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**Accompanying document to the
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT**

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

COM(2010) 511 final

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I. INTRODUCTION

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

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

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

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

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

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

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

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

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

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

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

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

II.2. General assessment

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

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

⁷ OJ C 331, 23.12.86, p. 2.

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

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

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

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

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

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

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

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

II.3. Structure of the Report

The report is divided into two parts:

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

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

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

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

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

PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2008

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

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

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

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

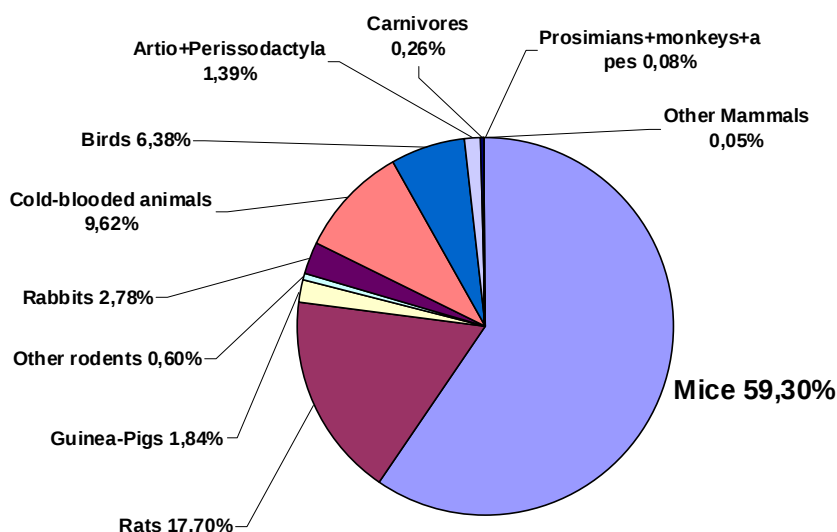
The total number of animals used in 2008 in the 27 Member States amounts to 12.0 million animals. It is important to note that the number of animals used in the new Member States who joined the EU in 2008 (Bulgaria and Romania) represents not even 1,0% of the total number of animals used in the EU 27.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Species		Number of animals in EU 25	Number of animals in EU 27	Change since 2005	% change by species	Change since 2005	Number of animals EU 25 2008 excl. RO,BG	% change by species
		2005	2008					
1.a	Mice (<i>Mus musculus</i>)	6430346	7122188	691842	9,71	630992	7061338	8,94
1.b	Rats (<i>Rattus norvegicus</i>)	2336032	2121727	-214305	-10,10	-223989	2112043	-10,61
1.c	Guinea-Pigs (<i>Cavia porcellus</i>)	257307	220985	-36322	-16,44	-46774	210533	-22,22
1.d	Hamsters (<i>Mesocricetus</i>)	31535	32739	1204	3,68	759	32294	2,35
1.e	Other Rodents (other Rodentia)	64474	39506	-24968	-63,20	-24968	39506	-63,20
1.f	Rabbits (<i>Oryctolagus cuniculus</i>)	312681	333213	20532	6,16	17514	330195	5,30
1.g	Cats (<i>Felis catus</i>)	3898	4088	190	4,65	179	4077	4,39
1.h	Dogs (<i>Canis familiaris</i>)	24119	21315	-2804	-13,16	-2819	21300	-13,23
1.i	Ferrets (<i>Mustela putorius furo</i>)	2690	3208	518	16,15	518	3208	16,15
1.j	Other Carnivores	8711	2853	-5858	-205,33	-5858	2853	-205,33
1.k	Horses, donkeys and cross breeds (<i>Equidae</i>)	5312	5976	664	11,11	633	5945	10,65
1.l	Pigs (<i>Sus</i>)	66305	92813	26508	28,56	26369	92674	28,45
1.m	Goats (<i>Capra</i>)	2146	3840	1694	44,11	1614	3760	42,93
1.n	Sheep (<i>Ovis</i>)	30021	30190	169	0,56	-212	29809	-0,71
1.o	Cattle (<i>Bos</i>)	36271	33952	-2319	-6,83	-2448	33823	-7,24
1.p	Prosimians (<i>Prosimia</i>)	677	1261	584	46,31	584	1261	46,31
1.q	New World Monkeys (<i>Cebioidea</i>)	1564	904	-660	-73,01	-660	904	-73,01
1.r	Old World Monkeys (<i>Cercopithecoidea</i>)	8208	7404	-804	-10,86	-804	7404	-10,86
1.s	Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0
1.t	Other Mammals (other Mammalia)	9950	5704	-4246	-74,44	-4246	5704	-74,44
1.u	Quail (<i>Coturnix coturnix</i>)	9246	9626	380	3,95	371	9617	3,86
1.v	Other birds (other Aves)	649813	754485	104672	13,87	101999	751812	13,57
1.w	Reptiles (<i>Reptilia</i>)	2477	4101	1624	39,60	1624	4101	39,60
1.x	Amphibians (<i>Amphibia</i>)	74620	61789	-12831	-20,77	-17631	56989	-30,94
1.y	Fish (<i>Pisces</i>)	1749178	1087155	-662023	-60,89	-662073	1087105	-60,90
1.z	TOTAL	12117583	12001022	-116561	-0,97	-209328	11908255	-1,76

There is an increase in the number of mice used since 2005 of 691,842 which is 9,71% of the total number of mice used in 2008 and a decrease for rats and fish. The largest change in 2008, increase in the use of mice, is almost entirely compensated for by the decrease in the use of fish.

The total number of pigs, goats, prosimians, and reptiles has increased by between 28 - 46%.

The total number of rats, guinea-pigs, other rodents, dogs, cattle and other mammals as well as amphibians and fish used has decreased substantially since the last report. When expressed in percentages these decreases range from more than 70% to around 10%.

The largest percentile change has, however, been noted in the decrease of the use of other carnivores. However, these species are not used in great numbers (from 8,711 to 2,853). There is also a large decrease of 75% in the total number of 'other mammals'.

It is also worth noting the large decrease in the use of new world monkeys of 73% as well as a decrease of 11% of old world monkeys. Prosimian use overall, however, has increased by 46%.

For species used in greater numbers, significant increases occurred in 2008 for mice, rabbits, pigs and 'other birds' where percentage changes ranged from 5% to 28%.

The following animals which are normally used in fewer numbers show an increase in use: ferrets (16%), horses, donkeys and cross-breeds (11%), goats (44%) and reptiles (39%).

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

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

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

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

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

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

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

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

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

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

(*) France is reporting for 2007

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

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

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

FR(*) France reporting for 2007

(1) reptiles + amphibians + fish

(2) Quails and other birds

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

(4) Cats + dogs + ferrets + other carnivores

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

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

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

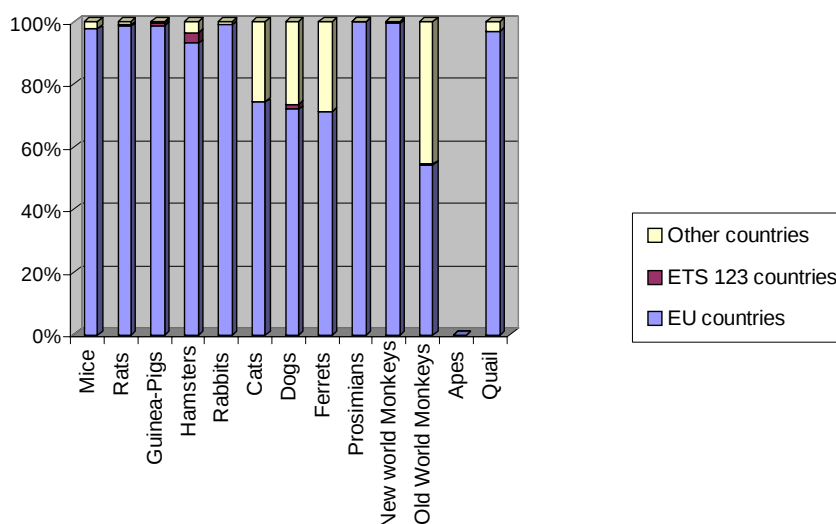
In addition, EU Table 1.3 contains information on the number of animals re-used in experiments.

III.2.2. Treatment and interpretation of the data

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

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

Figure 1.2: Origin of species



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

III.2.3. Comparison with data of the previous report

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

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

1.1 Species	1.2. Total	1.3. Animals coming from registered breeding or supplying establishments within the reporting country	1.4. Animals coming from elsewhere in the EC	1.5. Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6. Animals coming from other origins	1.7. Re-used animals
1.a. Mice (<i>Mus musculus</i>)	7122188	6042205	900230	21382	158371	3768
1.b. Rats (<i>Rattus norvegicus</i>)	2121727	1761785	329385	9844	20713	3035
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	220985	161973	56167	2051	792	962
1.d. Hamsters (<i>Mesocricetus</i>)	32739	24999	5476	1074	1190	54
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	333213	315006	14753	364	3087	15958
1.g. Cats (<i>Felis catus</i>)	4088	2306	726	14	1042	1181
1.h. Dogs (<i>Canis familiaris</i>)	21315	12467	2885	309	5654	4178
1.i. Ferrets (<i>Mustela putorius furo</i>)	3208	1847	442	0	919	64
1.p. Prosimians (<i>Prosimia</i>)	1261	718	543	0	0	33
1.q. New World Monkeys (<i>Ceboidea</i>)	904	816	83	5	0	346
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	7404	3213	850	5	3336	1509
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	9626	7824	1500	0	302	0
1.z. TOTAL	9878658	8335159	1313040	35048	195406	

* France: data of 2007

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

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

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

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

III.3.1. The data on purposes of the experiments

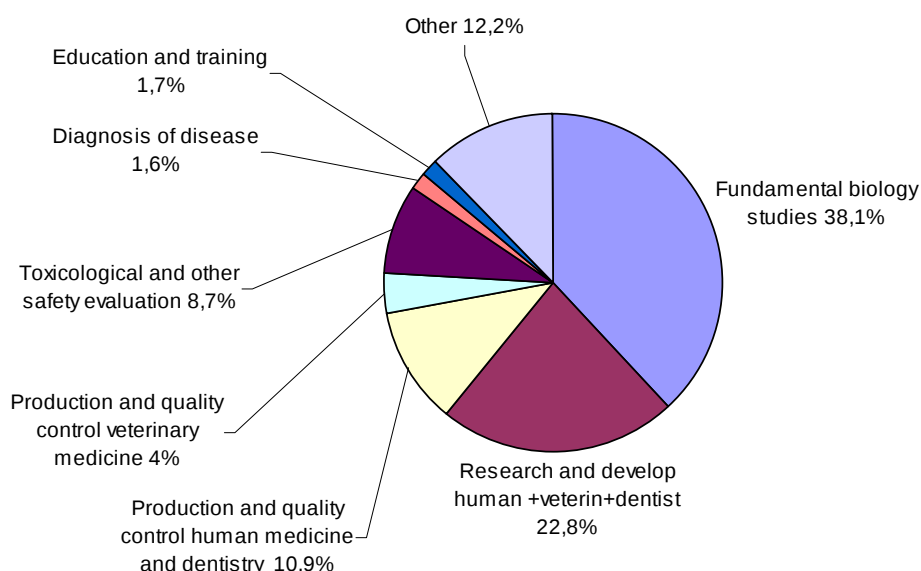
The consolidated data on purposes of the experiments of the 27 Member States are presented in Table 2.1 at the end of this chapter.

III.3.2. Treatment and interpretation of the data

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

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

Figure 2.1
Purposes of experiments



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

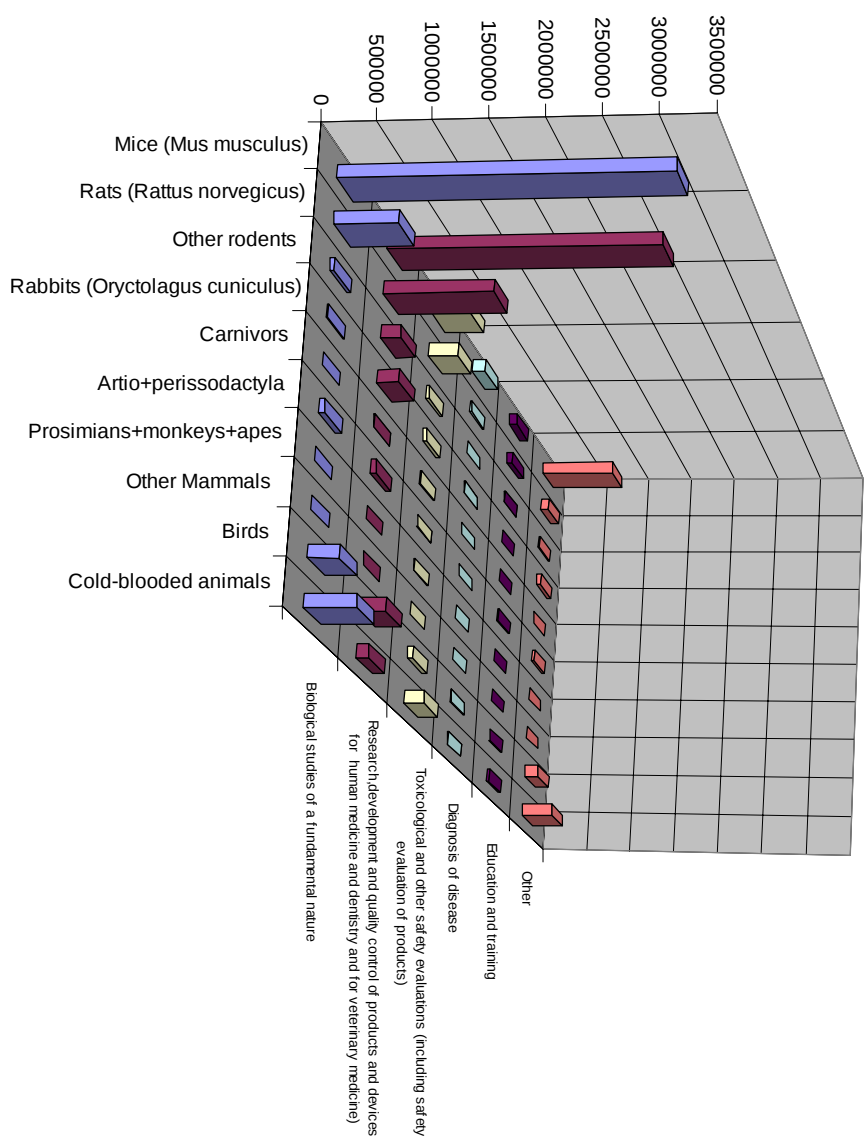
Species	Biological studies of a fundamental nature	Research, development and quality control of products and devices for human medicine and dentistry and for veterinary medicine	Toxicological and other safety evaluations (including safety evaluation of products)	Diagnosis of disease	Education and training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

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

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

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

Figure 2.2
Species and experimental purposes



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

2.1.Species	2.2.Biological studies of a fundamental nature	2.3. Research and development of products and devices for human medicine and dentistry and for veterinary medicine(excluding toxicological and other safety evaluations counted in column 2.6)	2.4. Production and quality control of products and devices for human medicine and dentistry	2.5. Production and quality control of products and devices for veterinary medicine	2.6. Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine	2.7. Diagnosis of disease	2.8. Education and training	2.9. Other	2.10. Total
1.a. Mice (<i>Mus musculus</i>)	3080775	1597381	856048	171427	398199	137578	82606	798174	7122188
1.b. Rats (<i>Rattus norvegicus</i>)	595542	840909	181140	38241	294683	22997	59412	88803	2121727
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	10632	44344	103852	17265	31883	1940	5804	5265	220985
1.d. Hamsters (<i>Mesocricetus</i>)	6994	8041	376	12513	1580	278	520	2437	32739
1.e. Other Rodents (other Rodentia)	26614	9006	30	0	395	927	1502	1032	39506
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	17813	29764	131031	51823	39987	3376	3326	56093	333213
1.g. Cats (<i>Felis catus</i>)	560	1738	57	679	322	124	97	514	4091
1.h. Dogs (<i>Canis familiaris</i>)	1814	4405	157	2070	11077	1111	362	316	21312
1.i. Ferrets (<i>Mustela putorius furo</i>)	551	1287	564	8	269	45	56	428	3208
1.j. Other Carnivores (other Carnivora)	1879	75	0	338	296	80	0	185	2853
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	1402	728	224	2559	22	239	489	313	5976
1.l. Pigs (<i>Sus</i>)	23531	22799	423	9001	8065	1452	8134	19408	92813
1.m. Goats (<i>Capra</i>)	1098	721	93	26	43	90	422	1347	3840
1.n. Sheep (<i>Ovis</i>)	9727	4098	6020	2149	409	1616	1243	4928	30190
1.o. Cattle (<i>Bos</i>)	19322	3990	214	3314	457	1223	2846	2586	33952
1.p. Prosimians (Prosimia)	568	0	0	0	543	150	0	0	1261
1.q. New World Monkeys (Ceboidea)	235	235	33	0	270	0	0	131	904
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	410	761	231	0	5694	3	10	295	7404
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	5279	86	28	63	0	12	25	211	5704
1.u. Quail (<i>Coturnix coturnix</i>)	5520	57	0	0	2170	9	1575	295	9626
1.v. Other birds (other Aves)	287375	77748	10593	159220	51307	8406	9869	149967	754485
1.w. Reptiles (<i>Reptilia</i>)	3781	94	0	0	0	0	147	79	4101
1.x. Amphibians (<i>Amphibia</i>)	32780	1914	0	0	291	202	12213	14389	61789
1.y. Fish (<i>Pisces</i>)	440852	83525	20418	7815	194191	3449	16799	320106	1087155
1.z. TOTAL	4575054	2733706	1311532	478511	1042153	185307	207457	1467302	12001022

(*) France is reporting for 2007

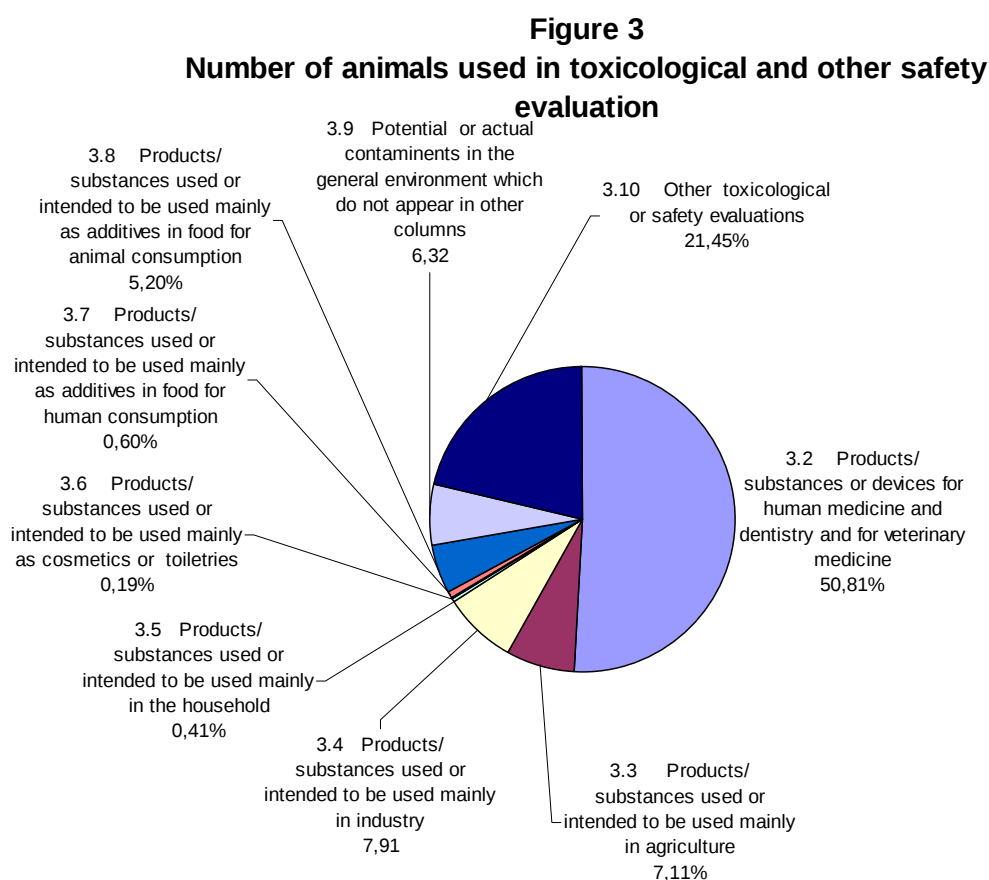
III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoint

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

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

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

III.4.2. Treatment and interpretation of the data



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

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

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

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

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

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

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

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

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

Data of 2008*

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

(*) France reporting for 2007

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

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

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

III.5.2. Treatment and interpretation of the data

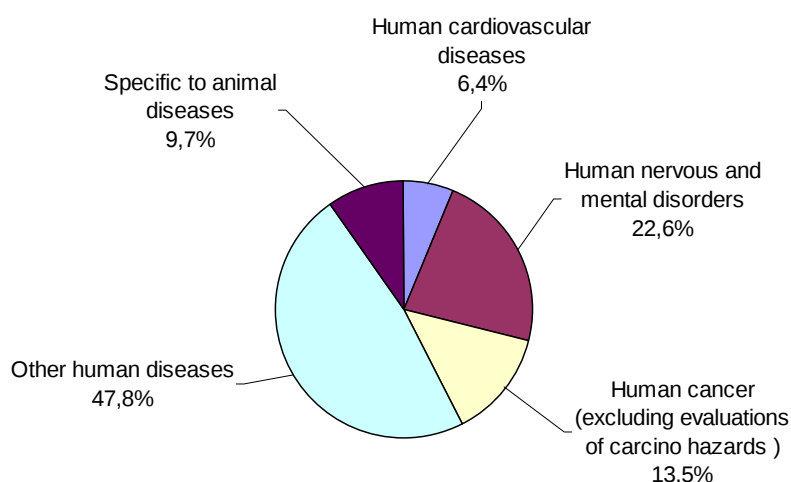
Table 4.1 gives the number of animals used per type of studies on diseases.

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

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

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

Figure 4.1
Proportion of animals used for the studies of diseases



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

Interesting to note is that despite the overall decrease, the use of mice increased substantially in 2008. Around 35% of the increase (about 681,000) can be attributed to different studies of diseases (see also observations under chapter III.3.3).

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

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

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

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

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

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
1.a. Mice (<i>Mus musculus</i>)	249486	858612	803038	1883499	292772	4087407
1.b. Rats (<i>Rattus norvegicus</i>)	125904	489630	43336	600979	16909	1276758
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	2856	5004	262	47326	3252	58700
1.d. Hamsters (<i>Mesocricetus</i>)	1940	2986	791	6751	3104	15572
1.e. Other Rodents (other Rodentia)	673	6737	239	5093	4617	17359
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	5373	1386	1781	28138	6983	43661
1.g. Cats (<i>Felis catus</i>)	14	169	0	126	1930	2239
1.h. Dogs (<i>Canis familiaris</i>)	1233	207	144	4544	3810	9938
1.i. Ferrets (<i>Mustela putorius furo</i>)	20	184	0	2153	105	2462
1.j. Other Carnivores (other Carnivore)	72	0	0	468	411	951
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	3	0	0	154	1614	1771
1.l. Pigs (<i>Sus</i>)	4638	417	100	9589	17299	32043
1.m. Goats (<i>Capra</i>)	170	39	87	478	1014	1788
1.n. Sheep (<i>Ovis</i>)	597	601	24	8065	6833	16120
1.o. Cattle (<i>Bos</i>)	243	36	0	2860	13756	16895
1.p. Prosimians (Prosimia)	0	40	0	311	370	721
1.q. New World Monkeys (Ceboidea)	7	101	0	419	21	548
1.r. Old World Monkeys (Cercopithecoidea)	111	261	6	3173	8	3559
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	29	55	5	887	449	1425
1.u. Quail (<i>Coturnix coturnix</i>)	0	400	0	177	413	990
1.v. Other birds (other Aves)	4769	4563	47	21365	194727	225471
1.w. Reptiles (Reptilia)	0	90	0	0	934	1024
1.x. Amphibians (Amphibia)	362	603	2886	10852	2022	16725
1.y. Fish (Pisces)	5841	57964	2458	381109	40958	488330
1.z. TOTAL	404341	1430085	855204	3018516	614311	6322457

France reporting for 2007

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

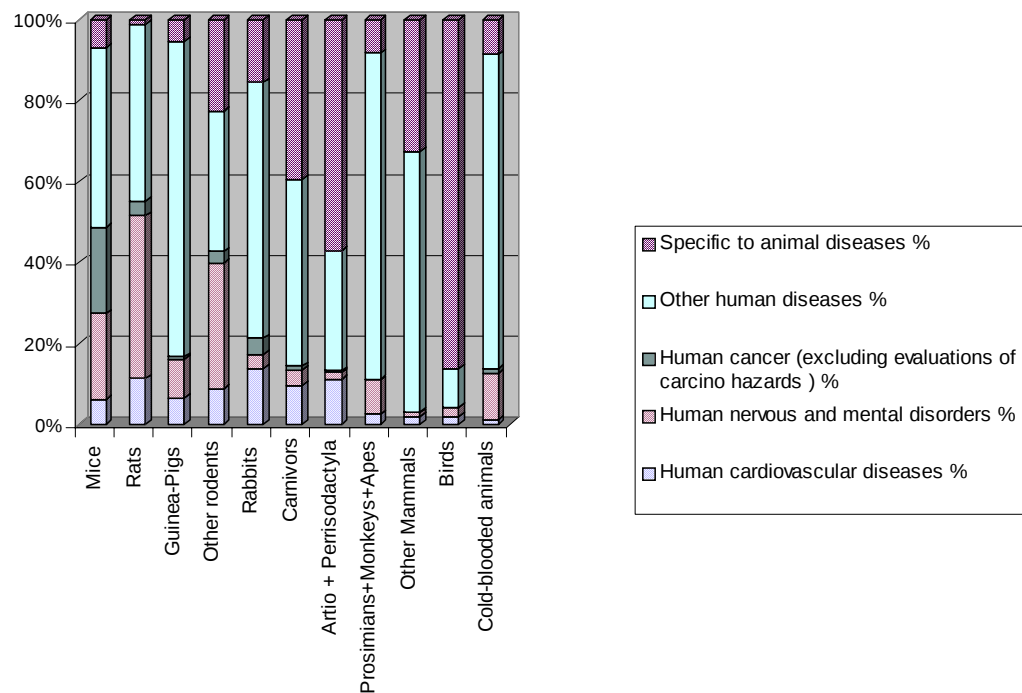
Classes of animals	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino. hazards)	Other human diseases	Specific animal diseases	Total
Mice	249486	858612	803038	1883499	292772	4087407
Rats	125904	489630	43336	600979	16909	1276758
Guinea-Pigs	2856	5004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

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

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

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

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



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

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

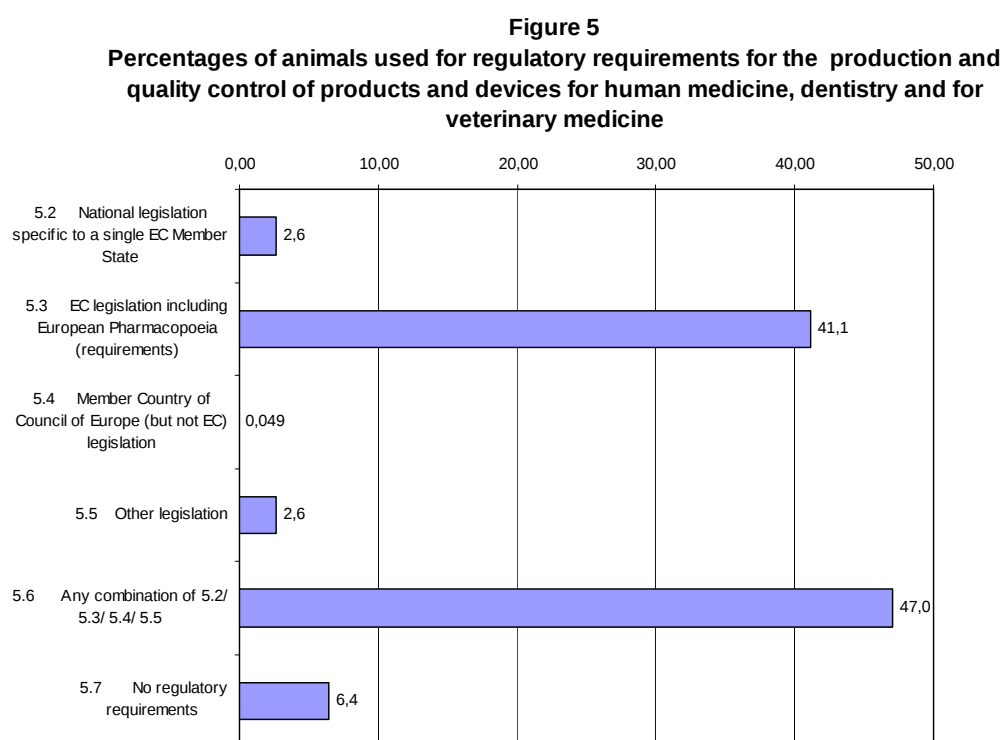
III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

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

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

III.6.2. Treatment and interpretation of the data

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



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

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

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

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

5.1. Species	5.2. National legislation specific to a single EC Member State1	5.3. EC legislation including European Pharmacopoeia (requirements)	5.4. Member Country of Council of Europe (but not EC) legislation2)	5.5. Other legislation	5.6. Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7. No regulatory requirements	5.8. Total
1.a. Mice (<i>Mus musculus</i>)	33233	359722	371	21567	569279	43303	1027475
1.b. Rats (<i>Rattus norvegicus</i>)	5107	86403	405	16406	105741	5319	219381
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	2519	43916	0	6494	62550	5615	121094
1.d. Hamsters (<i>Mesocricetus</i>)	0	8916	0	358	3613	2	12889
1.e. Other Rodents (other Rodentia)	0	0	0	0	30	0	30
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	851	107271	0	1077	53039	20539	182777
1.g. Cats (<i>Felis catus</i>)	43	614	0	8	58	10	733
1.h. Dogs (<i>Canis familiaris</i>)	208	985	0	0	982	55	2230
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	2	0	0	522	48	572
1.j. Other Carnivores (other Carnivore)	27	311	0	0	0	0	338
1.k. Horses, donkeys and cross breeds (<i>Equidae</i>)	307	225	0	0	164	2087	2783
1.l. Pigs (<i>Sus</i>)	518	5436	0	91	2385	994	9424
1.m. Goats (<i>Capra</i>)	68	27	0	3	10	11	119
1.n. Sheep (<i>Ovis</i>)	805	1523	54	5	703	5079	8169
1.o. Cattle (<i>Bos</i>)	139	2500	0	6	414	469	3528
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0	0
1.q. New World Monkeys (<i>Ceboidea</i>)	0	0	0	0	33	0	33
1.r. Old World Monkeys (<i>Cercopithecoidea</i>)	0	0	0	0	231	0	231
1.s. Apes (<i>Hominoidea</i>)	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	13	50	0	0	0	28	91
1.u. Quail (<i>Coturnix coturnix</i>)	0	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	1887	117540	60	1676	41194	7556	169913
1.w. Reptiles (<i>Reptilia</i>)	0	0	0	0	0	0	0
1.x. Amphibians (<i>Amphibia</i>)	0	0	0	0	0	0	0
1.y. Fish (<i>Pisces</i>)	2260	1430	0	0	406	24137	28233
1.z. TOTAL	47985	736871	890	47691	841354	115252	1790043

(*) France reporting for 2007

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

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

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

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

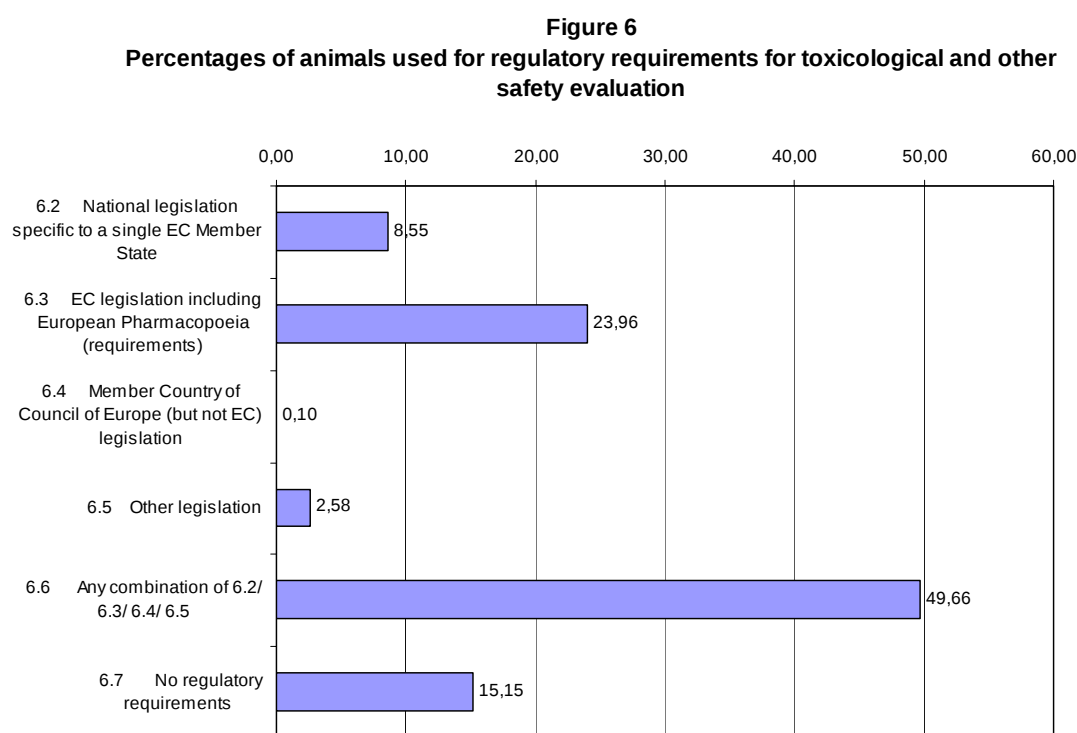
III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

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

III.7.2. Treatment and interpretation of the data

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

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



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

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

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

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

The testing carried out in 2008 to satisfy national legislation specific to a single Member State showed a decrease of about 7,500 animals which represents roughly a 1,2% decrease compared to the last report.

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

Data of 2008*

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

(*)France is reporting for 2007

Examples:

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

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

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

Footnotes:

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

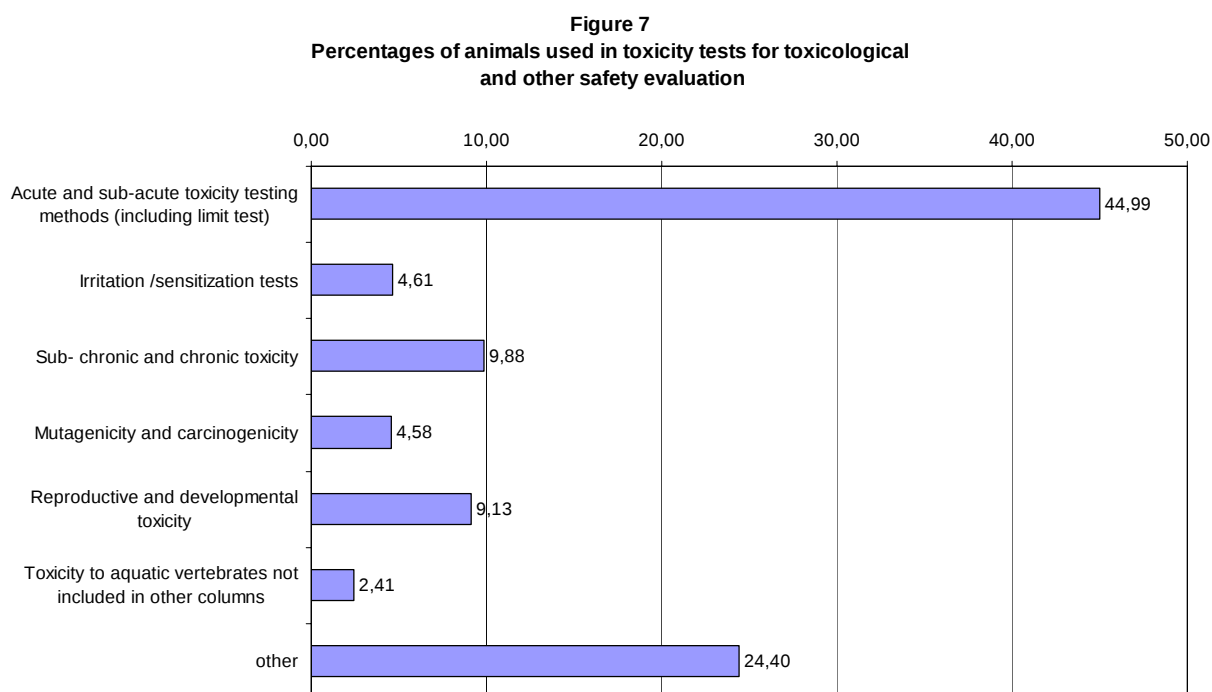
III.8. Results of EU Table 7: Animals used in toxicity tests for toxicological and other safety evaluations

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

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

III.8.2. Treatment and interpretation of the data

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



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

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

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

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

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

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

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

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

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

Data of 2008*

7.1. Species	7.2. Acute and sub-acute toxicity testing methods (including limit test)			7.3. Skin irritation	7.4. Skin sensitisation	7.5. Eye irritation	7.6. Sub-chronic and chronic toxicity	7.7. Carcinogenicity	7.8. 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>)	87440	87455	46654	926	16742	30	27173	10375	3744	12858	2759	200	101843	398199
1.b. Rats (<i>Rattus norvegicus</i>)	7060	12651	74924	768	1465	78	54915	10219	20263	14043	51314	26	46957	294683
1.c. Guinea-Pigs (<i>Cavia porcellus</i>)	1000	303	3363	140	20198	6	618	0	120	0	101	7	6027	31883
1.d. Hamsters (<i>Mesocricetus</i>)	16	0	343	22	0	0	310	0	0	21	0	0	868	1580
1.e. Other Rodents (other Rodentia)	27	0	0	0	0	0	204	0	0	0	0	0	164	395
1.f. Rabbits (<i>Oryctolagus cuniculus</i>)	110	38	5875	4200	32	2105	1240	0	6047	0	5349	7	14984	39987
1.g. Cats (<i>Felis catus</i>)	0	0	24	0	0	0	62	0	0	0	0	0	236	322
1.h. Dogs (<i>Canis familiaris</i>)	15	339	4637	0	0	0	4582	0	0	0	20	0	1484	11077
1.i. Ferrets (<i>Mustela putorius furo</i>)	0	0	211	0	0	0	0	0	0	0	0	0	58	269
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0	0	296	296
1.k. Horses, donkeys and cross breeds (Equidae)	0	0	0	0	0	0	0	0	0	0	0	0	22	22
1.l. Pigs (<i>Sus</i>)	0	11	535	115	0	0	937	0	0	0	112	0	6355	8065
1.m. Goats (<i>Capra</i>)	0	0	0	0	0	0	0	0	0	0	0	0	43	43
1.n. Sheep (<i>Ovis</i>)	0	0	36	0	0	0	34	0	0	0	0	0	339	409
1.o. Cattle (<i>Bos</i>)	0	0	60	0	0	0	12	0	0	0	22	0	359	453
1.p. Prosimians (Prosimia)	0	0	261	0	0	0	143	0	0	0	0	0	139	543
1.q. New World Monkeys (Ceboidea)	0	0	65	0	0	0	71	0	64	0	0	0	70	270
1.r. Old World Monkeys (Cercopithecoidea)	18	0	1735	0	0	0	2861	0	176	0	58	0	846	5694
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.u. Quail (<i>Coturnix coturnix</i>)	819	241	0	0	0	0	0	0	0	0	176	0	934	2170
1.v. Other birds (other Aves)	456	135	5937	1020	0	65	0	0	0	0	108	0	43510	51231
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	0	0	0	0	108	0	4	0	0	0	179	291
1.y. Fish (Pisces)	50983	70000	5110	119	0	0	9735	213	868	0	3796	24857	28590	194271
1.z. TOTAL	147944	171173	149770	7310	38437	2284	103005	20807	31286	26922	63815	25097	254303	1042153

(*) France reporting for 2007

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

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

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

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

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

III.9.2. Treatment and interpretation of the data

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

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

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

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

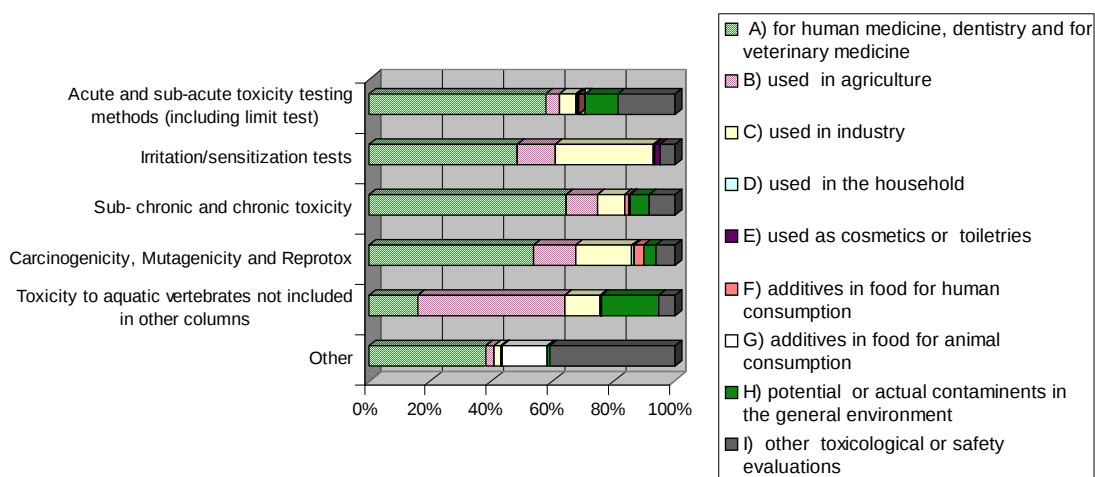


Figure 8 shows that the majority of animals tested in acute/sub-acute toxicity are intended for the purpose of human medicine, dentistry and veterinary medicine. This is followed by tests carried out for other toxicological or safety evaluation and then for agriculture and industrial products.

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

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

Data of 2008*

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

(*) France reporting for 2007

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

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