats (*Capra*)	64	58	6	0	0	12
1.n. Sheep (*Ovis*)	477	469	3	0	5	142
1.o. Cattle (*Bos*)	518	421	94	0	3	3
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	62	59	2	0	1	73
1.r. Old World Monkeys (*Cercopithecoidea*)	450	25	163	0	262	100
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	25	0	25	0	0	0
1.u. Quail (*Coturnix coturnix*)	226	226	0	0	0	0
1.v. Other birds (other *Aves*)	15680	14759	380	0	541	0
1.w. Reptiles (*Reptilia*)	1410	1160	50	0	200	0
1.x. Amphibians (*Amphibia*)	2940	2497	0	0	443	20
1.y. Fish (*Pisces*)	3528	3154	0	0	374	0
1.z. TOTAL	980442	939561	20392	7949	12540	5217

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	147044	136132	47910	978	41229	15027	363	7798	396481
2.b. Rats	79135	110252	281652	1962	16901	439	2173	1598	494112
2.c. Guinea-Pigs	3903	1324	8908	10	2675	615	8	1031	18474
2.d. Hamsters	2245	1259	0	0	31	60	0	0	3595
2.e. Other Rodents	468	1680	0	0	0	280	0	0	2428
2.f. Rabbits	3104	6505	3826	174	1805	108	22	961	16505
2.g. Cats	14	0	4	0	11	0	0	0	29
2.h. Dogs	32	291	0	0	416	0	0	6	745
2.i. Ferrets	4	12	0	0	0	0	0	0	16
2.j. Other Carnivores	0	0	0	0	0	0	0	0	0
2.k. Horses, donkeys and cross breds	5	0	0	0	0	0	0	15	20
2.l. Pigs	415	466	0	171	52	4	92	849	2049
2.m. Goats	26	0	0	0	0	0	0	15	41
2.n. Sheep	156	93	0	35	27	56	30	223	620
2.o. Cattle	78	26	0	84	0	7	16	331	542
2.p. Prosimians	0	0	0	0	0	0	0	0	0
2.q. New World Monkeys	28	22	0	0	0	0	0	0	50
2.r. Old World Monkeys	6	70	56	0	317	0	0	1	450
2.s. Apes	0	0	0	0	0	0	0	0	0
2.t. Other Mammals	25	0	0	0	0	0	0	0	25
2.u. Quail	66	0	0	160	0	0	0	0	226
2.v. Other birds	3463	7048	0	3997	3785	40	0	1598	19931
2.w. Reptiles	1410	0	0	0	0	0	0	0	1410
2.x. Amphibians	2184	0	0	0	0	0	0	0	2184
2.y. Fish	2460	0	0	0	374	0	11	800	3645
2.z. TOTAL	246271	265180	342356	7571	67623	16636	2715	15226	963578

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	32102			678	0	9472	0	308	14412	57732
3.b. Rats	16672			200	98	66	187	44	4167	22911
3.c. Guinea-Pigs	940			0	0	0	0	0	1272	2650
3.d. Hamsters	31			0	0	0	0	0	0	31
3.e. Other Rodents	0			0	0	0	0	0	0	0
3.f. Rabbits	1917			12	0	0	0	11	317	2449
3.g. Cats	3			0	0	0	0	0	0	3
3.h. Dogs	380			0	0	0	0	0	36	416
3.i. Ferrets	0			0	0	0	0	0	0	0
3.j. Other Carnivores	0			0	0	0	0	0	0	0
3.k. Horses, donkeys and cross breds	0			0	0	0	0	0	0	0
3.l. Pigs	101			0	0	0	0	0	18	119
3.m. Goats	0			0	0	0	0	0	0	0
3.n. Sheep	27			0	0	0	0	0	0	27
3.o. Cattle	0			0	0	0	0	0	0	0
3.p. Prosimians	0			0	0	0	0	0	0	0
3.q. New World Monkeys	0			0	0	0	0	0	0	0
3.r. Old World Monkeys	292			0	0	0	0	0	24	317
3.s. Apes	0			0	0	0	0	0	0	0
3.t. Other Mammals	0			0	0	0	0	0	0	0
3.u. Quail	0			0	0	0	0	0	0	0
3.v. Other birds	3987			0	0	0	0	0	15	4002
3.w. Reptiles	0			0	0	0	0	0	0	0
3.x. Amphibians	0			0	0	0	0	0	0	0
3.y. Fish	240			0	0	0	0	0	22	614
3.z. TOTAL	56692			890	98	9538	187	363	20283	91271

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	8728	31020	58763	112714	5179	216404
4.b. Rats	10047	44607	8904	43042	336	106936
4.c. Guinea-Pigs	644	67	70	1194	596	2571
4.d. Hamsters	1144	420	12	53	60	1689
4.e. Other Rodents	0	1712	0	0	290	2002
4.f. Rabbits	1234	104	491	2906	183	4918
4.g. Cats	6	0	3	60	0	69
4.h. Dogs	65	30	122	312	0	529
4.i. Ferrets	0	0	12	4	0	16
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	49	8	8	241	45	351
4.m. Goats	2	0	0	0	0	2
4.n. Sheep	29	0	0	38	0	67
4.o. Cattle	2	0	0	0	7	9
4.p. Prosimians	0	0	0	0	0	0
4.q. New World Monkeys	0	22	0	0	0	22
4.r. Old World Monkeys	0	0	162	128	0	290
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	8	534	0	50	246	838
4.w. Reptiles	0	0	0	0	0	0
4.x. Amphibians	20	41	0	830	0	891
4.y. Fish	0	0	0	0	0	0
4.z. TOTAL	21978	78565	68547	161572	6942	337604

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	11422						
5.b. Rats	478						
5.c. Guinea-Pigs	2726						
5.d. Hamsters	0						
5.e. Other Rodents	0						
5.f. Rabbits	444						
5.g. Cats	65						
5.h. Dogs	0						
5.i. Ferrets	0						
5.j. Other Carnivores	0						
5.k. Horses, donkeys and cross breds	15						
5.l. Pigs	96						
5.m. Goats	0						
5.n. Sheep	111						
5.o. Cattle	87						
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	160						
5.v. Other birds	1070						
5.w. Reptiles	0						
5.x. Amphibians	70						
5.y. Fish	0						
5.z. TOTAL	16744	0	0	0	0	0	16744

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	6000	8539	0	0	11690	8228	34457
6.b.	Rats	357	1218	0	21	12423	57	14076
6.c.	Guinea-Pigs	1472	72	0	0	949	110	2603
6.d.	Hamsters	0	0	0	0	31	0	31
6.e.	Other Rodents	0	0	0	0	6	0	6
6.f.	Rabbits	99	265	0	0	1007	3	1374
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	384	0	384
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	18	34	0	0	0	0	52
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	19	0	0	0	0	19
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	317	0	317
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	775	0	0	0	0	775
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	374	240	614
6.z.	TOTAL	7946	10922	0	21	27181	8638	54708

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	1807	11340	4945	0	0	0	1678	2685	1725	861	274	0	14362	39677
7.b. Rats	1672	2553	3833	161	0	0	2840	1525	549	508	1369	0	1249	16259
7.c. Guinea-Pigs	60	19	1016	70	1412	0	0	0	0	0	0	0	37	2614
7.d. Hamsters	0	0	0	0	0	31	0	0	0	0	0	0	0	31
7.e. Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f. Rabbits	6	0	639	262	0	428	65	0	344	0	126	0	141	2011
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h. Dogs	0	19	106	0	0	0	264	0	0	0	0	0	27	416
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	18	0	0	0	0	0	0	0	0	0	34	52
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	19	19
7.o. Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r. Old World Monkeys	0	1	118	0	0	0	176	0	0	0	0	0	22	317
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	518	518
7.u. Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v. Other birds	0	0	3770	0	0	0	0	0	0	0	0	0	28	3798
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	350	0	0	0	0	0	0	0	0	0	0	0	386	736
7.z. TOTAL	3895	13932	14445	493	1412	459	5023	4210	2618	1369	1769	0	16823	66448

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	3074	9929	10269	347	934	245	4871	3820	1354	1496	1357	0	2113	39809
8.b.	Products/substances used or intended to be used mainly in agriculture	120	0	3960	0	40	0	0	0	0	0	0	0	1081	5201
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	106	207	0	6	86	6	0	0	570	55	410	0	60	1506
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	25	455	6	100	352	78	0	0	0	108	2	0	352	1478
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														
8.i.	Other toxicological or safety evaluations														
8.j.	TOTAL	3325	10591	14235	453	1412	329	4871	3820	1924	1659	1769	0	3606	47994

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

No comments

Remark:
Please note that only relevant EU tables containing data are included in this report. No 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*)	20		20			
1.c. Guinea-Pigs (*Cavia porcellus*)	20		20			
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	3060					

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		20							20
2.c. Guinea-Pigs		20							20
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	3060	0	0	0	0	0	0	3060

THE NETHERLANDS

Statistical data submitted

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

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.

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. In 2001, after a three years period, the functioning of these committees will be evaluated.

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.

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.

In 1999, for the creation of transgenic animals, 39,275 animals were used.

Collection of data

83 establishments (with 330 sub-units) completed the 1999 registration form.

These establishments can be categorized as follows:

a) Universities and university hospitals	16
b) Other hospitals, regional public health laboratories	5
c) Public health research institutes	9
d) Agricultural and veterinary research institutes	10
e) Other research institutes	4
f) Industries	27
g) Schools for vocational training	10
h) Miscellaneous	2

Up to 1999 data of animal experiment had to be registered in advance. Therefore, the degree of discomfort had to be estimated. However, as from 1999 a new system is in use which obliges licence holders to fill in the forms *after* the experiment has been performed.

This data collection system is based on

- the old system.

- additional national requirements, such as a breakdown of the nature of the animals used: genetically modified, from the wild, other animals.

- the so called EU Tables to be used by the EU Members States to provide for data to be included in the European Commission’s report on animal experimentation to be sent to the European Parliament.

The killing of an animal without any previous intervention

In the Netherlands, if an animal is killed without any previous intervention in the framework of research or testing, e.g. for organ/blood collection, the killing 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. In 1999, 63,920 animals were killed without previous intervention.

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.

Total number of animals used

In 1999, according to the EU Tables, the total number of animals used was 621,466.

Discomfort and pain prevention

General

As mentioned before, 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 will be exchanged and discussed to promote consensus of opinion.

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*)	277774	242358			35416	
1.b. Rats (*Rattus norvegicus*)	159758	139179			20579	
1.c. Guinea-Pigs (*Cavia porcellus*)	10246	5557			4689	
1.d. Hamsters (*Mesocricetus*)	4661	4344			317	
1.e. Other Rodents (other *Rodentia*)	606					
1.f. Rabbits (*Oryctolagus cuniculus*)	9222	6512			2710	196
1.g. Cats (*Felis catus*)	222	188			34	25
1.h. Dogs (*Canis familiaris*)	803	503			300	173
1.i. Ferrets (*Mustela putorius furo*)	64	64				5
1.j. Other Carnivores (other *Carnivora*)	64					
1.k. Horses, donkeys and cross breds (*Equidae*)	219					
1.l. Pigs (*Sus*)	12299					
1.m. Goats (*Capra*)	334					
1.n. Sheep (*Ovis*)	3121					
1.o. Cattle (*Bos*)	1457					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	42	32			10	35
1.r. Old World Monkeys (*Cercopithecoidea*)	272	166			106	175
1.s. Apes (*Hominoidea*)	6	6				1
1.t. Other Mammals (other *Mammalia*)	45					
1.u. Quail (*Coturnix coturnix*)	4738				4738	
1.v. Other birds (other *Aves*)	88085					
1.w. Reptiles (*Reptilia*)	34					
1.x. Amphibians (*Amphibia*)	3186					
1.y. Fish (*Pisces*)	44208					
1.z. TOTAL	621466					

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	172635	56208	27418	6848	10762	2972	886	45	277774
2.b. Rats	58524	21971	47844	4579	23443	49	3348		159758
2.c. Guinea-Pigs	1256	1938	1201	928	4821	20	82		10246
2.d. Hamsters	557	4013	0	83	0	0	8		4661
2.e. Other Rodents	476	120				6	4		606
2.f. Rabbits	1227	3392	126	73	4271	13	120		9222
2.g. Cats	94	80	0	6	41	0	1		222
2.h. Dogs	208	195		38	332		30		803
2.i. Ferrets	53						11		64
2.j. Other Carnivores	64								64
2.k. Horses, donkeys and cross breds	38	126	38	10	0	0	7		219
2.l. Pigs	5935	4316	83	1471	336	41	117		12299
2.m. Goats	239	11					84		334
2.n. Sheep	319	2402	73	190	24	2	111		3121
2.o. Cattle	570	594	0	148	37		108		1457
2.p. Prosimians	0								0
2.q. New World Monkeys	16	19			7				42
2.r. Old World Monkeys	109	155	7		1				272
2.s. Apes	0	6							6
2.t. Other Mammals	34	11							45
2.u. Quail	0				4738				4738
2.v. Other birds	25448	51670	231	6387	3252	118	979		88085
2.w. Reptiles	0						34		34
2.x. Amphibians	3053				50		83		3186
2.y. Fish	23937				20067		204		44208
2.z. TOTAL	294792	147227	77021	20761	72182	3221	6217	45	621466

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	3487		1375			629		112	5159	10762
3.b. Rats	13212	41	6560			1758			1872	23443
3.c. Guinea-Pigs	1487	23	2880	16					415	4821
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	3759		504			6			2	4271
3.g. Cats	41									41
3.h. Dogs	332									332
3.i. Ferrets										0
3.j. Other Carnivores										0
3.k. Horses, donkeys and cross breds										0
3.l. Pigs	300								36	336
3.m. Goats										0
3.n. Sheep									24	24
3.o. Cattle	36								1	37
3.p. Prosimians										0
3.q. New World Monkeys	1								6	7
3.r. Old World Monkeys	1									1
3.s. Apes										0
3.t. Other Mammals										0
3.u. Quail		4738								4738
3.v. Other birds	322	2930								3252
3.w. Reptiles										0
3.x. Amphibians								50		50
3.y. Fish		342	5173					10519	4033	20067
3.z. TOTAL	22978	8074	16492	16	0	2393	0	10681	11548	72182

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	19566	3270	80267	70240	22159	195502
4.b. Rats	9604	17341	7443	32048	678	67114
4.c. Guinea-Pigs	20	150	100	1214	1376	2860
4.d. Hamsters	99	55	69	195	3818	4236
4.e. Other Rodents				120	0	120
4.f. Rabbits	437	33	82	2146	1580	4278
4.g. Cats	4	43		26	74	147
4.h. Dogs	96			96	198	390
4.i. Ferrets				53		53
4.j. Other Carnivores				0		0
4.k. Horses, donkeys and cross breds				28	82	110
4.l. Pigs	488		26	328	4932	5774
4.m. Goats	71		3	35		109
4.n. Sheep	53			2447	176	2676
4.o. Cattle				36	704	740
4.p. Prosimians						0
4.q. New World Monkeys		12		23		35
4.r. Old World Monkeys	1	2	14	214	0	231
4.s. Apes				6		6
4.t. Other Mammals				0	11	11
4.u. Quail					0	0
4.v. Other birds				28	59574	59602
4.w. Reptiles						0
4.x. Amphibians			132	3		135
4.y. Fish				0	637	637
4.z. TOTAL	30439	20906	88136	109286	95999	344766

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	150	28034		93	1515	4474	34266
5.b. Rats		397	150	132	50133	1611	52423
5.c. Guinea-Pigs	70	237	25	380	737	680	2129
5.d. Hamsters					83		83
5.e. Other Rodents							0
5.f. Rabbits		12	24	64	12	87	199
5.g. Cats					6	0	6
5.h. Dogs					26	12	38
5.i. Ferrets							0
5.j. Other Carnivores							0
5.k. Horses, donkeys and cross breds					0	48	48
5.l. Pigs		462			397	695	1554
5.m. Goats							0
5.n. Sheep		180				83	263
5.o. Cattle		115			0	33	148
5.p. Prosimians							0
5.q. New World Monkeys							0
5.r. Old World Monkeys					2	5	7
5.s. Apes							0
5.t. Other Mammals							0
5.u. Quail							0
5.v. Other birds		934			2874	2810	6618
5.w. Reptiles							0
5.x. Amphibians							0
5.y. Fish							0
5.z. TOTAL	220	30.371	199	669	55785	10538	97782

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		55			4096	6611	10762
6.b. Rats		684		419	19638	2702	23443
6.c. Guinea-Pigs					3453	1368	4821
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits		38			4231	2	4271
6.g. Cats					40	1	41
6.h. Dogs		52		45	231	4	332
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs		50				286	336
6.m. Goats							0
6.n. Sheep						24	24
6.o. Cattle		30				7	37
6.p. Prosimians							0
6.q. New World Monkeys					1	6	7
6.r. Old World Monkeys						1	1
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail					4738		4738
6.v. Other birds		287			2942	23	3252
6.w. Reptiles							0
6.x. Amphibians						50	50
6.y. Fish	3123	1309	260	482	3997	10896	20067
6.z. TOTAL	3123	2505	260	946	43367	21981	72182

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		340	1188		702		1226	1741		3372	717		1476	10762
7.b. Rats		1753	6588	587			1891		3820	130	7781		893	23443
7.c. Guinea-Pigs		128	186		4215		46						246	4821
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits		2	19	475	28	322					3260		165	4271
7.g. Cats			40										1	41
7.h. Dogs			242				78						12	332
7.i. Ferrets														0
7.j. Other Carnivores														0
7.k. Horses, donkeys and cross breds														0
7.l.. Pigs			60	6									270	336
7.m. Goats														0
7.n. Sheep			24											24
7.o. Cattle			37											37
7.p. Prosimians														0
7.q. New World Monkeys			7											7
7.r. Old World Monkeys			1											1
7.s. Apes														0
7.t. Other Mammals														0
7.u. Quail	356	24							4358					4738
7.v. Other birds	152								2790				310	3252
7.w. Reptiles														0
7.x. Amphibians			50											50
7.y. Fish	4754	627	2880				6205		2910				2691	20067
7.z. TOTAL	5262	2874	11322	1068	4945	322	9446	1741	13878	3502	11758	0	6064	72182

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

Types of tests versus products

8.1 Products	8.2 Acute and sub-acute toxicity testing methods (including limit test)			8.3 Skin irritation	8.4 Skin sensitisation	8.5 Eye irritation	8.6 Sub-chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop-mental toxicity	8.9 Muta-genicity	8.10 Repro-ductive toxicity	8.11 Toxicity to aquatic vertebra-tes not included in other columns	8.12 Other	8.13 Total
	8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine	12	80	3598	100	1509	275	1502	724	2166	0	11353		1659	22978
8.b. Products/substances used or intended to be used mainly in agriculture	496	36	29		23				7148				342	8074
8.c. Products/substances used or intended to be used mainly in industry	2876	1456	3517	959	2903	44	660		1458	1100			1519	16492
8.d. Products/substances used or intended to be used mainly in the household			16											16
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			735	3		3	947	330			195		180	2393
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	1878	627	2506				4570		28	112			960	10681
8.i. Other toxicological or safety evaluations		675	921	6	510		1767	687	3078	2290	210		1404	11548
8.j. TOTAL	5262	2874	11322	1068	4945	322	9446	1741	13878	3502	11758	0	6064	72182

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Statistical data submitted

The statistical data have been submitted by the "*Bundesministerien (Land und Forstwirtshaft, Umwelt und Wasserwirtschaft, Soziale Sicherheit und Generationen, Bildung, Wissenschaft und Kultur)*" Federal Ministries (Agriculture and Forestry, the Environment and Water Resources; Social Security and the Generations; Economic Affairs and Labour; Education, Science and Culture).

Comments of Austrian authorities

There is a clear further downward trend in the number of animal experiments and animals used for experimental purposes in Austria. The statistics on animal experiments for 1999 (the statistics are published each year for the previous year in accordance with the Animal Experiments Act) show that a total of 130 295 animals were used for experimental purposes in 1999, i.e. 26 953, or about 17%, fewer than in 1998 (157 248). For comparison: 1997 (168 696); 1993 (272 371) and 1992 (308 308). Compared with 1991 (the first year in which statistics were recorded), the number of animals used has been reduced by almost three-quarters: 482 166 animals were still being used for experimental purposes in that year.

Following the 1999 amendment to the Animal Experiments Act, BGBl. (*Federal Law Gazette*) No 169/1999, the statistics on animal experiments have for the first time been produced in standard EU format. The full animal experiment statistics, with the tables for the Federal Ministries (Agriculture and Forestry, the Environment and Water Resources; Social Security and the Generations; Economic Affairs and Labour; Education, Science and Culture) responsible for the implementation of the Animal Experiments Act are given on the homepage of the Federal Ministry for Education, Science and Culture under hap://www.bt_nbwk.gy.at/4fte/tierversuch/sta.99.htm.

The right trend in animal experiments

"This clear reduction in the numbers of animals used for experiments, a 73% reduction since 1991, is, " according to Science Minister, Elisabeth Gehrer, "due to at least two related courses of development in animal experiments":

The three Rs

Firstly the three Rs: reduction, refinement (improvement of scientific methods) and replacement (substitution of other scientific methods for experimental animals) by scientists, researchers and scientific workers themselves and efforts to use alternative methods as far as possible instead of experiments on animals, as specifically provided for in the Austrian Animal Experiments Act.

Note:

In addition, in November 1998, during the Austrian EU Presidency (the second half of 1998), the Ministry of Science held a widely-reported meeting on the

"Implementation of the 3 Rs - Targets in the EU, in science and industry", in cooperation with the Commission and with participants from all EU Member States and, for the first time, the East European candidate countries to support and promote the aims of the three Rs in the EU framework as well. One of the resolutions adopted at this meeting was forwarded to the EU Council of Ministers and the European Commission for further consideration. Special attention was recently drawn to Austria's initiatives for the recognition and implementation of methods at Community level to replace animal experiments at a follow-up meeting held last year in Berlin (during the German EU Presidency) and these initiatives have since been on the agenda at all EU discussions of animal experiments.

A restrictive approach and the promotion of alternative methods

Secondly, a restrictive approach is taken by all competent authorities as regards licences for animal experiments under Austria's strict Animal Experiments Act, which was refined even further last year and allows animal experiments only under very restrictive conditions and only if the experimental objectives cannot be achieved by other methods or processes (substitute methods).

Lastly, the government's pro-active approach, which includes competitions with national awards for research projects to find alternative methods and efforts to increase the use, both within Austria and abroad, of procedures to replace animal experiments, has also made scientists and researchers more aware of their responsibility in this area. The Ministry of Science has already spent over SCH 20 million in the last two years on research contracts to find substitutes for animal experiments.

Experimental animals mainly rats and mice

The total number of animals used for experimental purposes in 1999 in Austria was 130 295: 103 893 rats and mice; 15 056 rabbits; 670 farm animals (sheep, goats, pigs, cattle, etc.); 3 367 birds; 738 fish; 709 amphibians; 68 dogs and 24 cats.

Publication of

the Austrian Federal Ministry of Economic Affairs and Labour

(Line 30.581/5-III/A/9/2000);

the Austrian Federal Ministry for Social Security and the Generations

(Line 20.903/8-VIII/A/8/2000);

the Austrian Federal Ministry of Agriculture and Forestry, the Environment and Water Resources

(Line 12 4650/1-I/2U/200) and

the Austrian Federal Ministry for Education, Science and Culture

(Line 5436/7-Pr/S/2000)

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*)	91194	19280	64883	35	6996	
1.b. Rats (*Rattus norvegicus*)	12699	7657	4301	0	741	80
1.c. Guinea-Pigs (*Cavia porcellus*)	7367	1013	6354	0	0	
1.d. Hamsters (*Mesocricetus*)	208	0	208	0	0	
1.e. Other Rodents (other *Rodentia*)	188	38	0	150	0	
1.f. Rabbits (*Oryctolagus cuniculus*)	15056	1829	12482	0	745	614
1.g. Cats (*Felis catus*)	24	0	8	0	16	
1.h. Dogs (*Canis familiaris*)	68	33	21	0	14	73
1.i. Ferrets (*Mustela putorius furo*)	0	0	0	0	0	
1.j. Other Carnivores (other *Carnivora*)	0	0	0	0	0	
1.k. Horses, donkeys and cross breds (*Equidae*)	21	9	0	0	12	
1.l. Pigs (*Sus*)	366	59	69	0	238	
1.m. Goats (*Capra*)	23	18	0	0	5	
1.n. Sheep (*Ovis*)	142	88	26	0	28	
1.o. Cattle (*Bos*)	118	91	10	0	17	
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	
1.q. New World Monkeys (*Ceboidea*)	0	0	0	0	0	
1.r. Old World Monkeys (*Cercopithecoidea*)	7	7	0	0	0	
1.s. Apes (*Hominoidea*)	0	0	0	0	0	127
1.t. Other Mammals (other *Mammalia*)	0	0	0	0	0	
1.u. Quail (*Coturnix coturnix*)	50	50	0	0	0	
1.v. Other birds (other *Aves*)	1317	23	0	0	1294	60
1.w. Reptiles (*Reptilia*)	0	0	0	0	0	
1.x. Amphibians (*Amphibia*)	709	0	0	0	709	
1.y. Fish (*Pisces*)	738	83	0	0	655	
1.z. TOTAL	130295	30278	88362	185	11470	954

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	8561	42764	31713	0	4140	3657	118	241	91194
2.b. Rats	5499	3292	1446	0	1419	0	223	820	12699
2.c. Guinea-Pigs	129	482	5694	0	976	0	86	0	7367
2.d. Hamsters	0	208	0	0	0	0	0	0	208
2.e. Other Rodents	150	0	0	0	0	38	0	0	188
2.f. Rabbits	839	403	12974	0	758	0	82	0	15056
2.g. Cats	8	0	0	0	16	0	0	0	24
2.h. Dogs	0	54	0	0	0	0	14	0	68
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	0	0	0	0	0	9	12	0	21
2.l. Pigs	46	197	0	0	0	0	123	0	366
2.m. Goats	0	5	2	0	0	0	16	0	23
2.n. Sheep	42	58	12	10	0	0	14	6	142
2.o. Cattle	50	17	0	0	3	0	48	0	118
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	4	3	0	0	0	0	0	7
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	50	50
2.v. Other birds	1192	0	5	0	0	0	104	16	1317
2.w. Reptiles	0	0	0	0	0	0	0	0	0
2.x. Amphibians	709	0	0	0	0	0	0	0	709
2.y. Fish	83	0	0	0	655	0	0	0	738
2.z. TOTAL	17308	47484	51849	10	7967	3704	840	1133	130295

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	2995	0	350	0	0	0	0	0	795	4140
3.b. Rats	500	0	919	0	0	0	0	0	0	1419
3.c. Guinea-Pigs	35	0	941	0	0	0	0	0	0	976
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	433	0	325	0	0	0	0	0	0	758
3.g. Cats	0	0	0	0	0	0	0	0	16	16
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	0	0	0	0	0	0	0	0	0	0
3.l. Pigs	0	0	0	0	0	0	0	0	0	0
3.m. Goats	0	0	0	0	0	0	0	0	0	0
3.n. Sheep	0	0	0	0	0	0	0	0	0	0
3.o. Cattle	0	0	0	0	0	0	0	0	3	3
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	400	0	0	0	0	255	0	655
3.z. TOTAL	3963	0	2935	0	0	0	0	255	814	7967

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	272	120	9326	11818	30	21566
4.b. Rats	546	1211	283	3960	0	6000
4.c. Guinea-Pigs	0	101	0	98	0	199
4.d. Hamsters	0	0	0	208	0	208
4.e. Other Rodents	0	0	0	0	0	0
4.f. Rabbits	153	0	10	174	0	337
4.g. Cats	0	0	0	0	16	16
4.h. Dogs	0	0	0	5	0	5
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	9	9
4.l. Pigs	152	0	4	78	0	234
4.m. Goats	4	0	0	3	0	7
4.n. Sheep	3	1	0	79	0	83
4.o. Cattle	2	0	0	0	10	12
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	7	0	7
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	7	0	0	801	0	808
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	0	0
4.z. TOTAL	1139	1433	9623	17231	65	29491

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	791	12643	0	0	18279	0	31713
5.b. Rats	444	0	0	0	1002	0	1446
5.c. Guinea-Pigs	306	3377	0	0	2011	0	5694
5.d. Hamsters	0	0	0	0	0	0	0
5.e. Other Rodents	0	0	0	0	0	0	0
5.f. Rabbits	184	12101	0	0	659	30	12974
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	2	0	0	0	0	0	2
5.n. Sheep	12	0	0	0	0	10	22
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	3	3
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	5	0	0	0	0	0	5
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	1744	28121	0	0	21951	43	51859

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	2180	0	0	1960	0	4140
6.b. Rats	0	490	0	0	929	0	1419
6.c. Guinea-Pigs	0	0	0	0	976	0	976
6.d. Hamsters	0	0	0	0	0	0	0
6.e. Other Rodents	0	0	0	0	0	0	0
6.f. Rabbits	0	381	0	0	377	0	758
6.g. Cats	0	16	0	0	0	0	16
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	0	0	0	0	0	0	0
6.l. Pigs	0	0	0	0	0	0	0
6.m. Goats	0	0	0	0	0	0	0
6.n. Sheep	0	0	0	0	0	0	0
6.o. Cattle	0	3	0	0	0	0	3
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	655	0	655
6.z. TOTAL	0	3070	0	0	4897	0	7967

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.**

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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	86	240	1695	0	0	0	0	0	0	510	0	0	1609	4140
7.b. Rats	598	373	230	0	0	0	156	0	0	12	0	0	50	1419
7.c. Guinea-Pigs	0	0	0	0	976	0	0	0	0	0	0	0	0	976
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	36	165	0	160	0	0	0	0	0	0	397	758
7.g. Cats	0	0	0	0	0	0	0	0	0	0	0	0	16	16
7.h. Dogs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.i. Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j. Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k. Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.l.. Pigs	0	0	0	0	0	0	0	0	0	0	0	0	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	3	0	0	0	0	0	0	0	0	0	0	3
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	400	0	0	0	0	0	0	0	0	0	0	255	0	655
7.z. TOTAL	1084	613	1964	165	976	160	156	0	0	522	0	255	2072	7967

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	66	450	1196	3	35	6	0	0	0	0	0	0	2056	3812
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	
8.c. Products/substances used or intended to be used mainly in industry	876	163	0	162	941	154	156	0	0	522	0	0	0	2974
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	
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	
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	
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	
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	112	0	0	0	0	0	0	0	0	0	0	255	0	367
8.i. Other toxicological or safety evaluations	30	0	768	0	0	0	0	0	0	0	0	0	16	814
8.j. TOTAL	1084	613	1964	165	976	160	156			522		255	2072	7967

PORTUGAL

Statistical data submitted

The statistical data have been submitted by the "*Ministério da Agricultura, Desenvolviementos 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. To reduce difficulties associated with the completion of the statistical tables and, in the process, to improve the quality of the future statistics, we are going to reword the guidelines as requested earlier by the bodies conducting experiments on animals.

2. Preparations are being made for further revision of Portugal's national legislation on the protection of animals used for experimental and other scientific purposes. In principle, the main changes to be made will be:

- to make it compulsory for all bodies using animals for the purposes in question to have a code of ethics;

- to change the membership of the advisory committee set up at national level to include new Ministries and replace the members who have left;

- to add a classification of the level of suffering caused to any animal.

3. We consider it necessary to lay down uniform criteria at Member State level for vocational training for researchers and laboratory technicians handling animals in order to bring credibility to this category of technicians and promote equivalence within the European Union.

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*)	26020	17024	1784	516	6696	
1.b. Rats (*Rattus norvegicus*)	8848	5534	3294		20	
1.c. Guinea-Pigs (*Cavia porcellus*)	2170	1457			713	
1.d. Hamsters (*Mesocricetus*)	1182	895			287	
1.e. Other Rodents (other *Rodentia*)	29				29	
1.f. Rabbits (*Oryctolagus cuniculus*)	806	532	3		271	70
1.g. Cats (*Felis catus*)						
1.h. Dogs (*Canis familiaris*)	94	74	20			59
1.i. Ferrets (*Mustela putorius furo*)						
1.j. Other Carnivores (other *Carnivora*)						
1.k. Horses, donkeys and cross breds (*Equidae*)	3					
1.l. Pigs (*Sus*)	546					
1.m. Goats (*Capra*)	138					
1.n. Sheep (*Ovis*)	700					
1.o. Cattle (*Bos*)	365					
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*)	301					
1.u. Quail (*Coturnix coturnix*)						
1.v. Other birds (other *Aves*)	267					
1.w. Reptiles (*Reptilia*)	110					
1.x. Amphibians (*Amphibia*)	79					
1.y. Fish (*Pisces*)	350					
1.z. TOTAL	42008					

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	8661	800	195	3503	4498	7248	461	654	26020
2.b. Rats	4015	3262			791	143	571	66	8848
2.c. Guinea-Pigs	9		20	573	45	331	25	1167	2170
2.d. Hamsters	1172						10		1182
2.e. Other Rodents	29								29
2.f. Rabbits	163	34	94	248	130	105	18	14	806
2.g. Cats									
2.h. Dogs	23		65				6		94
2.i. Ferrets									
2.j. Other Carnivores									
2.k. Horses, donkeys and cross breds							3		3
2.l. Pigs	292	24	134	90				6	546
2.m. Goats	114		4				20		138
2.n. Sheep	650		10	30			10		700
2.o. Cattle	354						10	1	365
2.p. Prosimians									
2.q. New World Monkeys									
2.r. Old World Monkeys									
2.s. Apes									
2.t. Other Mammals		301							301
2.u. Quail									
2.v. Other birds				124		41	60	42	267
2.w. Reptiles	110								110
2.x. Amphibians							78	1	79
2.y. Fish	350								350
2.z. TOTAL	15942	4421	522	4568	5464	7868	1272	1951	42008

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	886					3100	20	100	392	4498
3.b. Rats	641								150	791
3.c. Guinea-Pigs	15						30			45
3.d. Hamsters										
3.e. Other Rodents										
3.f. Rabbits	130									130
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										
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	1672					3100	50	100	542	5464

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			70	5425	508	6003
4.b. Rats	150	570	96	679		1495
4.c. Guinea-Pigs				225	9	234
4.d. Hamsters				1172	1467	2639
4.e. Other Rodents						
4.f. Rabbits				227	37	264
4.g. Cats	16					16
4.h. Dogs				47	23	70
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs			24	134		158
4.m. Goats				4		4
4.n. Sheep				10		10
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				43		43
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	166	570	190	7966	2044	10936

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		370			3503		3873
5.b. Rats							
5.c. Guinea-Pigs		15			573		588
5.d. Hamsters							
5.e. Other Rodents							
5.f. Rabbits		50			342		392
5.g. Cats							
5.h. Dogs							
5.i. Ferrets							
5.j. Other Carnivores							
5.k. Horses, donkeys and cross breds							
5.l. Pigs					90		90
5.m. Goats							
5.n. Sheep					30		30
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					124		124
5.w. Reptiles							
5.x. Amphibians							
5.y. Fish							
5.z. TOTAL		435			4662		5097

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

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

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

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

Regulatory requirements versus species

6.1 Species		6.2 National legislation specific to a single EC Member State **1)**	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation **2)**	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a.	Mice	500	3300			350	162	4312
6.b.	Rats					150		150
6.c.	Guinea-Pigs		15				30	45
6.d.	Hamsters							
6.e.	Other Rodents							
6.f.	Rabbits		130					130
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							
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	500	3445			500	192	4637

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.**

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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		3120	200							100		42	350	3812
7.b. Rats													150	150
7.c. Guinea-Pigs		30												30
7.d. Hamsters														
7.e. Other Rodents														
7.f. Rabbits						80							50	130
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														
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		3150	200			80				100		42	550	4122

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			200			80								
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		3150												
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										100				
8.i. Other toxicological or safety evaluations	42	500												
8.j. TOTAL	42	3650	200			80				100				

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

The amount of used animals has grown a little from the last year. One explanation to that according to the information from the Provincial State Offices is the development and increased use of gene technology. The amount of animals, mostly mice, can be quite large in a single study that develops a new strain with altered genes. The growth in animal numbers is indeed all due to the increase in the amount of mice.

- Table 1: The largest group is mice. Proportion of mice is about 39 % of all the animals. Fish are the second largest group (about 38 % of all the animals) and the third largest group is rats (about 14 % of all the animals). There was nine primates (Old World Monkey) used in 1999. Animals that were not used at all are cats, Prosimians, New World monkeys and apes.

- Table 2: Biological studies of a fundamental nature (2.2) are the major purposes of the experiments. The amount of animals used in biological studies of a fundamental nature is about 86 % compared to all animals used .

- Table 3: The number of animals used in toxicological and other safety evaluations is only <2 % of all animals used. There has been no testing for cosmetic or toiletries products (3.6) or for products used or intended to be used mainly as additives in food for human consumption (3.7).

- Table 4: About 90 % of the used animals are used in studies concerning human diseases or disorders. The most used animal in studies specific to animal diseases is fish.

- Table 5: The proportion of animals used because of EC legislation or European Pharmacopoeia requirements (5.3.) is 83 % of all the animals used in production and quality control of products and devices for human medicine and dentistry and for veterinary medicine.

- Table 6: The proportion of animals used with no regulatory requirements (6.7) is 49 % of all the animals used in toxicological and other safety evaluations.

- Table 7: Proportion of animals used in acute and sub-acute toxicity testing using lethal methods (7.2.1 and 7.2.2) is about 6 % of all the animals used in testing in toxicological and other safety evaluations.

- Table 8: Potential or actual contaminants in the general environment (8.h, 38 %) and products/substances or devices for human medicine and dentistry and for veterinary medicine (8.a, 46 %) are the largest groups that within most of the animals are being used in the field of toxicological and other safety evaluations.

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*)	89959	78490	10703		766	
1.b. Rats (*Rattus norvegicus*)	32519	21371	10688		460	
1.c. Guinea-Pigs (*Cavia porcellus*)	1737	109	1628			
1.d. Hamsters (*Mesocricetus*)	100		100			
1.e. Other Rodents (other *Rodentia*)	1663					
1.f. Rabbits (*Oryctolagus cuniculus*)	1686	1043	643			
1.g. Cats (*Felis catus*)	0					
1.h. Dogs (*Canis familiaris*)	104	55	49			17
1.i. Ferrets (*Mustela putorius furo*)	90	90				
1.j. Other Carnivores (other *Carnivora*)	1650					
1.k. Horses, donkeys and cross breds (*Equidae*)	93					
1.l. Pigs (*Sus*)	1163					
1.m. Goats (*Capra*)	38					
1.n. Sheep (*Ovis*)	439					
1.o. Cattle (*Bos*)	614					
1.p. Prosimians (*Prosimia*)	0					
1.q. New World Monkeys (*Ceboidea*)	0					
1.r. Old World Monkeys (*Cercopithecoidea*)	9				1	8
1.s. Apes (*Hominoidea*)	0					
1.t. Other Mammals (other *Mammalia*)	2148					
1.u. Quail (*Coturnix coturnix*)	62	62				
1.v. Other birds (other *Aves*)	5166					
1.w. Reptiles (*Reptilia*)	182					
1.x. Amphibians (*Amphibia*)	246					
1.y. Fish (*Pisces*)	88666					
1.z. TOTAL	228334					

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	76984	7118	2818	745	980	30	861	423	89959
2.b. Rats	22758	8103	94		771	20	720	53	32519
2.c. Guinea-Pigs	1284		346	51		1		55	1737
2.d. Hamsters		100							100
2.e. Other Rodents	1644						19		1663
2.f. Rabbits	867	586	122		68	1	28	14	1686
2.g. Cats									0
2.h. Dogs	45	13			36	10			104
2.i. Ferrets								90	90
2.j. Other Carnivores	1002							648	1650
2.k. Horses, donkeys and cross breds	73						20		93
2.l. Pigs	843	182	90				39	9	1163
2.m. Goats	38								38
2.n. Sheep	18	37	382					2	439
2.o. Cattle	530	78						6	614
2.p. Prosimians									0
2.q. New World Monkeys									0
2.r. Old World Monkeys	9								9
2.s. Apes									0
2.t. Other Mammals	2140							8	2148
2.u. Quail	39						23		62
2.v. Other birds	4467	646					53		5166
2.w. Reptiles	182								182
2.x. Amphibians	53						193		246
2.y. Fish	84977	516			465	947	761	1000	88666
2.z. TOTAL	197953	17379	3852	796	2320	1009	2717	2308	228334

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	203			253				476	48	980
3.b. Rats	771									771
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	53		9	6						68
3.g. Cats										0
3.h. Dogs	36									36
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								400	65	465
3.z. TOTAL	1063	0	9	259	0	0	0	876	113	2320

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	1647	5144	2962	23183	12	32948
4.b. Rats	2187	7874	1763	7211		19035
4.c. Guinea-Pigs	288			990	1	1279
4.d. Hamsters		100				100
4.e. Other Rodents						0
4.f. Rabbits	354	1		736		1091
4.g. Cats						0
4.h. Dogs		13			10	23
4.i. Ferrets						0
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	176		7	175		358
4.m. Goats				16		16
4.n. Sheep				55		55
4.o. Cattle				41	111	152
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	320			449	23	792
4.w. Reptiles				182		182
4.x. Amphibians				13		13
4.y. Fish				200	6113	6313
4.z. TOTAL	4972	13132	4732	33251	6270	62357

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

Regulatory requirements versus species

5.1 Species	5.2 National legislation specific to a single EC Member State **1)**	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation **2)**	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a. Mice	54	3389				120	3563
5.b. Rats		94					94
5.c. Guinea-Pigs		356				41	397
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits		19				103	122
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					90		90
5.m. Goats							0
5.n. Sheep					382		382
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	54	3858	0	0	472	264	4648

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		48			203	253	504
6.b. Rats	101	150			520	476	1247
6.c. Guinea-Pigs							0
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits					68		68
6.g. Cats							0
6.h. Dogs		36					36
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					65	400	465
6.z. TOTAL	101	234	0	0	856	1129	2320

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		262	506				240						952	2940
7.b. Rats							1040				300		202	2313
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				12		18							106	204
7.g. Cats														0
7.h. Dogs							72							108
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											740	190		1395
7.z. TOTAL	0	393	759	18	0	27	2028	0	0	0	1560	285	1890	9280

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		83					676				150		154	1063
8.b. Products/substances used or intended to be used mainly in agriculture				3		6								9
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			253	3		3						65		324
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											370	30	476	876
8.i. Other toxicological or safety evaluations		48												48
8.j. TOTAL	0	131	253	6	0	9	676	0	0	0	520	95	630	2320

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 1999 to the EU commission was in June 2000, a much earlier date than previous years. This resulted in some problems when collecting and compiling our data. Most university researchers were prompt and submitted their reports in March, although some were as late as May despite several reminders from the National Board for Laboratory Animals (CFN). Unfortunately, three responsible researchers had to be warned by legal action over their failure to supply the required data on their animal experimentation. Hopefully, the collecting of statistical data from the universities will work smoother next year.

EU-Directive

According to the EU definition (Directive 86/609/EEC) the number of laboratory animals used during 1999 in Sweden reached approx. 324 000. This is a 7.6 % increase (about 23 000 animals) compared to 1998. The reasons behind this increase are hard to interpret and could be due to a number of factors including an increased input in biomedical research, more accurate reporting of the numbers of animals or simply just a natural fluctuation. The Swedish statistical record show that throughout the 1990s, three kinds of animals were predominantly used in animal experimentation, the mice, the rats and fish. Indeed, these three groups comprised about 90% of all laboratory animals used during 1999. The most noticeable change observed for 1999 was an increase in the number of mice, which were 27 000 individuals more than previous year. This probably reflects the increased use of transgenic mice in biomedical research. At the same time the number of rats used in animal experimentation decreased. The number of fish used also increased during 1999 compared to the previous year.

The Swedish statistical records also indicates that whereas the number of laboratory animals used by the biomedical companies remained the same as in 1998, the numbers used in university research increased over the same period.

Specific use of animals

As in previous years most laboratory animals were used in either fundamental biological research (51%) or in development of product/devices (41%) used in human or veterinary medicine. In 1999, 5% of the animals were used in toxicological research, and finally, less than 3 % of the total number of laboratory animals were used for diagnosing animal 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 whereas fish are mainly used in the evaluation of hazardous environmental substances.

Swedish definition

Apart from the information required according to the EU directive, 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 1999 about

228 000 animals were reported according to this definition. The dominating animals were fish and birds, the latter being mainly roosters in which the comb was used for extraction of hyaloronic acids.

Transgenic animals

The Swedish statistical records do not separate the use of transgenic animals from other laboratory animals. In agreement with EU directive, Sweden do 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.

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*)	184.230	125.871	56.866	0	1.493	
1.b. Rats (*Rattus norvegicus*)	84.374	51.120	32.564	0	690	
1.c. Guinea-Pigs (*Cavia porcellus*)	9.355	1.551	7.804	0	0	
1.d. Hamsters (*Mesocricetus*)	315	170	145	0	0	
1.e. Other Rodents (other *Rodentia*)	235					
1.f. Rabbits (*Oryctolagus cuniculus*)	5.031	4.459	572	0	0	6
1.g. Cats (*Felis catus*)	155	155	0	0	0	9
1.h. Dogs (*Canis familiaris*)	412	402	2	8	0	234
1.i. Ferrets (*Mustela putorius furo*)	132	126	0	0	6	0
1.j. Other Carnivores (other *Carnivora*)	75					
1.k. Horses, donkeys and cross breds (*Equidae*)	71					
1.l. Pigs (*Sus*)	3.278					
1.m. Goats (*Capra*)	6					
1.n. Sheep (*Ovis*)	104					
1.o. Cattle (*Bos*)	706					
1.p. Prosimians (*Prosimia*)	0	0	0	0	0	0
1.q. New World Monkeys (*Ceboidea*)	6	6	0	0	0	30
1.r. Old World Monkeys (*Cercopithecoidea*)	60	0	0	0	60	62
1.s. Apes (*Hominoidea*)	0	0	0	0	0	0
1.t. Other Mammals (other *Mammalia*)	353					
1.u. Quail (*Coturnix coturnix*)	0	0	0	0	0	
1.v. Other birds (other *Aves*)	6.920					
1.w. Reptiles (*Reptilia*)	10					
1.x. Amphibians (*Amphibia*)	1.585					
1.y. Fish (*Pisces*)	26.654					
1.z. TOTAL	324.067					

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	91617	78538	6484		3213	171	1463	2744	184230
2.b. Rats	45041	31979	15		3138	1517	1847	837	84374
2.c. Guinea-Pigs	1013	6651	1569				14	108	9355
2.d. Hamsters	238	65					12		315
2.e. Other Rodents	185	50							235
2.f. Rabbits	1862	1265	583		412	31	75	803	5031
2.g. Cats	96	8				51			155
2.h. Dogs	6	222			160		24		412
2.i. Ferrets	118	12				2			132
2.j. Other Carnivores	75								75
2.k. Horses, donkeys and cross breds							48	23	71
2.l. Pigs	1637	614	35				465	527	3278
2.m. Goats	6								6
2.n. Sheep	14	63						27	104
2.o. Cattle	144	50					414	98	706
2.p. Prosimians									0
2.q. New World Monkeys	6								6
2.r. Old World Monkeys	3	52	5						60
2.s. Apes									0
2.t. Other Mammals	353								353
2.u. Quail									0
2.v. Other birds	6097	733						90	6920
2.w. Reptiles	10								10
2.x. Amphibians	1585								1585
2.y. Fish	15854	1500			9210		90		26654
2.z. TOTAL	165960	121802	8691	0	16133	1772	4452	5257	324067

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	3129							84		3213
3.b. Rats	3073							65		3138
3.c. Guinea-Pigs										0
3.d. Hamsters										0
3.e. Other Rodents										0
3.f. Rabbits	412									412
3.g. Cats										0
3.h. Dogs	160									160
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			15	70	15			8110	1000	9210
3.z. TOTAL	6774	0	15	70	15	0	0	8259	1000	16133

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	12276	27852	28802	88384	1151	158465
4.b. Rats	11656	23807	5344	34908		75715
4.c. Guinea-Pigs	270	421		8527	15	9233
4.d. Hamsters	135			123		258
4.e. Other Rodents		50		173	12	235
4.f. Rabbits	559	340	524	1856	20	3299
4.g. Cats	51	48		56		155
4.h. Dogs	118	5		72	33	228
4.i. Ferrets	2	118		12		132
4.j. Other Carnivores						0
4.k. Horses, donkeys and cross breds						0
4.l. Pigs	782		3	998	178	1961
4.m. Goats						0
4.n. Sheep	63	7		1	6	77
4.o. Cattle					76	76
4.p. Prosimians						0
4.q. New World Monkeys		6				6
4.r. Old World Monkeys		3		57		60
4.s. Apes						0
4.t. Other Mammals					120	120
4.u. Quail						0
4.v. Other birds		2	75	3592	565	4234
4.w. Reptiles				10		10
4.x. Amphibians		25				25
4.y. Fish					4000	4000
4.z. TOTAL	25912	52684	34748	138769	6176	258289

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	274	825		110	4986	289	6484
5.b. Rats						15	15
5.c. Guinea-Pigs					1255	314	1569
5.d. Hamsters							0
5.e. Other Rodents							0
5.f. Rabbits					581	2	583
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						35	35
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						5	5
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	274	825	0	110	6822	660	8691

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	20			1245	1864	84	3213
6.b.	Rats					3073	65	3138
6.c.	Guinea-Pigs							0
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits				178	234		412
6.g.	Cats							0
6.h.	Dogs					160		160
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	7440					1770	9210
6.z.	TOTAL	7460	0	0	1423	5331	1919	16133

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.		647	1832				342			382			10	3213
7.b. Rats		237	1060				843		633		124		241	3138
7.c. Guinea-Pigs														0
7.d. Hamsters														0
7.e. Other Rodents														0
7.f. Rabbits				78					320				14	412
7.g. Cats														0
7.h. Dogs			80				64						16	160
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		1000	400						5400		270	2140		9210
7.z. TOTAL	0	1884	3372	78	0	0	1249	0	6353	382	394	2140	281	16133

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		884	2972	78			1249		953	382	124		281	6923
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												15		15
8.d. Products/substances used or intended to be used mainly in the household			50									20		70
8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries												15		15
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		1000	350						5400		270	2090		9110
8.i. Other toxicological or safety evaluations														0
8.j. TOTAL	0	1884	3372	78	0	0	1249	0	6353	382	394	2140	281	16133

UNITED KINGDOM

Statistical data submitted

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

Comments of United Kingdom authorities

Some 1.9 million animals were used for the first time in procedures started in 1999. This figure cannot be directly compared to previous years – see note below.

The statistical data for the United Kingdom were published in the UK in two separate reports – one for Great Britain and the other for Northern Ireland. Overall there was a decrease in the number of animals used for the first time in procedures regulated in the UK compared with use in 1998.

About one third of animals received 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.

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

4 in 5 procedures (80% of the total) were carried out on mice or rats.

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

Cold blooded animals (fish and amphibians) represented 7% of the total animal use.

Fundamental biological research, or applied studies in human medicine or dentistry, or veterinary medicine accounted for the use of 1.3 million animals – 68% of the total animal use.

Slightly less than 30% of the animals were used for toxicological or other safety evaluation, or for production and quality control of products and devices for human medicine, dentistry or veterinary medicine. The majority of that use (over 80%) was to fulfil European or other regulatory requirements.

No animals were used in 1999 for the purpose of evaluating the safety of either cosmetic products or cosmetic ingredients.

The use of animals for the production of monoclonal antibodies fell due to widespread use of the *in vitro* alternative to live animal use.

Note: Due to revisions in the method of collecting data, in 1999 the animal use submitted does NOT include those animals used for the breeding of genetically engineered (transgenic/mutant) animals, although those animals used to generate such strains are included.

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*)	990162	980612	3756	386	5408	
1.b. Rats (*Rattus norvegicus*)	526904	525316	443	30	1115	
1.c. Guinea-Pigs (*Cavia porcellus*)	61308	61193	89	26	-	
1.d. Hamsters (*Mesocricetus*)	10186	9686	-	500	-	
1.e. Other Rodents (other *Rodentia*)	8662					
1.f. Rabbits (*Oryctolagus cuniculus*)	27578	27511	54	-	13	802
1.g. Cats (*Felis catus*)	683	658	10	-	15	375
1.h. Dogs (*Canis familiaris*)	5938	5793	70	-	75	656
1.i. Ferrets (*Mustela putorius furo*)	1115	961	-	-	154	15
1.j. Other Carnivores (other *Carnivora*)	2896					
1.k. Horses, donkeys and cross breds (*Equidae*)	519					
1.l. Pigs (*Sus*)	9135					
1.m. Goats (*Capra*)	419					
1.n. Sheep (*Ovis*)	14462					
1.o. Cattle (*Bos*)	4841					
1.p. Prosimians (*Prosimia*)	-	-	-	-	-	-
1.q. New World Monkeys (*Ceboidea*)	1073	1036	-	-	37	165
1.r. Old World Monkeys (*Cercopithecoidea*)	2118	1786	-	-	332	164
1.s. Apes (*Hominoidea*)	-	-	-	-	-	-
1.t. Other Mammals (other *Mammalia*)	937					
1.u. Quail (*Coturnix coturnix)*	-	-	-	-	-	
1.v. Other birds (other *Aves*)	105931					
1.w. Reptiles (*Reptilia*)	56					
1.x. Amphibians (*Amphibia*)	9254					
1.y. Fish (*Pisces*)	121285					
1.z. TOTAL	1905462					

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	371162	206040	129261	21887	75818	8980	1807	175207	990162
2.b. Rats	165057	176418	15521	344	155088	664	2484	11328	526904
2.c. Guinea-Pigs	6492	14053	12195	2368	22391	112	168	3529	61308
2.d. Hamsters	4797	606	46	491	2324	1559	4	359	10186
2.e. Other Rodents	3681	4277	-	-	158	29	17	500	8662
2.f. Rabbits	6037	3034	3406	1055	10295	3240	132	379	27578
2.g. Cats	296	106	10	171	29	-	7	64	683
2.h. Dogs	218	1065	22	63	4479	31	-	60	5938
2.i. Ferrets	505	538	40	-	10	9	13	-	1115
2.j. Other Carnivores	2795	-	-	-	-	98	-	3	2896
2.k. Horses, donkeys and cross breds	155	241	-	2	3	91	6	21	519
2.l. Pigs	5019	564	6	1209	708	792	-	837	9135
2.m. Goats	309	18	1	-	3	15	-	73	419
2.n. Sheep	9034	942	92	681	221	1363	74	2055	14462
2.o. Cattle	2085	589	-	890	112	132	107	926	4841
2.p. Prosimians	-	-	-	-	-	-	-	-	-
2.q. New World Monkeys	239	276	-	-	550	-	-	8	1073
2.r. Old World Monkeys	100	102	36	-	1684	22	-	174	2118
2.s. Apes	-	-	-	-	-	-	-	-	-
2.t. Other Mammals	852	-	-	-	4	-	-	81	937
2.u. Quail	-	-	-	-	-	-	-	-	-
2.v. Other birds	30235	2304	521	11135	3786	3278	121	54551	105931
2.w. Reptiles	56	-	-	-	-	-	-	-	56
2.x. Amphibians	6797	41	-	-	795	-	1371	250	9254
2.y. Fish	47184	8632	-	11820	41640	310	2	11697	121285
2.z. TOTAL	663105	419846	161157	52116	320098	20725	6313	262102	1905462

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	37942	4050	5630	-	-	189	408	420	27179	75818
3.b. Rats	75663	28647	33687	341	-	2117	-	1702	12931	155088
3.c. Guinea-Pigs	5397	4597	10898	-	-	-	-	-	1499	22391
3.d. Hamsters	1267	871	-	-	-	-	-	-	186	2324
3.e. Other Rodents	-	-	-	-	-	-	-	158	-	158
3.f. Rabbits	4376	1359	4079	-	-	51	-	192	238	10295
3.g. Cats	29	-	-	-	-	-	-	-	-	29
3.h. Dogs	4042	357	3	-	-	-	-	-	77	4479
3.i. Ferrets	10	-	-	-	-	-	-	-	-	10
3.j. Other Carnivores	-	-	-	-	-	-	-	-	-	-
3.k. Horses, donkeys and cross breds	3	-	-	-	-	-	-	-	-	3
3.l. Pigs	646	-	-	-	-	-	-	-	62	708
3.m. Goats	-	3	-	-	-	-	-	-	-	3
3.n. Sheep	144	77	-	-	-	-	-	-	-	221
3.o. Cattle	49	57	-	-	-	6	-	-	-	112
3.p. Prosimians	-	-	-	-	-	-	-	-	-	-
3.q. New World Monkeys	484	-	-	-	-	-	-	-	66	550
3.r. Old World Monkeys	1678	-	-	-	-	-	-	-	6	1684
3.s. Apes	-	-	-	-	-	-	-	-	-	-
3.t. Other Mammals	-	-	-	-	-	-	-	4	-	4
3.u. Quail	-	-	-	-	-	-	-	-	-	-
3.v. Other birds	1267	2519	-	-	-	-	-	-	-	3786
3.w. Reptiles	-	-	-	-	-	-	-	-	-	-
3.x. Amphibians	-	-	-	-	-	-	-	795	-	795
3.y. Fish	510	5906	3128	-	-	-	-	31374	722	41640
3.z. TOTAL	133507	48443	57425	341	-	2363	408	34645	42966	320098

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	18963	156316	128378	561931	42723	908311
4.b. Rats	31956	176698	8755	222025	9178	448612
4.c. Guinea-Pigs	2083	7190	816	31812	2934	44835
4.d. Hamsters	134	1468	276	6761	605	9244
4.e. Other Rodents	69	4617	-	3736	6	8428
4.f. Rabbits	3065	809	181	16164	1554	21773
4.g. Cats	6	264	-	105	301	676
4.h. Dogs	935	70	35	4249	286	5575
4.i. Ferrets	157	493	-	452	-	1102
4.j. Other Carnivores	-	28	-	2865	-	2893
4.k. Horses, donkeys and cross breds	16	-	-	230	267	513
4.l. Pigs	728	100	29	5633	2236	8726
4.m. Goats	50	-	-	366	-	416
4.n. Sheep	212	517	32	10239	3264	14264
4.o. Cattle	143	-	-	2076	2442	4661
4.p. Prosimians	-	-	-	-	-	-
4.q. New World Monkeys	37	172	-	864	-	1073
4.r. Old World Monkeys	66	395	-	1633	-	2094
4.s. Apes	-	-	-	-	-	-
4.t. Other Mammals	68	22	-	762	-	852
4.u. Quail	-	-	-	-	-	-
4.v. Other birds	1718	7387	-	24929	69112	103146
4.w. Reptiles	-	24	-	32	-	56
4.x. Amphibians	530	354	358	5596	-	6838
4.y. Fish	18	883	-	48300	32060	81261
4.z. TOTAL	60954	357807	138860	950760	166968	1675349

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	10879	56470	27	1797	53835	33250	156258
5.b. Rats	1383	2613	-	252	6547	12845	23640
5.c. Guinea-Pigs	5721	5601	14	298	1625	1544	14803
5.d. Hamsters	-	-	376	21	115	108	620
5.e. Other Rodents	-	-	-	-	-	-	-
5.f. Rabbits	119	1901	200	198	831	1365	4614
5.g. Cats	-	165	-	-	12	4	181
5.h. Dogs	-	35	-	-	22	160	217
5.i. Ferrets	-	-	-	-	24	104	128
5.j. Other Carnivores	-	-	-	-	-	-	-
5.k. Horses, donkeys and cross breds	-	-	-	-	-	51	51
5.l. Pigs	50	170	5	-	708	291	1224
5.m. Goats	-	-	-	-	-	1	1
5.n. Sheep	169	266	-	-	92	371	898
5.o. Cattle	160	440	55	-	200	57	912
5.p. Prosimians	-	-	-	-	-	-	-
5.q. New World Monkeys	-	-	-	-	-	35	35
5.r. Old World Monkeys	-	-	-	12	-	24	36
5.s. Apes	-	-	-	-	-	-	-
5.t. Other Mammals	-	-	-	-	-	-	-
5.u. Quail	-	-	-	-	-	-	-
5.v. Other birds	65	3807	48	670	5678	1388	11656
5.w. Reptiles	-	-	-	-	-	-	-
5.x. Amphibians	-	-	-	-	-	-	-
5.y. Fish	-	2850	4690	-	4280	-	11820
5.z. TOTAL	18546	74318	5415	3248	73969	51598	227094

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	4905	9721	1129	3270	32646	24147	75818
6.b.	Rats	7013	13497	8516	15851	97605	12606	155088
6.c.	Guinea-Pigs	3447	3920	662	3500	9982	880	22391
6.d.	Hamsters	247	-	500	-	1506	71	2324
6.e.	Other Rodents	-	-	-	-	-	158	158
6.f.	Rabbits	1125	562	894	2329	5190	195	10295
6.g.	Cats	-	-	-	-	29	-	29
6.h.	Dogs	36	156	1284	44	2836	123	4479
6.i.	Ferrets	-	-	-	-	10	-	10
6.j.	Other Carnivores	-	-	-	-	-	-	-
6.k.	Horses, donkeys and cross breds	-	-	-	-	3	-	3
6.l.	Pigs	60	-	18	-	586	44	708
6.m.	Goats	-	-	-	-	3	-	3
6.n.	Sheep	17	110	-	-	89	5	221
6.o.	Cattle	26	64	4	-	18	-	112
6.p.	Prosimians	-	-	-	-	-	-	-
6.q.	New World Monkeys	-	-	192	-	357	1	550
6.r.	Old World Monkeys	-	299	605	1	729	50	1684
6.s.	Apes	-	-	-	-	-	-	-
6.t.	Other Mammals	-	-	-	-	-	4	4
6.u.	Quail	-	-	-	-	-	-	-
6.v.	Other birds	584	691	162	150	2135	64	3786
6.w.	Reptiles	-	-	-	-	-	-	-
6.x.	Amphibians	-	-	-	-	-	795	795
6.y.	Fish	4229	7437	2860	4832	8468	13814	41640
6.z.	TOTAL	21689	36457	16826	29977	162192	52957	320098

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	8328	1496	11086	-	2304	-	3528	6082	124	7104	801	-	34965	75818
7.b. Rats	5583	10698	38529	3	-	-	13337	4936	3420	5089	49477	-	24016	155088
7.c. Guinea-Pigs	-	332	627	89	17485	-	220	-	-	-	-	-	3638	22391
7.d. Hamsters	-	-	538	-	-	-	515	1029	-	-	-	-	242	2324
7.e. Other Rodents	-	-	-	-	-	-	-	-	-	-	-	-	158	158
7.f. Rabbits	-	110	563	3443	-	1910	630	-	2840	-	188	-	611	10295
7.g. Cats	-	-	-	-	-	-	-	-	-	-	-	-	29	29
7.h. Dogs	-	-	2515	-	-	-	1353	-	-	-	-	-	611	4479
7.i. Ferrets	-	-	-	-	-	-	-	-	-	-	-	-	10	10
7.j. Other Carnivores	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.k. Horses, donkeys and cross breds	-	-	3	-	-	-	-	-	-	-	-	-	-	3
7.l.. Pigs	-	30	130	-	-	-	-	-	-	-	-	-	548	708
7.m. Goats	-	-	-	-	-	-	-	-	-	-	-	-	3	3
7.n. Sheep	-	-	94	-	-	-	-	-	-	-	-	-	127	221
7.o. Cattle	-	-	10	-	-	-	-	-	-	-	-	-	102	112
7.p. Prosimians	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.q. New World Monkeys	-	-	226	-	-	-	184	-	-	-	-	-	140	550
7.r. Old World Monkeys	-	-	829	-	-	-	490	-	-	-	-	-	365	1684
7.s. Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.t. Other Mammals	-	-	-	-	-	-	-	-	-	-	-	-	4	4
7.u. Quail	1210	80	114	-	-	-	120	50	-	-	360	-	-	1934
7.v. Other birds	100	4	492	-	-	-	-	-	-	-	-		1256	1852
7.w. Reptiles	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.x. Amphibians	-	-	-	-	-	-	-	-	-	-	-	-	795	795
7.y. Fish	13692	9115	5570	-	-	-	968	-	-	-	8461	-	3834	41640
7.z. TOTAL	28913	21865	61326	3535	19789	1910	21345	12097	6384	12193	59287	-	71454	320098

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	1632	1992	39023	217	2050	214	15241	9306	5158	8165	22062	-	54126	159186
8.b. Products/substances used or intended to be used mainly in agriculture	4696	4920	6280	554	4889	534	2868	2173	342	791	14301	-	6095	48443
8.c. Products/substances used or intended to be used mainly in industry	3763	7879	11614	2731	11925	1138	1290	-	604	2816	13071	-	594	57425
8.d. Products/substances used or intended to be used mainly in the household	-	-	-	-	-	-	-	-	-	-	-	-	341	341
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	-	-	32	-	-	-	-	-	-	129	-	-	-	161
8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption	-	-	-	-	-	-	-	408	-	-	-	-	-	408
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	10622	6752	2618	-	-	-	968	-	-	-	8461	-	3142	32563
8.i. Other toxicological or safety evaluations	8200	322	1759	33	925	24	978	210	280	292	1392	-	7156	21571
8.j. TOTAL	28913	21865	61326	3535	19789	1910	21345	12097	6384	12193	59287	-	71454	320098