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PART I

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Annex to the:

**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT**

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

{COM (2007) 675 final}

TABLE OF CONTENTS

I.	INTRODUCTION	3
II.	DATA SUBMITTED AND GENERAL ASSESSMENT	4
II.1.	Data submitted by the Member States	4
II.2.	General assessment	4
II.3.	Structure of the Report	6
PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005		7
III.1.	Results of EU Table 1: <i>Species and number of animals</i>	7
III.2.	Results of EU Table 1: <i>Origin of animals used</i>	21
III.3.	Results of EU Table 2: <i>Purposes of the experiments</i>	25
III.4.	Results of EU Table 3: <i>Toxicological and safety evaluation by type of product/endpoints</i>	31
III.5.	Results of EU Table 4: <i>Animals used for studies of diseases</i>	35
III.6.	Results of EU Table 5: <i>Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine</i>	41
III.7.	Results of EU harmonized Table 6: <i>Origin of regulatory requirements for animals used in toxicological and other safety evaluations</i>	44
III.8.	Results of EU Table 7: <i>Animals used in toxicity test for toxicological and other safety evaluations</i>	48
III.9.	Results of EU Table 8: <i>Type of toxicity tests carried out for toxicological and other safety evaluations of products</i>	54

I. INTRODUCTION

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

The first two statistical reports published in 1994² and 1999³ covering data on experimental animals collected in 1991 and 1996 respectively provided a limited amount of statistical analysis due to the absence of a consistent system of reporting the data on the use of experimental animals in the Member States. In 1997 an agreement was reached between the competent authorities of the Member States and the Commission to submit data for the future reports under a format of eight harmonized tables. The third and the fourth statistical reports published in 2003⁴ and 2005⁵ covering data collected in 1999 and 2002 were based on these agreed harmonized tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. In spite of the progress made in the content of these two last statistical reports, it ought to be stressed that there were some inconsistencies in the data submitted by the Member States and also that in all cases except the report of 2003, one Member State collected data from another year.

This Fifth Statistical Report covers for the first time data collected by 25 Member States as a result of the accession of 10 new Member States in 2005. It gives an overview of the year 2005 with the exception of one Member State who reported data of 2004.

The Commission Staff Working Document accompanies the “Report from the Commission to the Council and the European Parliament – Fifth Report on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union”. The report summarizes the data and conclusions presented in this Staff Working Document.

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

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

All 25 Member States submitted the data in the agreed EU format.

Regarding the quality of data, in most cases, Member States have applied a quality control check on the set of data submitted for 2005. This exercise was the first for the 10 new Member States (EU 10), and in general the coherence of the data has greatly improved for the other Member States.

The quality check of the data submitted by the Member States is essentially governed by four criteria based on certain relationship between the data in the different tables.

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

For the present report it was generally considered that the quality criteria had sufficiently been respected to allow an analysis at European level of all eight EU tables.

II.2. General assessment

Each Member State is requested, pursuant to Articles 13 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. The data covers the year 2005 with the exception of France who reported on the year 2004. Malta has reported no animal use in 2005.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes⁶ 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 the Resolution in the report.

⁶ OJ C 331, 23.12.86, p. 2.

The first part of this report aims at providing a comprehensive overview on the numbers of animals used for various experimental purposes in the Community in 2005. The analysis will look at the purposes of the use of animals. Some of these purposes will be broken down further into more precise parameters. It will also look at the different legislative requirements regarding the use of experimental animals and also the type of testing carried out on the different species of animals. For the first time the analysis will cover all eight tables submitted by the Member States in 2005.

Because 10 new Member States are reporting data for the first time it will not be possible to draw conclusions on the evolution of the use of animals for experimental purposes in the EU by comparing data with those of the previous reports. However, some comparisons in trends will be attempted and significant changes in use will be highlighted in the report.

The number of animals used in the 10 new Member States (EU 10) represents 8,6% of the total number of animals used in the 25 Member States (EU 25). Therefore, when any of the categories reported in the different areas show a significant increase or decrease beyond the 8,6%, this will be highlighted in the report

In addition, in the first chapter of this report, Table 1bis with the data of EU 15 and Table 1tris with the data of EU 10 have been prepared to see the effects of the new Member States on the EU statistics. Furthermore, an attempt will be made to compare the results of the total number of animals used in 2005 within the “old” EU 15 with those submitted for the previous reports.

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

In the EU, the total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States amounts to 12,1 million (with data from France of 2004).

As in previous reports rodents together with rabbits represent almost 78% of the total number of animals used in the EU. Mice are by far the most commonly used species covering 53% of the total use, followed by rats with 19%.

The second most used group of animals was, as in previous years, cold-blooded animals representing 15%. The third biggest group of animals was birds with a little over 5% of the total use.

As in 2002, no Great Apes were used in experiments in the EU in 2005.

II.3. Structure of the Report

The report is divided into two parts:

- A A global compilation and overview for the European Union of the statistical data of the Member States for 2005.

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

Similarly to what happened in 2002, the complete data for 2005 include statistics from the year 2004 in France. Therefore, the totals used in this report are a mixture of years. Comparisons were nevertheless made on this basis since no other data were available.

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

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

PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005

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

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

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

Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by 25 Member States. Since the previous report of 2002, Table 1.1 includes the data on the number of animals used also in the 10 new Member States.

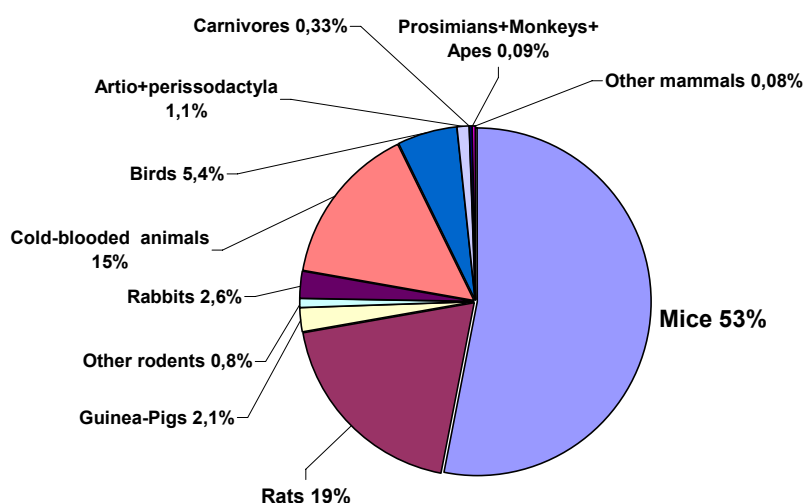
Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used in 2005 (France reporting for 2004) in the 25 Member States (EU 25) amounts to 12.1 million animals. It is important to note that the number of animals used in the 10 new Member States (EU 10) represents 8,6% of the total number of animals in the EU 25. This proportion will be used as the basis to highlight any changes in trends which significantly deviate from it.

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

In order to present an overall evaluation and subsequently a graphical analysis, animals were grouped in classes. The result of this exercise is presented in Table 1.2 at the end of this chapter. Table 1.2 is illustrated by Figure 1.1.

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



Rodents together with rabbits represent 77,5% of the total number of animals used. Within the rodents class, mice (53%) and rats (19%) are by far the most used species.

The second most used group is represented by cold-blooded animals with 15%.

Birds is the next highest animal group being used for experimental purposes with 5,4%

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

Carnivores represent 0,3% of the total number of animals used and non-human primates represent 0,1% of the animals used in 2005.

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

In this chapter, and the following chapters dealing with comparisons, the reader is invited to take note of the fact that in 1996, in 2002 and 2005 one Member State (France) has reported data respectively for 1997, for 2001 and 2004. Nevertheless, assuming that fluctuations in the annual numbers of animals used per species in a country are limited, it is possible to make semi-quantitative estimates of the observed trends by comparing changes in proportions of use, expressed in percent.

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

Class of species	1996(*)	1999	2002(**)	2005(***)
% Rodents-rabbits	81,3	86,9	78,0	77,5
% Cold-blooded animals	12,9	6,6	15,4	15,

% Birds		4,7	5	5,4
% Artio Perissodactyla		1,2	1,2	1,1

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

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

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

In overall, the percentages of rodents and rabbits show some fluctuation around 80%. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 10 to 15% but a much lower use of 6,6% was observed in 1999.

Birds representing the third largest percentage of animal used, varies between 4 to 5%. The group of artio and perissodactyla fluctuates around 1%.

The inclusion of the data of the new Member States (EU 10) should in principle increase the actual numbers of animals of each species with the magnitude of around 8,6%. However, the use of some species has decreased compared to the 2002 report. This is illustrated in Table 1.0 below.

Three other columns were included in Table 1.0 to show the change between 2002 and 2005 among EU 15, and to further analyse the changes in total numbers. More substantial overall changes have been highlighted and in particular any changes among EU 15 contrary to the overall change.

Table 1.0 : Changes in species number and proportion between 2002 and 2005

Species	Animal numbers in EU 25 2005	Animal numbers in EU 15 2002	Change since 2002	%change since 2002	Animal numbers in EU 15 2005	Change since 2002 in EU 15	%change since 2002 in EU 15
1.a Mice (<i>Mus musculus</i>)	64303 46	54597 29	9706 17	17,8	60388 46	57911 7	10,6
1.b Rats (<i>Rattus norvegicus</i>)	23360 32	23113 44	2468 8	1,1	21304 46	- 18089 8	-7,8
1.c Guinea-Pigs (<i>Cavia porcellus</i>)	25730 7	22633 9	3096 8	13,7	23318 0	6841	3,0
1.d Hamsters (<i>Mesocricetus</i>)	31535	52382	- 2084 7	- 39,8	30935	- 21447	- 40,9
1.e Other Rodents (other Rodentia)	64474	58827	5647	9,6	47451	- 11376	- 19,3
1.f Rabbits (<i>Oryctolagus cuniculus</i>)	31268 1	26767 5	4500 6	16,8	29315 6	25481	9,5
1.g Cats (<i>Felis catus</i>)	3898	3808	90	2,4	3624	-184	-4,8
1.h Dogs (<i>Canis familiaris</i>)	24119	21116	3003	14,2	22010	894	4,2
1.i Ferrets (<i>Mustela putorius furo</i>)	2690	2078	612	29,4	2512	434	20,1
1.j Other Carnivores	8711	3110	5601	180, 1	1734	-1376	- 44,2
1.k Horses, donkeys and cross breeds (<i>Equidae</i>)	5312	4677	635	13,6	4310	-367	-7,8
1.l Pigs (<i>Sus</i>)	66305	61164	5141	8,4	56657	-4507	-7,4
1.m Goats (<i>Capra</i>)	2146	3016	-870	- 28,8	1958	-1058	- 35,1
1.n Sheep (<i>Ovis</i>)	30021	30979	-958	-3,1	26840	-4139	- 13,4
1.o Cattle (<i>Bos</i>)	36271	26569	9702	36,5	21694	-4875	- 18,3
1.p Prosimians (<i>Prosimia</i>)	677	1095	-418	- 38,2	677	-418	- 38,2
1.q New World Monkeys (<i>Ceboidea</i>)	1564	1192	372	31,2	1564	372	31,2
1.r Old World Monkeys (<i>Cercopithecoidea</i>)	8208	8075	133	1,6	8151	76	0,9
1.s Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0

1.t Other Mammals (other Mammalia)	9950	3618	6332	175,0	4701	1083	29,9
1.u Quail (Coturnix coturnix)	9246	12984	-3738	-28,8	7212	-5772	-44,4
1.v Other birds (other Aves)	64981 3	52198 3	1278 30	24,5	44528 1	- 76702	- 14,7
1.w Reptiles (Reptilia)	2477	3168	-691	-21,8	853	-2315	-73,1
1.x Amphibians (Amphibia)	74620	59689	1493 1	25,0	59402	-287	-0,5
1.y Fish (Pisces)	17491 78	15864 03	1627 75	10,3	16271 03	40700	2,6
1.z TOTAL	12117 583	10731 020	1386 563	12,9	11070 299	33927 9	3,2

The total number of hamsters, goats, prosimians, quail and reptiles have all decreased from 40% to 22%.

The biggest percentual change has, however, been noted in the increase of the use of other carnivores. This increase is essentially due to the addition of data from the new Member States (see Table 1.0) although these species are not used in great numbers (from 3110 to 8711). This is further contrasted against a decrease in their use in EU 15. The other large increase both in EU 25 and also in EU 15 is for the use of other mammals (3618 to 9950).

One new Member State reported significant use of 'other carnivores', 'other mammals', cattle, 'other rodents', quails and horses, pigs and other birds, in comparison with other Member States. This was attributed to wildlife and environmental research studies in that specific geographical location, and testing in the areas of agricultural and animal breeding specific to that Member State. For further details see section B.

Among the other significant increases in the species used in greater numbers, one should mention the increase in the use of ferrets (29%), of cattle (36%), of other birds (25%) and of amphibians (25%). These increases, apart from ferrets, are all to be attributed to some of the new Member States.

The use of non-human primates remained as in previous reports at around 0,1% of the total number of animals used. However, by looking at the species, the number of prosimians used decreased by 38% while new world monkeys increased by 31%.

Member States reported that these changes may be attributed to changes in regulatory requirements for pharmaceuticals and in toxicological safety testing.

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

III.1.4. Comparison with the data of the previous reports for the EU 15

Since the total number of animals includes the data from the 10 new Member States it is not possible to draw a comparison *per se* with the results of the previous reports. However, to allow for some comparisons of trends of the animal use, separate Table 1 bis and 1 tris were drawn. Table 1 bis contains the data of EU 15 and Table 1 tris the data of EU 10 respectively.

In EU 15, the total number of animals used increased in 2005 by 339,279 which represents an increase of 3,1% with regard to 2002.

By examining the data by species, the major increase observed in 2005 is the additional use of about 579,000 mice (10,6%). However this increase of mice is partly compensated by a decrease of the number of rats, hamsters and other rodents used (36%). In 2005 there is also an increase of the number of rabbits used for experimental purposes (9,5%).

Among the other classes of animals, the use of ferrets for carnivores (20,8%) and the use of other mammals (30%) has increased. The changes in the use of non-human primates as explained in chapter III.1.3 are mostly results of changes in EU 15 as only 57 old world monkeys were used in EU 10 in 2005.

On the other hand, the use of all species, within the class of artio and perissodactyla have decreased in comparison to 2002. The same is observed with birds. Finally, one can observe a substantial decrease of 73% in the use of reptiles.

Further breaking down the category 'other', Member States reported use of the following species:

Other rodents: gerbils, old world jerboas (*Jaculus jaculus*); chinchilla, beaver, ground squirrel, hamsters, aremenio (*Cricetulus migratorius*) and different species of mice;

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

Other mammals: boars, bats and shrews, llama, mole, European bison and red deer;

Other birds: mainly coturnix japonica and bob-white quail, poultry species, and zebra finches, canary, parakeet, parrot and farmed avian species for example, (*Gallus gallus domesticus*)

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

Data of 2005 (*)

Species	AT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	IE	IT	LV	LT	LU	MT	NL
1.a. Mice	128634	488125	967	82252	1084358	208375	15340	393217	4350	1510334	138312	17776	534614	10480	5116	3280	0	240048
1.b. Rats	11920	106483	0	31703	435417	85664	6024	125754	484	424387	109479	7722	279774	2376	493	720	0	116608
1.c. Guinea-Pigs	3149	39530	0	4075	37761	5046	574	16780	0	79350	8360	4	11533	297	0	100	0	7479
1.d. Hamsters	117	1874	0	220	7916	402	0	908	0	8691	137	0	1537	0	0	0	0	5322
1.e. Other Rodents	107	2260	0	5798	7622	6381	40	294	0	12683	381	0	2303	0	0	0	0	3089
1.f. Rabbits	18439	21159	0	5567	103329	5805	1255	11878	66	93282	9152	379	9916	166	158	20	0	8251
1.g. Cats	12	81	0	29	1023	16	0	168	0	1313	124	119	30	0	0	0	0	334
1.h. Dogs	85	1295	0	264	4868	566	14	685	0	5539	1206	167	1064	0	0	0	0	1049
1.i. Ferrets	0	154	0	159	560	19	0	237	0	155	0	0	0	0	0	0	0	256
1.j. Other Carnivores	0	0	0	7	235	242	0	0	0	0	0	0	0	0	0	0	0	151
1.k. Horses, donkeys and cross breeds	71	108	0	314	755	62	1	42	0	223	6	189	63	0	0	0	0	1705
1.l. Pigs	818	1876	0	1392	13166	7697	448	4818	0	6587	882	382	2579	0	0	0	0	9853
1.m. Goats	44	157	0	56	275	199	0	119	0	442	2	0	20	0	0	0	0	328
1.n. Sheep	195	445	0	720	3517	156	99	821	0	4992	381	601	584	0	0	0	0	2667
1.o. Cattle	536	944	0	711	2909	489	0	294	0	1296	32	2109	1174	0	0	0	0	4410
1.p. Prosimians	0	0	0	0	99	0	0	0	0	578	0	0	0	0	0	0	0	0
1.q. N W Monkeys	0	0	0	0	408	0	0	1	0	433	0	0	17	0	0	0	0	50

1.r. O W Monkeys	56	449	0	51	1579	0	1	81	0	2778	6	0	395	0	0	0	0	277
1.s Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals	0	59	0	188	115	185	0	60	0	0	0	48	68	0	0	0	0	13
1.u. Quail	14	425	0	30	2457	0	0	1	0	4023	283	0	0	0	0	0	0	152
1.v. Other birds	1011	13266	0	126211	39150	7784	21	8424	0	102240	17151	2024	31697	0	0	0	0	111081
1.w. Reptiles	40	144	0	1475	136	54	0	10	0	0	25	0	378	0	0	0	0	7
1.x. Amphibians	865	6177	0	293	10432	840	975	419	0	15675	1709	0	4636	0	0	0	0	3231
1.y. Fish	1199	33965	0	69418	64337	35958	901300	30584	0	50397	9581	6420	14584	0	0	0	0	14838
1.z. TOTAL	167312	718976	967	330933	1822424	365940	926092	595597	4900	2325398	297209	37940	896966	13319	5767	4120	0	531199

(*) France reporting for 2004

Table 1.1 Bis: Total number of animals used for experimental purposes in the 15 EU Member States reporting before 2005

Data of 2005 (*)

Species	AT	BE	DE	DK	EL	ES	FR	IE	IT	LU	NL	PT	FI	SE	UK	T
1.a. Mice	128634	488125	1084358	208375	15340	393217	1510334	17776	534614	3280	240048	28318	120636	213727	1052064	6
1.b. Rats	11920	106483	435417	85664	6024	125754	424387	7722	279774	720	116608	6793	28358	83321	411501	2
1.c. Guinea-Pigs	3149	39530	37761	5046	574	16780	79350	4	11533	100	7479	379	563	2014	28918	1
1.d. Hamsters	117	1874	7916	402	0	908	8691	0	1537	0	5322	129	126	167	3746	1
1.e. Other Rodents	107	2260	7622	6381	40	294	12683	0	2303	0	3089	0	3187	1269	8216	1
1.f. Rabbits	18439	21159	103329	5805	1255	11878	93282	379	9916	20	8251	594	1214	2112	15523	1
1.g. Cats	12	81	1023	16	0	168	1313	119	30	0	334	0	0	220	308	1
1.h. Dogs	85	1295	4868	566	14	685	5539	167	1064	0	1049	36	103	1166	5373	1
1.i. Ferrets	0	154	560	19	0	237	155	0	0	0	256	0	80	47	1004	1
1.j. Other Carnivores	0	0	235	242	0	0	0	0	0	0	151	0	5	163	938	1
1.k. Horses, donkeys and crossbreeds	71	108	755	62	1	42	223	189	63	0	1705	8	125	650	308	1
1.l. Pigs	818	1876	13166	7697	448	4818	6587	382	2579	0	9853	113	1471	2722	4127	1
1.m. Goats	44	157	275	199	0	119	442	0	20	0	328	4	73	23	274	1
1.n. Sheep	195	445	3517	156	99	821	4992	601	584	0	2667	290	445	256	11772	1
1.o. Cattle	536	944	2909	489	0	294	1296	2109	1174	0	4410	45	455	727	6306	1
1.p. Prosimians	0	0	99	0	0	0	578	0	0	0	0	0	0	0	0	1
1.q. N W	0	0	408	0	0	1	433	0	17	0	50	0	0	12	643	1

Monkeys																
1.r. O W Monkeys	56	449	1579	0	1	83	2778	0	395	0	277	0	0	63	2472	
1.s. Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1.t. Other Mammals	0	59	115	185	0	60	0	48	68	0	13	1	972	639	2541	
1.u. Quail	14	425	2457	0	0	1	4023	0	0	0	152	0	0	0	140	
1.v. Other birds	1011	13266	39150	7784	21	8424	102240	2024	31697	0	111081	112	5773	7838	114860	4
1.w. Reptiles	40	144	136	54	0	10	0	0	378	0	7	0	0	0	84	
1.x. Amphibians	865	6177	10432	840	975	419	15675	0	4636	0	3231	51	20	5496	10585	
1.y. Fish	1199	33965	64337	35958	901300	30584	50397	6420	14584	0	14838	4748	93220	183049	192504	10
1.z. TOTAL	167312	718976	1822424	365940	926092	595597	2325398	37940	896966	4120	531199	41621	256826	505681	1874207	110

(*) France reporting for 2004

Table 1.1 Tris: Total number of animals used for experimental purposes in the 10 New EU Member States

Reporting for 2005

Species	CY	CZ	EE	HU	LV	LT	MT	PO	SI	SK	Totals
1.a. Mice (<i>Mus musculus</i>)	967	82252	4350	138312	10480	5116	0	126492	8556	14975	391500
1.b. Rats (<i>Rattus norvegicus</i>)	0	31703	484	109479	2376	493	0	51558	2732	6761	205586
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	0	4075	0	8360	297	0	0	10763	38	594	24127
1.d. Hamsters (<i>Mesocricetus</i>)	0	220	0	137	0	0	0	243	0	0	600
1.e. Other Rodents (other Rode)		5798	0	381	0	0	0	10826	18	0	17023
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	0	5567	66	9152	166	158	0	3101	533	782	19525
1.g. Cats (<i>Felis catus</i>)	0	29	0	124	0	0	0	121	0	0	274
1.h. Dogs (<i>Canis familiaris</i>)	0	264	0	1206	0	0	0	618	15	6	2109
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	159	0	0	0	0	0	19	0	0	178
1.j. Other Carnivores (other Carnivores)	0	7	0	0	0	0	0	6970	0	0	6977
1.k. Horses, donkeys and crossbred	0	314	0	6	0	0	0	681	1	0	1002
1.l. Pigs (<i>Sus</i>)	0	1392	0	882	0	0	0	7358	16	0	9648
1.m. Goats (<i>Capra</i>)	0	56	0	2	0	0	0	130	0	0	188
1.n. Sheep (<i>Ovis</i>)	0	720	0	381	0	0	0	2023	57	0	3181
1.o. Cattle (<i>Bos</i>)	0	711	0	32	0	0	0	13834	0	0	14577
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	0	0	0	0	0	0	0
1.r. Old World Monkeys	0	51	0	6	0	0	0	0	0	0	57

(Cercopithecoidea)											
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	188	0	0	0	0	0	5061	0	0	5249
1.u. Quail (Coturnix coturnix)	0	30	0	283	0	0	0	1470	0	251	2034
1.v. Other birds (other Aves)	0	126211	0	17151	0	0	0	61148	22	0	204532
1.w. Reptiles (Reptilia)	0	1475	0	25	0	0	0	121	3	0	1624
1.x. Amphibians (Amphibia)	0	293	0	1709	0	0	0	13216	0	0	15218
1.y. Fish (Pisces)	0	69418	0	9581	0	0	0	43076	0	0	122075
1.z. TOTAL	967	330933	4900	297209	13319	5767	0	358829	11991	23369	1047284

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

Data of 2005 (*)

Species	AT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	IE	IT	LV	L
Mice	128634	488125	967	82252	1084358	208375	15340	393217	4350	1510334	138312	17776	534614	10480	5
Rats	11920	106483	0	31703	435417	85664	6024	125754	484	424387	109479	7722	279774	2376	4
Guinea-Pigs	3149	39530	0	4075	37761	5046	574	16780	0	79350	8360	4	11533	297	
Golden hamsters + other rodents	224	4134	0	6018	15538	6783	40	1202	0	21374	518	0	3840	0	
Rabbits	18439	21159	0	5567	103329	5805	1255	11878	66	93282	9152	379	9916	166	1
Cold-blooded animals(1)	2104	40286	0	71186	74905	36852	902275	31013	0	66072	11315	6420	19598	0	
birds (2)	1025	13691	0	126241	41607	7784	21	8425	0	106263	17434	2024	31697	0	
Artio+Perissodactyla (3)	1664	3530	0	3193	20622	8603	548	0	0	13540	1303	3281	4420	0	
Carnivores (4)	97	1530	0	459	6686	843	14	1090	0	7007	1330	286	1094	0	
Prosimians+monk3115+eys+ apes	56	449	0	51	2086	0	1	84	0	3789	6	0	412	0	
Other Mammals	0	59	0	188	115	185	0	60	0	0	0	48	68	0	
Total	167312	718976	967	330933	1822424	365940	926094	595597	4900	2325398	297209	37940	896966	13319	57

Species% total	AT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	IE	IT	LV	L
Mice	76,88	67,89	100	24,85	59,50	56,94	1,66	66,02	88,78	64,95	46,54	46,85	59,60	78,68	88
Rats	7,12	14,81	0,00	9,58	23,89	23,41	0,65	21,11	9,88	18,25	36,84	20,35	31,19	17,84	8
Guinea-Pigs	1,88	5,50	0,00	1,23	2,07	1,38	0,06	2,82	0,00	3,41	2,81	0,01	1,29	2,23	0
Golden hamsters + other rodents	0,13	0,57	0,00	1,82	0,85	1,85	0,00	0,20	0,00	0,92	0,17	0,00	0,43	0,00	0
Rabbits	11,02	2,94	0,00	1,68	5,67	1,59	0,14	1,99	1,35	4,01	3,08	1,00	1,11	1,25	2
Cold-blooded animals(1)	1,26	5,60	0,00	21,51	4,11	10,07	97,43	5,21	0,00	2,84	3,81	16,92	2,18	0,00	0
birds (2)	0,61	1,90	0,00	38,15	2,28	2,13	0,00	1,41	0,00	4,57	5,87	5,33	3,53	0,00	0
Artio+Perissodactyla (3)	0,99	0,49	0,00	0,96	1,13	2,35	0,06	1,02	0,00	0,58	0,44	8,65	0,49	0,00	0
Carnivores (4)	0,06	0,21	0,00	0,14	0,37	0,23	0,00	0,18	0,00	0,30	0,45	0,75	0,12	0,00	0
Prosimians+monkeys+ apes	0,03	0,06	0,00	0,02	0,11	0,00	0,00	0,01	0,00	0,16	0,00	0,00	0,05	0,00	0

Other Mammals	0,00	0,01	0,00	0,06	0,01	0,05	0,00	0,01	0,00	0,00	0,00	0,13	0,01	0,00	0
Total	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Malta has reported 0 animals used in 2005

(*) France reporting for 2004

(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 on the origin of the species

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 25 Member States are reported in Table 1.3 at the end of this chapter. The consolidated table only indicates species for which the origin must be reported.

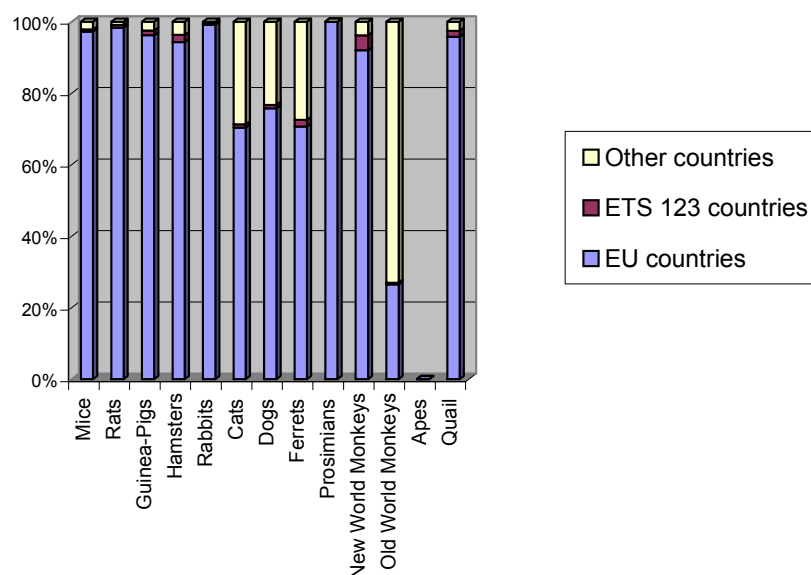
In addition, EU Table 1 requires that Member States report the number of animals re-used in experiments.

III.2.2. Treatment and interpretation of the data

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

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

Figure 1.2: Origin of species



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

III.2.3. Comparison with data of the previous report

The general pattern on the origin of the species is quite similar to that observed in the previous reports. It should be noted however, that for the first time in 2005 the prosimians

were all of EU origin. A similar trend can also be observed with the new world monkeys where an increasing amount was either of EU or ETS 123 origin at the expense of other countries. Also, old world monkeys coming from EU origins increased. On the other hand the number of cats not of European origin has increased in comparison to the report of 2002.

Table 1.3: Number of animals used in relation to their place of origin

Data of 2005

1.1.Species	1.2. Total	1.3.Animals coming from registered breeding or supplying establishments within the reporting country	1.4. Animals coming from elsewhere in the EC	1.5.Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6.Animals coming from other origins	1.7.Re-used animals
1.a. Mice (<i>Mus musculus</i>)	6430346	5408519	842034	38621	141172	254
1.b. Rats (<i>Rattus norvegicus</i>)	2336032	2002798	294875	17328	21031	118
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	257307	178363	69291	3245	6408	2
1.d. Hamsters (<i>Mesocricetus</i>)	31535	25276	4448	641	1170	0
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	312681	294616	15595	839	1631	13488
1.g. Cats (<i>Felis catus</i>)	3898	2251	492	34	1121	1007
1.h. Dogs (<i>Canis familiaris</i>)	24119	15542	2732	220	5625	3763
1.i. Ferrets (<i>Mustela putorius furo</i>)	2690	1662	240	50	738	22
1.p. Prosimians (<i>Prosimia</i>)	677	578	99	0	0	111
1.q. New World Monkeys (<i>Ceboidea</i>)	1564	1244	195	65	60	410
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	8210	1459	719	38	5994	1740
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0

1.u. Quail (<i>Coturnix coturnix</i>)	9246	8860	0	152	234	0
1.z. TOTAL	9418305	7941168	1230720	61233	185184	

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 species for which origin has to be reported are included in this table*)

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

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

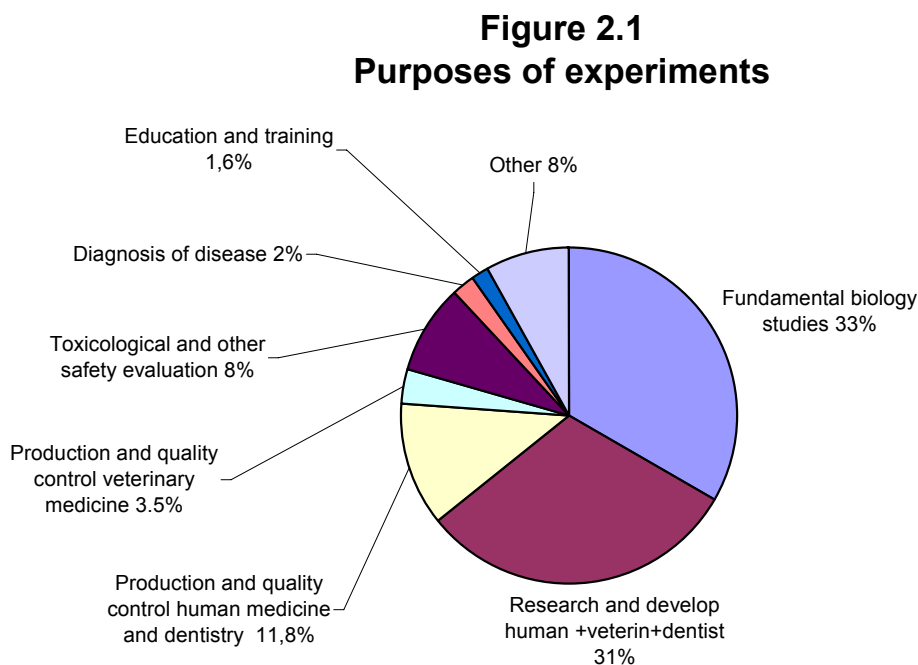
III.3.1. The data on purpose of the experiments

The consolidated data on purposes of the experiments of the 25 Member States are presented in Table 2.1 at the end of this chapter.

III.3.2. Treatment and interpretation of the data

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in the 25 Member States in 2005. In order to facilitate the presentation of results some species and some purposes were grouped.

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



As in previous years, more than 60% of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biology studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 15,3% of the total number of animals reported in 2005.

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

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

It must be remembered that the comparison is aiming to detect changes in trends rather than drawing formal conclusions. The most significant change that can be identified is the number of animals used for toxicological and other safety evaluation, which has dropped from about 9,9%

(data of 2002) to 8% for the data submitted by 25 Member States for this report. The decrease is also important in total numbers, i.e. from 1,066,047 to 1,026,286 animals while at the same time covering the 10 new Member States.

The percentage of animals used for education and training is also showing a decreasing trend while other purposes seem to indicate an increase. In terms of numbers of animals the decrease ranges from 341,967 to 198,994 and the increase from 597,960 to 984,238 respectively.

The decrease of animals used for education and training can be attributed to both an uptake of alternative techniques and the re-use of animals.

'Other' purposes covers amongst other things virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgenesis, oncological treatment, pharmaceutical R&D, combined drug testing and genetics.

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

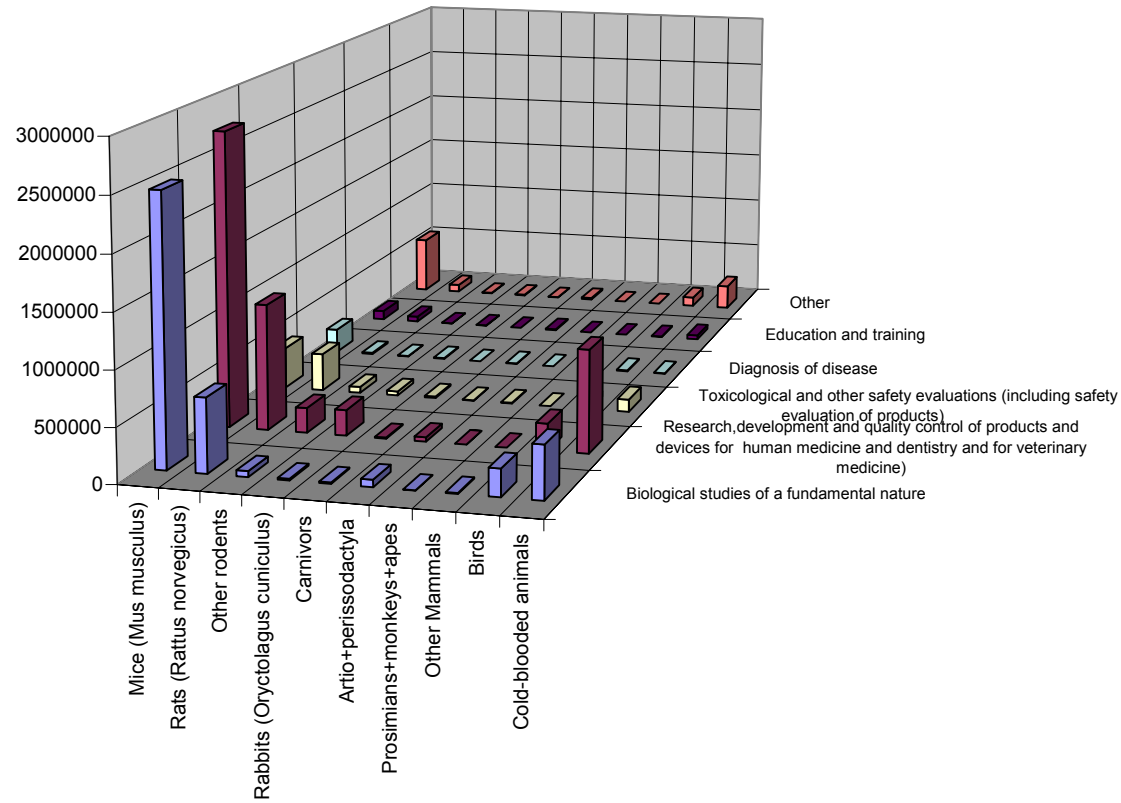
Species	Biological studies of a fundamental nature	Research, development and quality control of products and devices for human medicine and dentistry and for veterinary medicine)	Toxicological and other safety evaluations (including safety evaluation of products)	Diagnosis of disease	Education and training	Other	Total
Mice	2465474	2727254	384741	225524	86597	551356	6440946
Rats	677533	1161517	350275	13564	50048	72876	2325813
Other rodents	53241	230403	56006	4512	2606	6548	353316
Rabbits	15463	237411	38761	8322	3856	8829	312642
Carnivores	11605	9309	14884	348	674	2339	39159
Artio+perissodactyla	64419	41079	4542	4100	9491	16341	139972
Prosimians+monkeys+apes	1456	1397	7004	16	42	536	10451
Other mammals	8978	214	15	0	4	739	9950

Birds	251443	249024	53935	9723	5440	8949 4	659059
Cold-blooded animals	485858	942973	116123	5905	40236	2351 80	1826275
TOTAL	403547 0	560058 1	1026286	27201 4	198994	9842 38	1211758 3

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

From Figure 2.2 one can see that the highest amount of use of mice and rats is attributed to fundamental biology and also of research, development and control of products and devices for medicine, dentistry and veterinary medicine. The use of cold-blooded animals is following a similar pattern for different purposes.

Figure 2.2
Species and experimental purposes



**Table 2.1: Number of animals used in experiments for selected purposes
Purposes versus species
data of 2005***

2.1 Species	2.2. Biologic al studies of a fundam ental 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. Produc tion and quality control of products and devices for human medicine and dentistry	2.5. Producti on and quality control of products and devices for veterinary medicine	2.6. Toxicolo gical and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine	2.7. Dia gnosis of diseas e	2.8. Educ ation and training	2.9. Oth er	2.10. To tal
1.a. Mice (<i>Mus musculus</i>)	246547 4	1639698	902318	185238	384741	22552 4	86597	551356	644094 6
1.b. Rats (<i>Rattus norvegicus</i>)	677533	920875	209791	30851	350275	13564	50048	72876	232581 3
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	12911	47490	111505	24323	53498	2150	1691	3739	257307
1.d. Hamsters (<i>Mesocricetus</i>)	10716	6167	274	10098	1670	1395	390	825	31535
1.e. Other Rodents (other Rodentia)	29614	30359	0	187	838	967	525	1984	64474
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	15463	32814	185572	19025	38761	8322	3856	8829	312642
1.g. Cats (<i>Felis catus</i>)	1123	1044	138	687	222	64	129	491	3898
1.h. Dogs (<i>Canis familiaris</i>)	1997	4457	244	1182	14621	243	500	616	23860
1.i. Ferrets (<i>Mustela putorius furo</i>)	510	1299	42	14	41	41	45	698	2690
1.j. Other Carnivores (other	7975	0	0	202	0	0	0	534	8711

Carnivore)									
1.k. Horses, donkeys and cross breeds (Equidae)	1293	472	203	1957	40	182	973	192	5312
1.l. Pigs (Sus)	27052	15159	489	6610	3349	1888	5854	5821	66222
1.m. Goats (Capra)	828	280	84	41	39	214	317	343	2146
1.n. Sheep (Ovis)	10442	2721	5731	1217	457	871	956	7626	30021
1.o. Cattle (Bos)	24804	3691	55	2369	657	945	1391	2359	36271
1.p. Prosimians (Prosimia)	384	0	0	0	97	0	0	196	677
1.q. New World Monkeys (Ceboidea)	357	327	43	0	650	16	5	166	1564
1.r. Old World Monkeys (Cercopithecoidea)	715	654	373	0	6257	0	37	174	8210
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	8978	144	0	70	15	0	4	739	9950
1.u. Quail (Coturnix coturnix)	1722	0	0	0	3191	0	169	3913	8995
1.v. Other birds (other Aves)	249721	104833	12727	131464	50744	9723	5271	85581	650064
1.w. Reptiles (Reptilia)	1646	13	0	0	12	0	774	32	2477
1.x. Amphibians (Amphibia)	55349	253	0	0	542	99	15666	2711	74620
1.y. Fish (Pisces)	428863	933278	280	9149	115569	5806	23796	232437	1749178
1.z. TOTAL	4035470	3746028	1429869	424684	1026286	272014	198994	984238	12117583

(*)France reporting for 2004

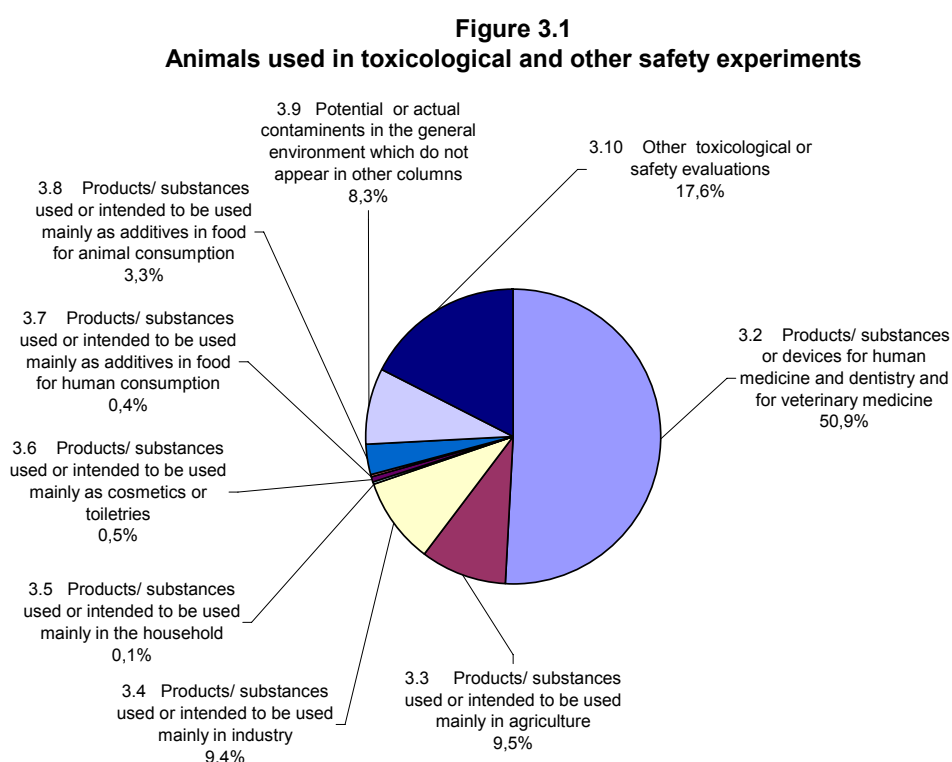
III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoints

III.4.1. The data on toxicological and safety evaluation by type of products/endpoints

The consolidated table giving the number of animals used in toxicological and other safety evaluation of products (EU Table 3) in 25 Member States is presented in Table 3.1 at the end of this chapter.

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

III.4.2. Treatment and interpretation of the data



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

Only 8% of the total number of animals used for experimental purposes is used for toxicological and other safety evaluation. This accounts for 1,026,286 animals (see III.3.3)

The percentage of animals used for toxicological evaluation of 4 groups of products/substances, i.e., animal feed, additives for human food consumption, cosmetics and household, is very small (4,3%) when compared to the other products groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents 50,9% of the animal used for toxicological or other safety evaluations.

The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used 19% of the animals for toxicological and other safety evaluations.

There is a strong decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture, products for potential contaminants of the environment (decrease ranging from above 123,000 to below 98,000) and also tests for products for household and for additives in food for human consumption, categories using lower numbers, in comparison to the data submitted in the last statistical report.

There is a noticeable increase (50%) in the number of animals used for testing cosmetics or toiletries, however, the actual numbers of animals in this category remain low (5,571 in total). This increase, attributed mainly to one old Member State, is worth noting in light of the legal requirement to phase out animal testing for cosmetics in the EU. There is also a significant increase in the number of animals used for tests for additives in food for animal consumption (3,447 to 34,225 - 10 fold).

It should also be noted that in comparison to the 2002 report there is a significant increase in the number of animals used for other toxicological or safety evaluation (ranging from around 110,000 to 180,000). This category could benefit from further analysis. Member States reported that it concerned new methods and tests, such as: tests on transmission of microcystins on embryonic membrane; bioassays; toxicity evaluation for humans via the environment; and control of safety for toys.

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

Data of 2005*

3.1.Species	3.2. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3. Products/ substances used or intended to be used mainly in agriculture	3.4. Products/ substances used or intended to be used mainly in industry	3.5. Products/ substances used or intended to be used mainly in the household	3.6. Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7. Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8. Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9. Potential or actual contaminants in the general environment which do not appear in other columns	3.10. Other toxicological or safety evaluations	3.11. Total
1.a. Mice (<i>Mus musculus</i>)	210 840	18 546	26 677	72	1 797	1 268	1 630	9 264	116 850	386 944
1.b. Rats (<i>Rattus norvegicus</i>)	210 719	41 903	44 768	294	2 226	2 644	704	8 883	36 707	348 648
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	35 123	3 051	7 128	177	940	46	0	156	6 877	53 498
1.d. Hamsters (<i>Mesocricetus</i>)	1 065	571	18	0	0	0	0	0	16	1 670
1.e. Other Rodents (other Rodentia)	300	68	28	0	0	0	0	442	0	838
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	26 030	3 593	4 433	116	608	141	113	25	4 094	39 153
1.g. Cats (<i>Felis catus</i>)	222	0	0	0	0	0	0	0	0	222
1.h. Dogs (<i>Canis familiaris</i>)	12 671	509	278	0	0	0	0	29	1 118	14 605
1.i. Ferrets (<i>Mustela putorius furo</i>)	41	0	0	0	0	0	0	0	0	41

1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (Equidae)	35	5	0	0	0	0	0	0	0	0	40
1.l. Pigs (Sus)	2 246	90	47	0	0	76	444	103	241	3 247	
1.m. Goats (Capra)	24	5	0	0	0	0	0	10	0	39	
1.n. Sheep (Ovis)	351	10	0	0	0	0	10	72	14	457	
1.o. Cattle (Bos)	489	48	0	0	0	0	105	0	15	657	
1.p. Prosimians (Prosimia)	97	0	0	0	0	0	0	0	0	97	
1.q. New World Monkeys (Ceboidea)	613	0	0	0	0	0	0	0	37	650	
1.r. Old World Monkeys (Cercopithecoidea)	5 057	0	6	0	0	0	0	0	1 194	6 257	
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	
1.t. Other Mammals (other Mammalia)	15	0	0	0	0	0	0	0	0	15	
1.u. Quail (Coturnix coturnix)	0	3 161	0	0	0	0	0	25	0	3 186	
1.v. Other birds (other Aves)	9 246	3 728	98	0	0	0	31 119	1 437	5 116	50 744	
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0	12	12	
1.x. Amphibians (Amphibia)	0	400	0	0	0	0	100	0	42	542	
1.y. Fish (Pisces)	6 937	21 944	12 998	560	0	0	0	64 286	7 799	114 524	
1.z. TOTAL	522 121	97 632	96 479	1 219	5 571	4 175	34 225	84 732	180 132	1 026 286	

(*) France reporting for 2004

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

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

The consolidated table of results on animals used for studies of diseases (EU Table 4) in the 25 Member States is presented in Table 4.1 at the end of this chapter.

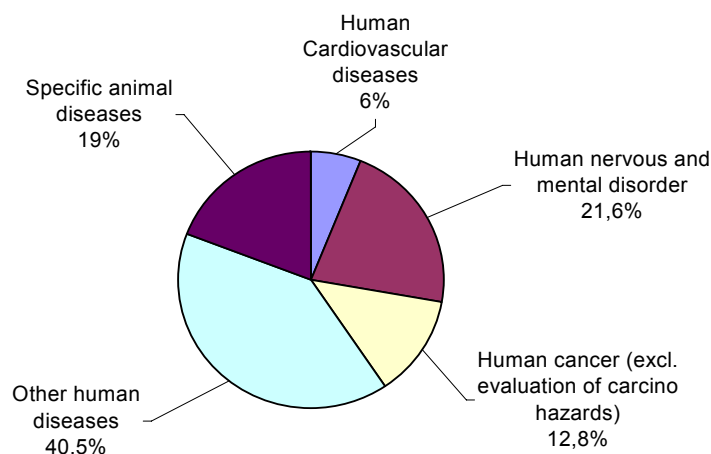
III.5.2. Treatment and interpretation of the data

Table 4.1 gives the number of animals used per type of studies on diseases. In 2005, the number of animals used for the study of both animal and human diseases represented more than half (57,5%) the total number of animals used for experimental purposes in the EU.

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

The percentage of the number of animals used for studies of human diseases represents 81% of the total number of animals used for all studies of diseases.

Figure 4.1
Proportion of animals used for the study of diseases



In 2005, the proportion and the number of animals used (ranging from 900,000 to 1,329,000) for the studies of animal diseases have increased significantly when compared with the report of 2002.

It should be remembered that the studies on specific animal diseases are important in the light of epidemics of farm animals such as in the case of cows, foot and mouth disease, swine fever and more recently avian flu. Animals used also covers studies on genetic diseases.

An important part, around 60%, of the increase of the total use of mice (579,000) in comparison with 2002, can be attributed to different studies of diseases.

**Table 4.1: Number of animals used in experiments for studies on human and animal diseases
Main category of diseases versus species
Data of 2005 ***

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
1.a. Mice (<i>Mus musculus</i>)	233054	843362	801787	1862317	158718	3899238
1.b. Rats (<i>Rattus norvegicus</i>)	154838	610191	80825	642300	5251	1493405
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	4721	7581	781	57019	5200	75302
1.d. Hamsters (<i>Mesocricetus</i>)	2121	4471	579	7302	2931	17404
1.e. Other Rodents (other Rodentia)	84	24311	487	12750	3038	40670
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	11601	3769	631	23941	7864	47806
1.g. Cats (<i>Felis catus</i>)	13	203	52	339	992	1599
1.h. Dogs (<i>Canis familiaris</i>)	1538	367	347	6001	2395	10648
1.i. Ferrets (<i>Mustela putorius furo</i>)	228	159	33	1693	71	2184
1.j. Other Carnivores (other Carnivore)	2	0	0	500	540	1042
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	8	29	8	110	919	1074
1.l. Pigs (<i>Sus</i>)	4902	943	198	8548	11226	25817
1.m. Goats (<i>Capra</i>)	184	25	3	481	205	898
1.n. Sheep (<i>Ovis</i>)	759	523	52	7138	7953	16425

1.o. Cattle (Bos)	140	1841	0	2608	7727	12316
1.p. Prosimians (Prosimia)	0	383	0	0	0	383
1.q. New World Monkeys (Ceboidea)	58	204	2	810	0	1074
1.r. Old World Monkeys (Cercopithecoidea)	53	167	179	2882	9	3290
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	250	189	3	1777	65	2284
1.u. Quail (Coturnix coturnix)	0	197	0	25	0	222
1.v. Other birds (other Aves)	1443	6282	0	27269	159253	194247
1.w. Reptiles (Reptilia)	13	115	0	24	79	231
1.x. Amphibians (Amphibia)	1067	1338	2923	10297	277	15902
1.y. Fish (Pisces)	300	3898	421	146936	954534	1106089
1.z. TOTAL	417377	1510548	889311	2823067	1329247	6969550

France reporting for 2004

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

Classes of animals	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	233054	843362	801787	1862317	158718	3899238
Rats	154838	610191	80825	642300	5251	1493405
Guinea-Pigs	4721	7581	781	57019	5200	75302
Other rodents	2205	28782	1066	20052	5969	58074
Rabbits	11601	3769	631	23941	7864	47806
Carnivores	1781	729	432	8533	3998	15473
Artio + Perrisodactyla	5993	3361	261	18885	28030	56530
Prosimians+Monkeys+Apes	111	754	181	3692	9	4747
Other Mammals	250	189	3	1777	65	2284
Birds	1443	6479	0	27294	159253	194469
Cold-blooded animals	1380	5351	3344	157257	954890	1122222
TOTAL	417377	1510548	889311	2823067	1329247	6969550

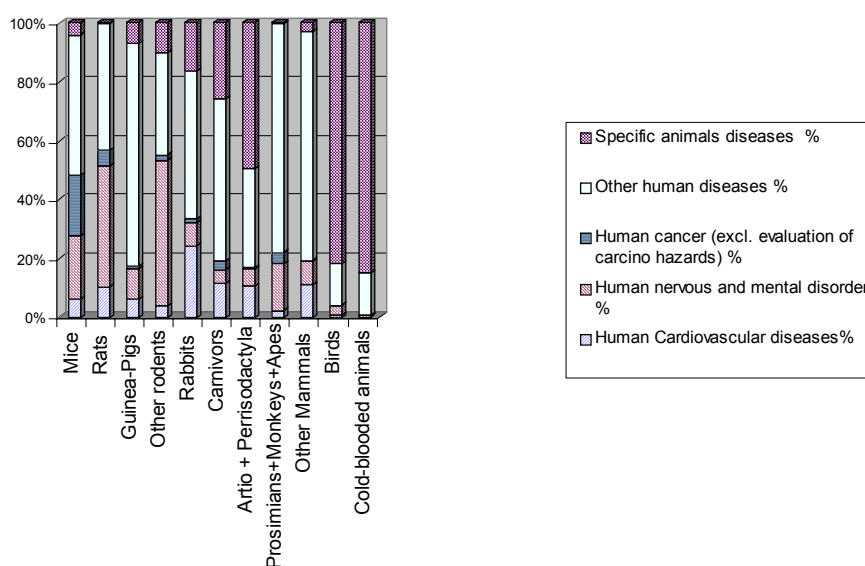
Classes of animals%	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	5,98	21,63	20,56	47,76	4,07	100,00
Rats	10,37	40,86	5,41	43,01	0,35	100,00
Guinea-Pigs	6,27	10,07	1,04	75,72	6,91	100,00
Other rodents	3,80	49,56	1,84	34,53	10,28	100,00
Rabbits	24,27	7,88	1,32	50,08	16,45	100,00

Carnivores	11,51	4,71	2,79	55,15	25,84	100,00
Artio + Perrisodactyla	10,60	5,95	0,46	33,41	49,58	100,00
Prosimians+Monkeys+Apes	2,34	15,88	3,81	77,78	0,19	100,00
Other Mammals	10,95	8,27	0,13	77,80	2,85	100,00
Birds	0,74	3,33	0,00	14,04	81,89	100,00
Cold-blooded animals	0,12	0,48	0,30	14,01	85,09	100,00
TOTAL	5,99	21,67	12,76	40,51	19,07	100,00

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

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

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



The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Two groups of animals i.e. birds and cold-blooded animals account for more than 80% of such studies. Member States reported that it is still current practice to test vaccines on these types of species. However, in some Member States only birds are used if the infection concerns bird species.

In 2005, the proportion of other mammals used for specific animal diseases has decreased but increased proportionally in studies of other human diseases.

Overall the general pattern of the proportion of animals used for the studies of diseases presented very little change when compared to the previous statistical report.

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

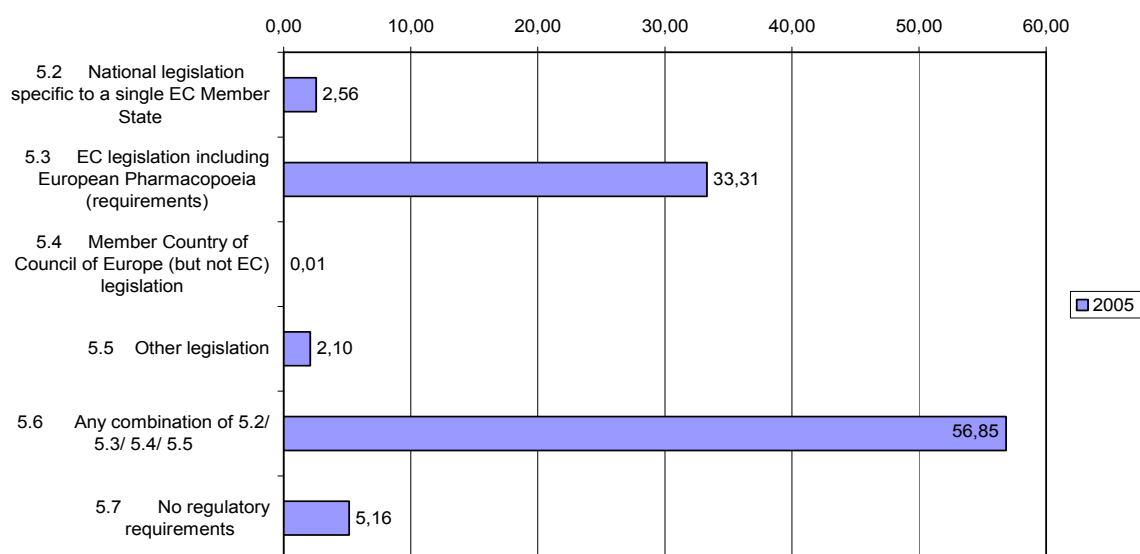
III.6.1. The data on animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The consolidated table for the 25 Member States reporting the origin of the regulatory requirements in relation to animals used for the production and quality control of products for human medicine and dentistry and for veterinary medicine (EU Table 5) is presented in Table 5.1 of this report.

III.6.2. Treatment and interpretation of the data

The number of animals used in tests for the production and quality control of products for human medicine and dentistry and for veterinary medicine represents 15,3% of the total number of animals used for experimental purposes. Figure 5.1 gives the percentages of the animals used for different regulatory purposes in this area.

Figure 5.1
Percentages of animals used for regulatory requirements for the production and quality control of products and devices for human medicine, dentistry and for veterinary medicine



The largest proportion of animals in this area (57%) was used to simultaneously satisfy requirements from several legislations such as national, Community, Council of Europe or others. The testing carried out to satisfy the EU legislation including the European Pharmacopoeia covered 33,3% of the animals used in this area.

The increase of the percentage, from 43,1% to 56,8%, of the number of animals used to satisfy simultaneously several pieces of legislation in comparison to 2002, is clearly showing an encouraging trend. This is likely to reflect a positive increase in harmonisation of different legislative requirements.

Another positive trend is the reduction of the number of animals, from 352,000 to 95,739, used for "no regulatory requirements".

Table 5.1: Number of animals used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine

Regulatory requirements versus species

Data of 2005 *

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
1.a. Mice (<i>Mus musculus</i>)	24912	326864	20	13463	685435	36912	1087606
1.b. Rats (<i>Rattus norvegicus</i>)	5551	82479	0	18436	127504	6822	240792
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	8558	44713	7	6041	73163	3346	135828
1.d. Hamsters (<i>Mesocricetus</i>)	0	4528	0	0	5449	395	10372
1.e. Other Rodents (other Rodentia)	0	0	0	0	187	0	187
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	2566	85556	0	308	87867	28300	204597
1.g. Cats (<i>Felis catus</i>)	76	607	0	13	111	18	825
1.h. Dogs (<i>Canis familiaris</i>)	21	1016	0	0	241	148	1426
1.i. Ferrets (<i>Mustela putorius furo</i>)	14	30	0	0	6	6	56
1.j. Other Carnivores (other Carnivore)	0	202	0	0	0	0	202
1.k. Horses, donkeys and cross bred (Equidae)	229	219	0	2	281	1429	2160
1.l. Pigs (<i>Sus</i>)	136	4363	0	9	1572	1019	7099
1.m. Goats (<i>Capra</i>)	0	4	0	0	118	3	125
1.n. Sheep (<i>Ovis</i>)	176	838	0	0	3650	2284	6948
1.o. Cattle (<i>Bos</i>)	125	1462	26	10	533	268	2424
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	35	0	0	0	8	43
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	6	0	0	357	10	373
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	10	60	0	0	0	0	70

1.u. Quail (<i>Coturnix coturnix</i>)	0	0	0	0	0	0	0
1.v. Other birds (other Aves)	3913	61303	152	683	63959	14181	144191
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	0	0	0	0	0
1.y. Fish (Pisces)	1222	3446	0	0	3971	590	9229
1.z. TOTAL	47509	617731	205	38965	1054404	95739	1854553

(*) France reporting for 2004

Examp
es:

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 on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

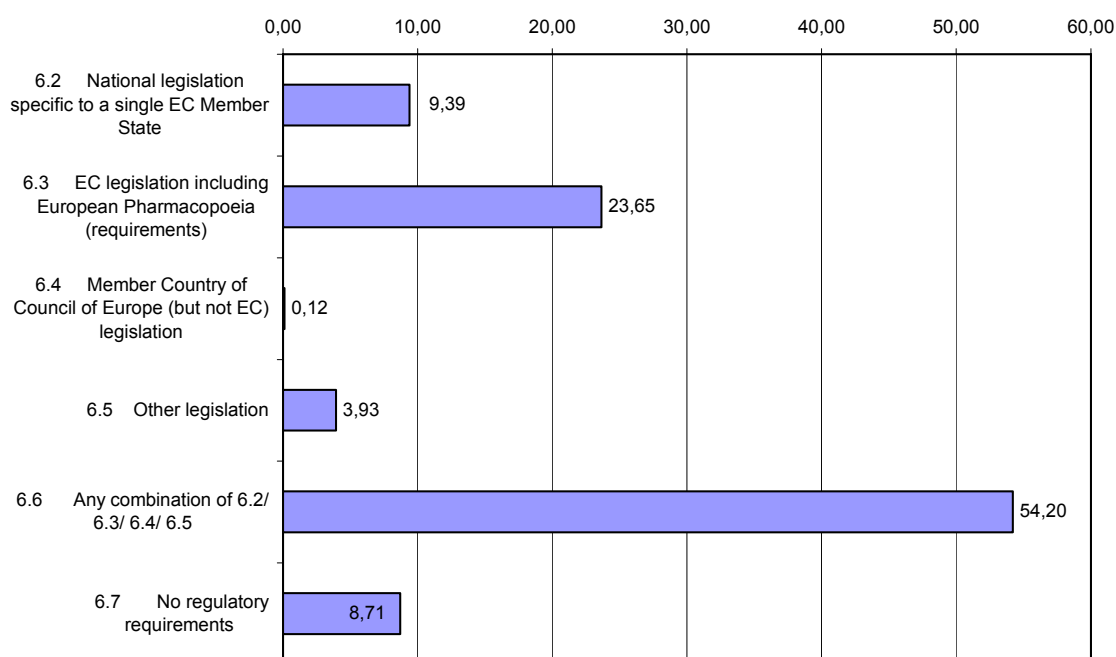
The consolidated table for the 25 Member States reporting data on animals used in toxicological and other safety evaluations in relation to the origin of regulatory requirements (EU Table 6) is presented in Table 6.1 at the end of this chapter.

III.7.2. Treatment and interpretation of the data

It can be observed that the use of animals for regulatory requirements in the area of toxicological or other safety evaluation presented in Figure 6.1 follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine presented in the Figure 5.1 in the previous chapter.

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

Figure 6.1
Percentages of animals used for regulatory requirements for toxicological and other safety evaluation



Animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered more than half of the animals used in this area (54,2%). The testing required under the EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area namely 23%.

It should be underlined that the proportional decrease of the numbers of animals used for toxicological and other safety evaluation since the last report, from 10% to 8%, represents at the same time a decrease of about 40,000 animals. The number of animals used "no regulatory requirements" decreased since the last report from 114,000 to 90,000 animals, a drop of 24,000 animals.

Member States who were asked to provide some further explanation as to the reasons for this clear decrease of animals used for no regulatory requirements compared to previous reports, indicated that the decrease was partially attributed to use of alternative in vitro methods and invertebrate animals. For example, safety pharmacological tests such as those used for supplementary batch control by the European Pharmacopoeia. In order to understand what is meant by the term 'no regulatory requirements', for example some Member States indicated that legal obligations to ensure quality and safety of imported drugs would be reported under this category.

The testing to satisfy national legislation specific to a single Member State showed a decrease in this report with respect to the previous one but it represents about 15,500 animals i.e. 1,5% of the total number used for toxicological and other safety evaluation.

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

Data of 2005*

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 5.2/ 5.3/ 5.4/ 5.5	6.7. No regulatory requirements	6.8.Total
1.a. Mice (<i>Mus musculus</i>)	39972	104143	170	15039	189776	37144	386244
1.b. Rats (<i>Rattus norvegicus</i>)	19368	61953	670	15875	224860	25772	348498
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	1009	21189	70	2052	27849	1329	53498
1.d. Hamsters (<i>Mesocricetus</i>)	0	182	0	0	1204	284	1670
1.e. Other Rodents (other Rodentia)	0	300	0	0	0	583	883
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	1398	9462	13	2653	23162	2420	39108
1.g. Cats (<i>Felis catus</i>)	166	46	0	6	4	23	245
1.h. Dogs (<i>Canis familiaris</i>)	977	1919	0	520	10842	324	14582
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	0	0	41	0	41
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0	5	0	0	25	10	40
1.l. Pigs (<i>Sus</i>)	57	1150	0	132	1642	266	3247
1.m. Goats (<i>Capra</i>)	0	26	0	0	3	44	73
1.n. Sheep (<i>Ovis</i>)	4	120	0	0	191	108	423
1.o. Cattle (<i>Bos</i>)	12	320	0	15	203	107	657
1.p. Prosimians (<i>Prosimia</i>)	0	97	0	0	0	0	97
1.q. New World Monkeys	0	0	0	0	599	51	638

(Ceboidea)							
1.r. Old World Monkeys (Cercopithecoidea)	0	304	0	488	5312	153	6257
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	15	0	0	0	0	15
1.u. Quail (Coturnix coturnix)	0	2124	0	0	1037	25	3186
1.v. Other birds (other Aves)	5519	4787	0	522	38262	1654	50744
1.w. Reptiles (Reptilia)	12	0	0	0	0	0	12
1.x. Amphibians (Amphibia)	542	0	0	0	0	0	542
1.y. Fish (Pisces)	27338	34565	312	3029	31210	19120	115574
1.z. TOTAL	96374	242707	1235	40331	556222	89417	1026286

(*)France reporting for 2004

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

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

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

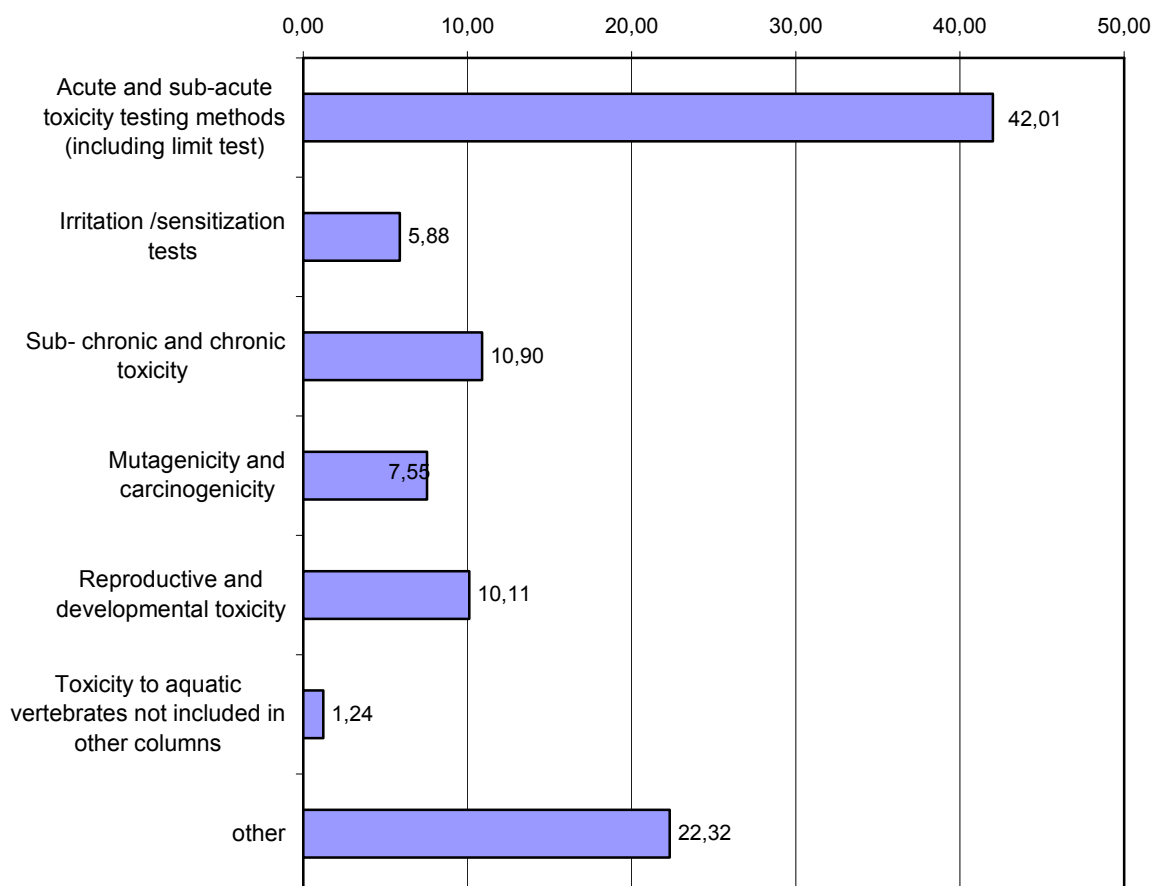
III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting on animals used in toxicity tests for the purpose of toxicological and other safety evaluations of products (EU Table 7) is presented in Table 7.1 at the end of this chapter.

III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of Table 7.1 have been grouped according to systemic and local toxicity and CMR effects in Table 7.2 of this report. A graph showing the percentage of animals used per toxicity test groups in 2005 is presented in Figure 7.1.

Figure 7.1
Percentages of animals used in toxicity tests for toxicological and other safety evaluation



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

It can be seen in Figure 7.1 that the largest percentage of use of animals is due to acute and sub-acute toxicity tests 42% in 2005. Taking also into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for 53% of the experimental animals used in this area.

About 17,5% of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction in 2005. Another important category of use of animals in 2005 is for "other tests" with 22,3%. Breaking down further the category 'other', Member States reported testing in areas such as biological screening for pharmaceutical, healthcare and veterinary products. This includes neurotoxicity, toxicokinetics, testing of acute dermal toxicity, testing of biological evaluation of medical devices: Intracutan testing of reactivity on rabbits, study into penetration of nanoparticle through tissue and their biocompatibility, study into evaluation of sensitization potential of dyestuffs used in textile industry and pharmacological studies included in safety tests.

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

One can observe a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests ranging from: 32%, 36% to 42% respectively. This represents in animal numbers an increase of 39,000 animals since the last report of 2002. Member States attributed the increase in part to several phases in new product development and new legislation for example requiring that all generic substances should be tested.

On the other hand one can observe a steady decrease over the last three reports of the proportion of animals used for toxicity tests to reproduction going down from: 15%, 12% to 10% respectively.

Another important decrease in the proportion of animals used is the decrease from 4,5% to 1,2% of animals used in toxicity test to aquatic vertebrates.

Some Member States presume that the decrease in regulatory testing can indeed be attributed to alternative methods but others think that replacement methods have a much greater impact on R&D than on regulatory requirements. They point out that the statistics drawn up annually include re-use of animals which plays an important role.

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

Type of tests versus species

Data of 2005*

7.1. Species	7.2. Acute and sub-acute toxicity testing methods (including limit test)			7.3. Skin irritation	7.4. Skin sensitisation	7.5. Eye irritation	7.6. Sub-chronic and chronic toxicity	7.7. Carcinogenicity	7.8. Developmental toxicity	7.9. Mutagenicity	7.10. Reproductive toxicity	7.11. Toxicity to aquatic vertebrates not included in other columns	7.12. Other	7.13. Total
	7.2.1. LD50, LC50	7.2.2. Other lethal methods	7.2.3. Non lethal clinical signs methods											
1.a. Mice (<i>Mus musculus</i>)	33024	86669	68682	2805	21350	0	25550	19624	2612	19479	908	0	105541	386244
1.b. Rats (<i>Rattus norvegicus</i>)	19756	18614	78707	1156	303	142	65466	22400	23886	15727	51518	0	50829	348504
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	1415	993	17572	2144	22184	0	628	0	0	0	0	0	8556	53492
1.d. Hamsters (<i>Mesocricetus</i>)	0	64	603	0	0	0	38	0	0	20	0	0	945	1670
1.e. Other Rodents (other Rodentia)	56	142	300	0	0	0	300	0	0	0	0	0	40	838
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	36	49	2944	5130	52	4033	1693	0	8078	31	4640	0	12467	39153
1.g. Cats (<i>Felis catus</i>)	0	0	108	0	0	0	0	0	0	0	0	0	114	222

1.h. Dogs (<i>Canis familiaris</i>)	182	659	5170	0	0	0	6998	0	0	0	29	0	1567	14605
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	41	0	0	0	0	0	0	0	0	0	0	41
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	0	0	10	0	0	0	0	0	0	0	0	0	30	40
1.l. Pigs (<i>Sus</i>)	8	49	304	8	0	0	971	0	89	0	100	0	1718	3247
1.m. Goats (<i>Capra</i>)	0	0	0	0	0	0	0	0	0	0	0	0	39	39
1.n. Sheep (<i>Ovis</i>)	0	0	32	0	0	0	0	0	35	0	37	0	353	457
1.o. Cattle (<i>Bos</i>)	0	0	73	0	0	0	0	0	0	0	0	0	584	657
1.p. Prosimians (<i>Prosimia</i>)	0	0	60	0	0	0	32	0	0	0	0	0	5	97
1.q. New World Monkeys (<i>Ceboidea</i>)	0	85	222	0	0	0	185	0	90	0	0	0	68	638
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	1	2014	0	0	33	3406	0	131	0	187	0	485	6257
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	0	0	0	0	0	0	0	0	0	0	0	0	15	15
1.u. Quail (<i>Coturnix coturnix</i>)	2253	348	105	0	0	0	0	0	0	0	480	0	0	3186
1.v. Other birds (other <i>Aves</i>)	1671	260	11403	1000	0	0	158	0	0	0	128	0	3612	50744
1.w. Reptiles (<i>Reptilia</i>)	0	0	0	0	0	0	0	0	0	0	0	0	12	12
1.x. Amphibians (<i>Amphibia</i>)	0	0	0	0	0	0	0	0	42	0	0	0	500	542
1.y. Fish (<i>Pisces</i>)	54830	10449	11146	0	0	0	6443	0	5484	226	5284	12675	9037	11557
1.z. TOTAL	11323	11838	199496	1224	4388	4208	11186	4202	40447	3548	6331	12675	2290	10262
	1	2		3	9		8	4		3	1		29	86

(*) France reporting for 2004

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

7.1. Species	Acute and sub-acute toxicity testing methods (including limit test)	Irritation /sensitization tests	Sub-chronic and chronic toxicity	Mutagenicity and carcinogenicity	Reproductive and developmental toxicity	Toxicity to aquatic vertebrates not included in other columns	other	Tot
1.a. Mice (<i>Mus musculus</i>)	188375	24155	25550	39103	3520	0	105541	380
1.b. Rats (<i>Rattus norvegicus</i>)	117077	1601	65466	38127	75404	0	50829	340
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	19980	24328	628	0	0	0	8556	50
1.d. Hamsters (<i>Mesocricetus</i>)	667	0	38	20	0	0	945	1
1.e. Other Rodents (other Rodentia)	498	0	300	0	0	0	40	
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	3029	9215	1693	31	12718	0	12467	30
1.g. Cats (<i>Felis catus</i>)	108	0	0	0	0	0	114	
1.h. Dogs (<i>Canis familiaris</i>)	6011	0	6998	0	29	0	1567	14
1.i. Ferrets (<i>Mustela putorius furo</i>)	41	0	0	0	0	0	0	
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	10	0	0	0	0	0	30	
1.l. Pigs (<i>Sus</i>)	361	8	971	0	189	0	1718	3
1.m. Goats (<i>Capra</i>)	0	0	0	0	0	0	39	
1.n. Sheep (<i>Ovis</i>)	32	0	0	0	72	0	353	
1.o. Cattle (<i>Bos</i>)	73	0	0	0	0	0	584	
1.p. Prosimians (<i>Prosimia</i>)	60	0	32	0	0	0	5	

1.q. New World Monkeys (Ceboidea)	307	0	185	0	90	0	68	
1.r. Old World Monkeys (Cercopithecoidea)	2015	33	3406	0	318	0	485	6
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	15	
1.u. Quail (Coturnix coturnix)	2706	0	0	0	480	0	0	3
1.v. Other birds (other Aves)	13334	1000	158	0	128	0	36124	50
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	12	
1.x. Amphibians (Amphibia)	0	0	0	0	42	0	500	
1.y. Fish (Pisces)	76425	0	6443	226	10768	12675	9037	115
1.z. TOTAL	431109	60340	111868	77507	103758	12675	229029	102

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

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

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products, for the 25 Member States reporting (EU Table 8) is presented in Table 8.1 of this report. There are discrepancies between the total numbers of animals *per types of tests* in Table 7 in comparison with the total numbers of animals *per types of tests* of Table 8. Logically these should be the same. These discrepancies originate from 10 Member States; however, when the data was submitted no explanation was given as to the reasons. The overall total number of animals for toxicological and other safety evaluations remains coherent.

III.9.2. Treatment and interpretation of the data

As pointed out earlier it is important to keep in mind that animals used in toxicological and other safety evaluation represent 8% of the total number of animals used for experimental purposes. The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products has not been done in the previous reports due to inconsistencies in the data in the past. The results in this area are therefore analysed and compared in this report for the first time.

Figure 8.1 represents the percentages of the number of animals used in toxicological testing or other safety evaluations in relation to the type of products or purposes. In order to give a better graphical presentation of the results, some type tests have been grouped according to systemic and local toxicity and carcinogenic, mutagenic and toxicity to reproduction effects in Table 8.2 of this report.

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

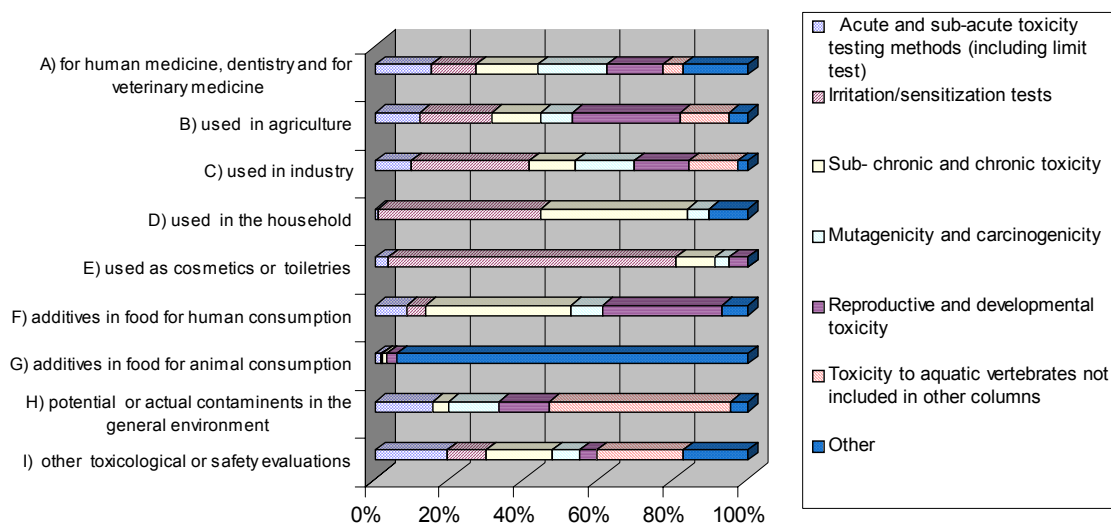


Figure 8.1 shows a decrease in the proportion of animals used in acute and sub-acute toxicity tests in comparison with other tests when moving down in the graph for products used A) for human medicine, dentistry and veterinary medicine, B) for agriculture, C) for industry, D) for household, E) for cosmetics, F) for additives in food consumption and G) for additives in food for animal consumption. However, the animals used in acute and sub-acute toxicity tests for other toxicological and safety evaluations would benefit from further analysis.

Contrary to acute and sub-acute toxicity one can observe an increase in the proportion of animals used for irritation and sensitization tests. While further down the graph amongst the four first types of products, a maximum amount of testing takes place for products used in cosmetics and toiletries.

The proportion of animals used in sub-chronic and chronic testing seems to follow the same pattern as for irritation sensitization tests with the highest proportion used for D) household products and F) additives in food for human consumption.

The pattern of use of carcinogenicity, mutagenicity and toxicity to reproduction tests is rather scattered between the different types of products and more difficult to interpret.

The proportion of animals used for G) additives in food for animal consumption is governed by about 90% by other tests. This group would benefit from further analysis.

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

Data of 2005*

8.1. Products	8.2. Acute and sub-acute toxicity testing methods (including limit test)			8.3. Skin irritation	8.4. Skin sensitisation	8.5. Eye irritation	8.6. Sub-chronic and chronic toxicity	8.7. Carcinogenicity	8.8. Developmental toxicity	8.9. Mutagenicity	8.10. Reproductive toxicity	8.11. Toxicity to aquatic vertebrates not included in other columns	8.12. Other	8.13. Total
	8.2.1. LD50, LC50	8.2.2. Other lethal methods	8.2.3. Non lethal clinical signs methods											
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	18820	38091	155459	4097	15296	1452	67651	26589	18238	21005	30788	3419	127284	528189
8.b. Products/ substances used or intended to be used mainly in agriculture	21368	5956	11467	872	6486	654	12535	3100	10158	1831	12599	1847	8687	97560
8.c. Products/ substances used or intended to be used mainly in industry	18963	4047	13416	4743	9264	1111	13177	2644	3230	8371	10043	2136	5684	96829

8.d. Products/ substances used or intended to be used mainly in the household	20	18	11	48	154	70	568	3	0	51	0	0	276	1219
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	0	349	684	469	2222	300	966	0	368	213	0	0	0	5571
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	6	40	1283	3	98	3	1767	0	0	239	1210	0	572	5221
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	0	907	239	30	0	0	160	24	0	0	423	0	3169 2	33475
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	32120	9894	5959	0	0	0	3793	7045	4541	594	5393	6524	7885	83748
8.i. Other toxicological or safety evaluations	20974	58282	8840	668	4921	478	23062	1459	2756	4836	2088	4593	4151 7	17447 4
8.j. TOTAL	112271	11758 4	197358	10930	38441	406 8	123679	4086 4	3929 1	3714 0	6254 4	18519	2235 97	10262 86

(*) France reporting for 2004

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

8.1. Products	Acute and sub-acute toxicity testing methods (including limit test)	Irritation/sensitization tests	Sub-chronic and chronic toxicity	Mutagenicity and carcinogenicity	Reproductive and developmental toxicity	Toxicity to aquatic vertebrates not included in other columns	Other	Total
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	212370	20845	67651	47594	49026	3419	127284	528189
8.b. Products/ substances used or intended to be used mainly in agriculture	38791	8012	12535	4931	22757	1847	8687	97560
8.c. Products/ substances used or intended to be used mainly in industry	36426	15118	13177	11015	13273	2136	5684	96829
8.d. Products/ substances used or intended to be used mainly in the household	49	272	568	54	0	0	276	1219
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	1033	2991	966	213	368	0	0	5571
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	1329	104	1767	239	1210	0	572	5221

8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	1146	30	160	24	423	0	31692	33475
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	47973	0	3793	7639	9934	6524	7885	83748
8.i. Other toxicological or safety evaluations	88096	6067	23062	6295	4844	4593	41517	174474
8.j. TOTAL	427213	53439	123679	78004	101835	18519	223597	1026286