



Brussels, 5.12.2013  
SWD(2013) 497 final

PART 1/5

**COMMISSION STAFF WORKING DOCUMENT**

**Accompanying document to the  
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT  
Seventh 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(2013) 859 final}

**COMMISSION STAFF WORKING DOCUMENT**

**Accompanying document to the  
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT  
Seventh Report on the Statistics on the Number of Animals used for Experimental and  
other Scientific Purposes in the Member States of the European Union**

## I. INTRODUCTION

The objective of this report is to present statistical data on the number of animals used for scientific purposes in the Member States of the European Union during the year 2011(\*) in accordance with provisions of Article 26 of Directive 86/609/EEC of 24 November 1986<sup>1</sup> regarding the protection of animals used for experimental and other scientific purposes.

The first two statistical reports drafted in accordance with the provisions of the above mentioned directive which were published in 1994<sup>2</sup> and 1999<sup>3</sup>, covering data on experimental animals collected in 1991 and 1996 respectively, allowed only 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 1997 an agreement was reached between the competent authorities of the Member States and the Commission to submit data for future reports under a format of eight harmonized tables. The Fifth Statistical report published in 2007<sup>4</sup> contained for the first time data collected in the 10 Member States which joined the EU in 2004. The Sixth Statistical Report published in 2010<sup>5</sup> gave an overview of the number of animals used in the year 2008 in 27 Member States.

This Seventh Statistical Report contains the results of the data collected by all 27 Member States in 2011 with the exception of one (France) which provided data from 2010.

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

(\*) Except for one Member State reporting for 2010

---

<sup>1</sup> OJL 358, 18.12.1986, p.1.  
<sup>2</sup> COM (94) 195 final  
<sup>3</sup> COM (1999) 191 final  
<sup>4</sup> COM (2007) 675 final  
<sup>5</sup> COM (2010) 1107 final/2

## **II. DATA SUBMITTED AND GENERAL ASSESSMENT**

### **II.1. Data submitted by the Member States**

As in 2008 all 27 Member States submitted the data in the agreed format of the eight EU Tables, referred to as table 1 to 8 hereunder.

A quality control check has been carried out on the set of data submitted for 2011 that is essentially governed by five criteria based on certain relationships between the data in the different tables.

- The first of these relationships concerns the total number of animals used by species of column 1.2 of table 1 and of column 2.10 of table 2. Since both tables concern the total of animals used by species the totals of the tables 1 and 2 should be identical.
- The second relationship concerns column 2.6 of table 2 'animals used for toxicological and other safety evaluation' which is broken down into types of products/endpoints in table 3; into Regulatory requirements in table 6; and into types of toxicological tests in table 7. Therefore, the totals 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'.
- The third relationship is that the sum of column 2.4 and 2.5 of table 2 must be equal to the total of table 5.
- The fourth relationship exists between the total row of table 3 and the total column of table 8. Both the row and the column concern the total number of animals used for toxicological and other safety test by type of products/procedure and should therefore be equal.
- In the fifth relationship, the total row of table 7 should be equal to the total row of table 8.

The first and last two criteria have not been fully respected in the most recent collection of data by some Member States and could unfortunately not be corrected in time for the start of the analysis for this report. Despite these marginal errors, the data provided by the Member States give a consistent basis for a sound statistical analysis of all eight EU Tables.

### **II.2. General assessment**

Each Member State is requested, pursuant to Article 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 2011 with the exception of France which provided data from 2010.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes<sup>6</sup> allowed the use of animals in experiments for education and training, but where the purposes of such experiments were not covered by the Directive, Member States according to the Resolution applied national provisions which are no less severe than those of the Directive. Therefore, when reporting a number of Member States have also included animals covered by the Resolution in the report.

It should be noted that this is the last time that animal use data has been collected in accordance with the requirements of Directive 86/609/EEC. This Directive has been replaced by Directive 2010/63/EU on the protection of animals used for scientific purposes, and the

---

<sup>6</sup> OJ C 331, 23.12.86, p. 2.

submission and publication of data have been completely revised with effect from 10 May 2013.

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 2011. 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.

Due to differences in the reporting year and an increase in the number of Member States over the years, it is not possible to draw accurate quantitative conclusions on the evolution of the use of animals for experimental purposes in the EU. However, some trend comparisons have been made, and any 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 the respective comments.

In the EU, the total number of animals used for experimental and other scientific purposes from the data collected in 2011 in accordance with the provision of the Directive for this report is just under 11,5 million (with data from France from 2010). This is a reduction of over half a million animals in the EU since the previous report covering the year 2008. The Member States contributing with a biggest net reduction include Belgium, France, Italy, Sweden and UK. In addition, credit should be given to some of the other Member States using smaller numbers of animals, however, with a significant drop in percentage terms.

As in previous reports rodents and rabbits represent 80% of the total number of animals used in the EU. Mice are by far the most commonly used species accounting for 61% of the total use, followed by rats with 14%.

The second most used group of animals was, as in previous years, cold-blooded animals which represent almost 12,5%. The third largest group of animals used was birds with 5,9% of the total use.

As stated in the previous three statistical reports no ‘Great Apes’ were used in experiments in the EU in 2011.

### **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 2011.

A consolidated table has been computed on the basis of the data submitted 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.

As France submitted data from 2010 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 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 Contains the data submitted by each Member State with Member State comments.

# PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2011

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

Two types of information can be drawn from the data submitted 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 Member States

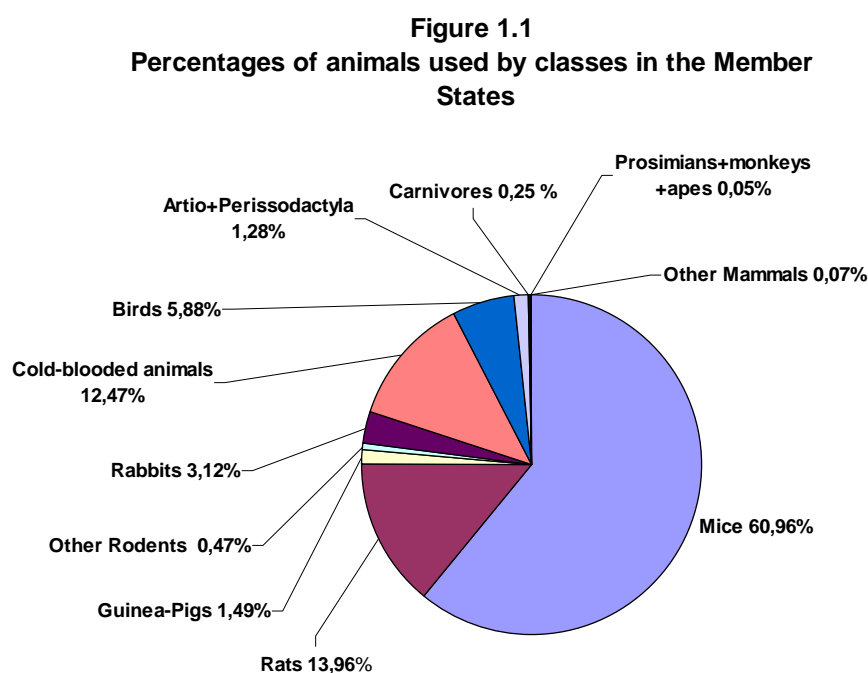
Table 1.1 of this report presents the consolidated data on the number of animals used by species.

The total number of animals used in 2011 in the 27 Member States amounts to 11 481 521 animals. It is important to note that the total number of animals used in 2011 has decreased by over 500 000 (4.3%) animals in comparison to 2008.

### 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 in classes. 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 as 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.



Rodents together with rabbits represent 80% of the total number of animals used. Mice (60,9%) and rats (13,9%) 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 12,4%.

Birds is the next highest animal group used for experimental purposes at 5,9%.

The *Artiodactyla* and *Perissodactyla* group including horses, donkeys and cross-bred animals (*Perissodactyla*), pigs, goats, sheep and cattle (*Artiodactyla*) represent only 1,2% of the total number of animals used in the Member States.

Carnivores represent 0,25% of the total number of animals used and non-human primates represent 0,05% of the animals used in 2011.

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

In this chapter, and the following chapters dealing with comparisons, it should be noted that in 1996, 2002, 2005, 2008 and for this report France reported data respectively for 1997, 2001, 2004, 2007 and 2010 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 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, 2008 and 2011

Class of species	1996(*)	1999	2002(**)	2005(***)	2008(****)	2011(*****)
% Rodents-rabbits	81,3	86,9	78,0	77,5	82,2	80,0
% Cold-blooded animals	12,9	6,6	15,4	15,	9,6	12,4
% Birds		4,7	5	5,4	6,4	5,9
% <i>Artio and Perissodactyla</i>		1,2	1,2	1,1	1,4	1,2

(\*) 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

(\*\*\*\*\*) 27 Member States reporting for 2011, one for 2010

The percentage of rodents and rabbits shows some fluctuation, but remains close to 80%. The proportion of cold-blooded animals used in 1996, in 2002, in 2005 and 2008 is between 9,6 to 15%. However, in 1999 a much lower percentage of 6,6% was observed. In 2011, the use of cold-blooded animals increased from the last report but the percentage of animals used seems to fit perfectly into the cohort from 9,6 to 15% of the total number of animals.

Birds representing the third largest percentage of animals, seem to have reached a plateau in 2008. For the first time in 2011 the number of birds has decreased (by over 88 000). The group of horses, donkeys and cross-bred animals (*Artiodactyla*) and pigs, goats, sheep and cattle (*Perissodactyla*) fluctuates at around 1%.

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 was already a decrease reported in 2008 and for 2011 the decrease has continued (by more than 500 000 animals). However, the use of some individual species has increased. This is displayed in Table 1.0 below.

Table 1.0 contains a comparison of the change that has taken place since 2008 for each species, expressed by number of animals per species, between EU 27 (data from 2011) and EU 27 (data from 2008) (first three columns) and in percentage per species (fourth column).



**Table 1.0: Changes in species number and proportion between 2008 and 2011**

Species	Number of animals in EU 27	Number of animals in EU 27	Change since 2008	% change by species
	2008	2011		
1.a Mice ( <i>Mus musculus</i> )	7122188	6999312	-122876	-1,73
1.b Rats ( <i>Rattus norvegicus</i> )	2121727	1602969	-518758	-24,45
1.c Guinea-Pigs ( <i>Cavia porcellus</i> )	220985	171584	-49401	-22,35
1.d Hamsters ( <i>Mesocricetus</i> )	32739	25251	-7488	-22,87
1.e Other Rodents (other Rodentia)	39506	28465	-11041	-27,95
1.f Rabbits ( <i>Oryctolagus cuniculus</i> )	333213	358213	25000	7,50
1.g Cats ( <i>Felis catus</i> )	4088	3713	-375	-9,17
1.h Dogs ( <i>Canis familiaris</i> )	21315	17896	-3419	-16,04
1.i Ferrets ( <i>Mustela putorius furo</i> )	3208	2540	-668	-20,82
1.j Other Carnivores	2853	4982	2129	74,62
1.k Horses, donkeys and cross-breds ( <i>Equidae</i> )	5976	6686	710	11,88
1.l Pigs ( <i>Sus</i> )	92813	77280	-15533	-16,74
1.m Goats ( <i>Capra</i> )	3840	2907	-933	-24,30
1.n Sheep ( <i>Ovis</i> )	30190	28892	-1298	-4,30
1.o Cattle ( <i>Bos</i> )	33952	30914	-3038	-8,95
1.p Prosimians ( <i>Prosimia</i> )	1261	83	-1178	-93,42
1.q New World Monkeys ( <i>Ceboidea</i> )	904	700	-204	-22,57
1.r Old World Monkeys ( <i>Cercopithecoidea</i> )	7404	5312	-2092	-28,25
1.s Apes ( <i>Hominoidea</i> )	0	0	0	0,00
1.t Other Mammals (other <i>Mammalia</i> )	5704	7888	2184	38,29
1.u Quail ( <i>Coturnix coturnix</i> )	9626	5614	-4012	-41,68
1.v Other birds (other <i>Aves</i> )	754485	669451	-85034	-11,27
1.w Reptiles ( <i>Reptilia</i> )	4101	3824	-277	-6,75
1.x Amphibians ( <i>Amphibia</i> )	61789	29583	-32206	-52,12
1.y Fish ( <i>Pisces</i> )	1087155	1397462	310307	28,54
1.z TOTAL	12001022	11481521	-519501	-4,33

There is a clear increase in the total numbers of five species out of the 25 species reported. For other species a net decrease is observed.

The changes per species are reported in table 1.0 under the last column 'percentage change by species' and in the column 'change since 2008' reflecting the magnitude of the change.

The highest increase is noted for fish used in comparison to 2008 (310 307).

There has been a significant proportional increase in the number of rabbits since 2008 (25 000).

For species used in lower numbers (i.e. in the thousands range) there is an increase in the number of animals in the category other carnivores (2 129), horses, donkeys and cross-breds (710) and other mammals (2 184).

The largest decrease observed in 2011 for species used in greater numbers (i.e. in the millions range) is for rats with a reduction of more than 500 000 animals. In the same range there is also a reduction in the use of mice (122 876). There is also a significant reduction in the use of 'other birds' (more than 85 000) and guinea-pigs (49 401).

There is a clear decrease in the use of prosimians and non-human primates. The most notable proportional reduction is in the use of prosimians (1 178) which represents a decrease of 94%. The total number of new world monkeys is down from 904 in 2008 to 700 in 2011 (22,5%), and use of old world monkeys has also decreased from 7 404 to 5 312 (28%).

No use of great apes has been reported in EU since in 1999.

Member States submitted a break down of the category 'other', for the following species:

*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, canary, parakeet, parrot and farmed avian species for example, chickens (*Gallus gallus domesticus*).

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

**Data of 2011 (\*)**

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	SI	SE	UK	Totals
1.a.Mice	153153	408883	3819	1328	72855	141991	26048	73503	1326274	1451046	24354	143755	248958	515946	6300	2131	470	0	237784	95115	24399	44575	634912	8747	11133	185913	1155920	6999312
1.b.Rats	9026	89547	2569	0	30829	67159	2556	18586	252589	312740	2266	70873	10476	155136	4020	1297	32	0	98881	38171	11290	5161	126406	5327	393	35202	252437	1602969
1.c. Guinea-Pigs	3797	24300	3700	0	3304	4672	72	11	35543	24258	39	9228	545	13784	0	177	0	0	5493	8943	4	6607	13749	645	48	1151	11514	171584
1.d. Hamsters	125	2435	516	0	119	178	120	201	8210	4187		88	0	517	0	0	0	0	3632	278	6	263	1492	0	0	881	2003	25251
1.e. Other Rodents	64	421			1316	115	0	2682	224	4111		0		1946				0	979	11710	74		80	17	0	1483	3243	28465
1.f. Rabbits	15633	54001	822	0	7677	3602	3	357	125913	87303	701	7567	715	8392	0	274	0	0	6293	2198	102	2195	21302	299	234	710	11920	358213
1.g.Cats	14	630	8	0	181	0	0	454	569	585	19	34	120	0	0	0	0	0	174	480		0	229	10	0	34	172	3713
1.h.Dogs	75	490	0	0	1386	470	0	2805	3032	2474	4	675	473	408	9	0	0	0	692	229	20	0	1252	0	0	530	2872	17896
1.i.Ferrets	12	192	0	0	193	129	0	0	351	96		0	0	0	0	0	0	0	852	0		0	87	0	0	76	552	2540
1.j. Other Carnivores	0	0			45	197	0	656	0	262		0		0				0	430	2149			245		0	256	742	4982
1.k. Horses, donkeys and cross-breeds	128	54			595	67	40	23	373	1140		9	238	34				0	2371	766		14	346		7	107	374	6686
1.l.Pigs	1553	2622	110		2283	8694	325	681	7364	15090	390	1278	286	2486		19		0	14686	1147	474	2	11046	84	13	2277	4370	77280
1.m Goats	60	86			106	74	0	40	710	394		0	39	34				0	284	396	99		455		0	13	117	2907
1.n. Sheep	683	542	320		1147	191	0	684	5491	3287	8	160	348	243				0	2600	379	29	131	2790	14	4	285	9556	28892
1.o.Cattle	1582	810			783	513	6750	63	2362	4300		5	1700	27				0	2383	3489		3	1464	0	0	370	4310	30914
1.p. Prosimians	0	0	0	0	0	0	0	0	83	0		0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	83
1.q. NW Monkeys	0	0	0	0	0	0	0	0	163	191		0	0	79	0	0	0	0	22	0		0	1	0	0	0	244	700
1.r. OW Monkeys	0	20	0	0	30	0	0	0	1564	1579		7	0	371	0	0	0	0	184	0		0	342	0	0	0	1215	5312
1.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	0
1.t.Other Mammals	0	64			2838	32	20	17	2	1154		0	480	184				10	41	594			56		0	1625	771	7888
1.u.Quail	0	651	0	0	230	0	0	0	122	2821		235	0	4	0	0	0	0	68	1247		9	105	88	0	0	34	5614
1.v.Other birds	1940	16493	1080		170261	3245	701	4426	71821	31271		36304	503	29305		20		0	99354	13615	433	1196	21341	486	0	2804	162852	669451
1.w.Reptiles	0	459			1258	237	0	15	74	1011		0		239				0	133	15			0		0	0	383	3824
1.x Amphibians	176	2113	4285		3989	115	0	73	3279	4453	220	725	21	894		149		0	1247	964	25		1097		0	1216	4542	29583
1.y.Fish	3267	60266	30		52771	51159	4400	30766	354039	119949		5236	88	51786				0	36034	100275	9601		61330		42	36108	420315	13974622
1.z.TOTAL	191288	665079	17259	1328	354196	282840	41035	136043	2200152	2073702	28001	276179	264990	781815	10329	4067	502	10	514617	282160	46556	60156	900127	15717	11874	271041	2050458	11481521

(\*) France is reporting for 2010

**Table 1.2: Classes of animals used for experimental purposes in the EU Member States  
Data of 2011 (\*)**

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	SI	SE	UK	Totals
Mice	153153	408883	3819	1328	72855	141991	26048	73503	1326274	1451046	24354	143755	248958	515946	6300	2131	470	0	237784	95115	24399	44575	634912	8747	11133	185913	1155920	6999312
Rats	9026	89547	2569	0	30829	67159	2556	18586	252589	312740	2266	70873	10476	155136	4020	1297	32	0	98881	38171	11290	5161	126406	5327	393	35202	252437	1602969
Guinea-Pigs	3797	24300	3700	0	3304	4672	72	11	35543	24258	39	9228	545	13784	0	177	0	0	5493	8943	4	6607	13749	645	48	1151	11514	171584
Hamsters+ other rodents	189	2856	516	0	1435	293	120	2883	8434	8298	0	88	0	2463	0	0	0	0	4611	11988	80	263	1572	17	0	2364	5246	53716
Rabbits	15633	54001	822	0	7677	3602	3	357	125913	87303	701	7567	715	8392	0	274	0	0	6293	2198	102	2195	21302	299	234	710	11920	358213
Cold-blooded animals (1)	3443	62838	4315	0	58018	51511	4400	30854	357392	125413	220	5961	109	52919	0	149	0	0	37414	101254	9626	0	62427	0	42	37324	425240	1430869
Birds (2)	1940	17144	1080	0	170491	3245	701	4426	71943	34092	0	36539	503	29309	0	20	0	0	99422	14862	433	1205	21446	574	0	2804	162886	675065
Artio+Perissod actyla (3)	4006	4114	430	0	4914	9539	7115	1491	16300	24211	398	1452	2611	2824	0	19	0	0	22324	6177	602	150	16101	98	24	3052	18727	146679
Carnivores	101	1312	8	0	1805	796	0	3915	3952	3417	23	709	593	408	9	0	0	0	2148	2858	20	0	1813	10	0	896	4338	29131
Prosimians+m onkeys+apes	0	20	0	0	30	0	0	0	1810	1770	0	7	0	450	0	0	0	0	206	0	0	0	343	0	0	0	1459	6095
Other Mammals	0	64			2838	32	20	17	2	1154		0	480	184				10	41	594			56		0	1625	771	7888
<b>TOTAL</b>	<b>191288</b>	<b>665079</b>	<b>17259</b>	<b>1328</b>	<b>354196</b>	<b>282840</b>	<b>41035</b>	<b>136043</b>	<b>2200152</b>	<b>2073702</b>	<b>28001</b>	<b>276179</b>	<b>264990</b>	<b>781815</b>	<b>10329</b>	<b>4067</b>	<b>502</b>	<b>10</b>	<b>514617</b>	<b>282160</b>	<b>46556</b>	<b>60156</b>	<b>900127</b>	<b>15717</b>	<b>11874</b>	<b>271041</b>	<b>2050458</b>	<b>11481521</b>

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	SI	SE	UK	Totals
Mice	80,06	61,48	22,13	100,00	20,57	50,20	63,48	54,03	60,28	69,97	86,98	52,05	93,95	65,99	60,99	52,40	93,63	0,00	46,21	33,71	52,41	74,10	70,54	55,65	93,76	68,59	56,37	60,96
Rats	4,72	13,46	14,88	0,00	8,70	23,74	6,23	13,66	11,48	15,08	8,09	25,66	3,95	19,84	38,92	31,89	6,37	0,00	19,21	13,53	24,25	8,58	14,04	33,89	3,31	12,99	12,31	13,96
Guinea-Pigs	1,98	3,65	21,44	0,00	0,93	1,65	0,18	0,01	1,62	1,17	0,14	3,34	0,21	1,76	0,00	4,35	0,00	0,00	1,07	3,17	0,01	10,98	1,53	4,10	0,40	0,42	0,56	1,49
Hamsters + other rodents	0,10	0,43	2,99	0,00	0,41	0,10	0,29	2,12	0,38	0,40	0,00	0,03	0,00	0,32	0,00	0,00	0,00	0,00	0,90	4,25	0,17	0,44	0,17	0,11	0,00	0,87	0,26	0,47
Rabbits	8,17	8,12	4,76	0,00	2,17	1,27	0,01	0,26	5,72	4,21	2,50	2,74	0,27	1,07	0,00	6,74	0,00	0,00	1,22	0,78	0,22	3,65	2,37	1,90	1,97	0,26	0,58	3,12
Cold-blooded animals (1)	1,80	9,45	25,00	0,00	16,38	18,21	10,72	22,68	16,24	6,05	0,79	2,16	0,04	6,77	0,00	3,66	0,00	0,00	7,27	35,89	20,68	0,00	6,94	0,00	0,35	13,77	20,74	12,46
Birds (2)	1,01	2,58	6,26	0,00	48,13	1,15	1,71	3,25	3,27	1,64	0,00	13,23	0,19	3,75	0,00	0,49	0,00	0,00	19,32	5,27	0,93	2,00	2,38	3,65	0,00	1,03	7,94	5,88
Artio+Perissodactyla (3)	2,09	0,62	2,49	0,00	1,39	3,37	17,34	1,10	0,74	1,17	1,42	0,53	0,99	0,36	0,00	0,47	0,00	0,00	4,34	2,19	1,29	0,25	1,79	0,62	0,20	1,13	0,91	1,28
Carnivores	0,05	0,20	0,05	0,00	0,51	0,28	0,00	2,88	0,18	0,16	0,08	0,26	0,22	0,05	0,09	0,00	0,00	0,00	0,42	1,01	0,04	0,00	0,20	0,06	0,00	0,33	0,21	0,25
Prosimians+monkeys+apes	0,00	0,00	0,00	0,00	0,01	0,00	0,00	0,00	0,08	0,09	0,00	0,00	0,00	0,06	0,00	0,00	0,00	0,00	0,04	0,00	0,00	0,00	0,04	0,00	0,00	0,00	0,07	0,05
Other Mammals	0,00	0,01	0,00	0,00	0,80	0,01	0,05	0,01	0,00	0,06	0,00	0,00	0,18	0,02	0,00	0,00	0,00	100,00	0,01	0,21	0,00	0,00	0,01	0,00	0,00	0,60	0,04	0,07
<b>TOTAL</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,0</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>	<b>100,00</b>

FR(\*) France reporting for 2010

(1) Reptiles + amphibians + fish

(2) Quails and Other birds

(3) Horses, donkeys, and cross-breds + 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.

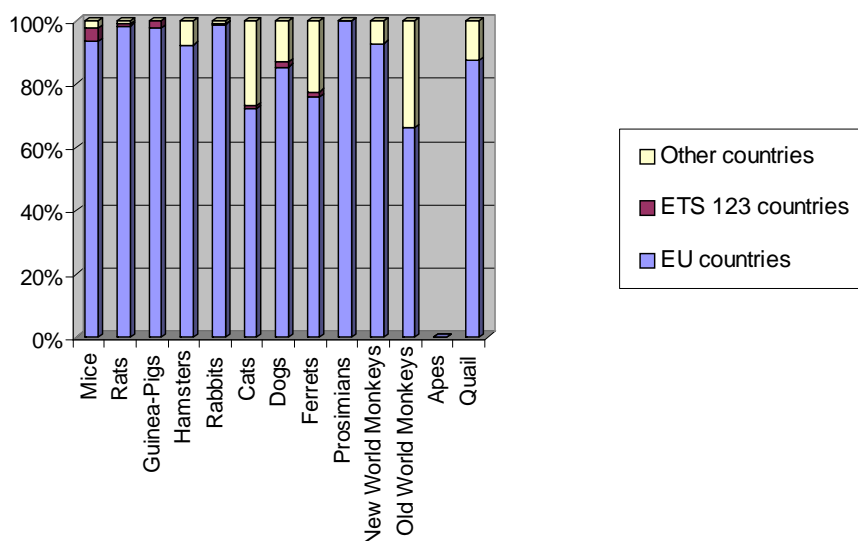
In addition, EU Table 1 contains information on the number of animals re-used in experiments.

#### 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 indicates that the majority of species used in 2011 originate from EU breeding centres. However, certain species such as cats, dogs, ferrets and old world monkeys originated from both EU and non-EU breeding centres.

### *III.2.3. Comparison with data of the previous year*

The general pattern shown in figure 1.2 on the origin of species remains rather similar to that of previous reports, with clear preference for animals which are bred in the EU. There is an increase in the use of dogs of EU origin from 72% to 85%, ferrets from 71% to 76% and old world monkeys from 54% to 66%. However, there is a decrease in use of new world monkeys from 99% to 92% and quails from 96% to 87% bred in the EU.

**Table 1.3: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Data of 2011 (\*)**

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> )	6999312	5651922	900047	274313	173030	3768
1.b. Rats ( <i>Rattus norvegicus</i> )	1602969	1253176	322045	13051	14697	3035
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	171584	120124	47311	3922	227	962
1.d. Hamsters ( <i>Mesocricetus</i> )	25251	18626	4676	0	1949	54
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	358213	336922	17009	1200	3082	15958
1.g. Cats ( <i>Felis catus</i> )	3713	2299	379	34	1001	1181
1.h. Dogs ( <i>Canis familiaris</i> )	17896	12246	3025	292	2333	4178
1.i. Ferrets ( <i>Mustela putorius furo</i> )	2540	1035	893	40	572	64
1.p. Prosimians ( <i>Prosimia</i> )	83	83	0	0	0	33
1.q. New World Monkeys ( <i>Ceboidea</i> )	700	630	19	0	51	322
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	5312	1698	1813	5	1796	1492
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.u. Quail ( <i>Coturnix coturnix</i> )	5614	4914	0	0	700	0
1.z. TOTAL	9193187	7403665	1297217	292857	199445	

\* France reporting for 2010

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

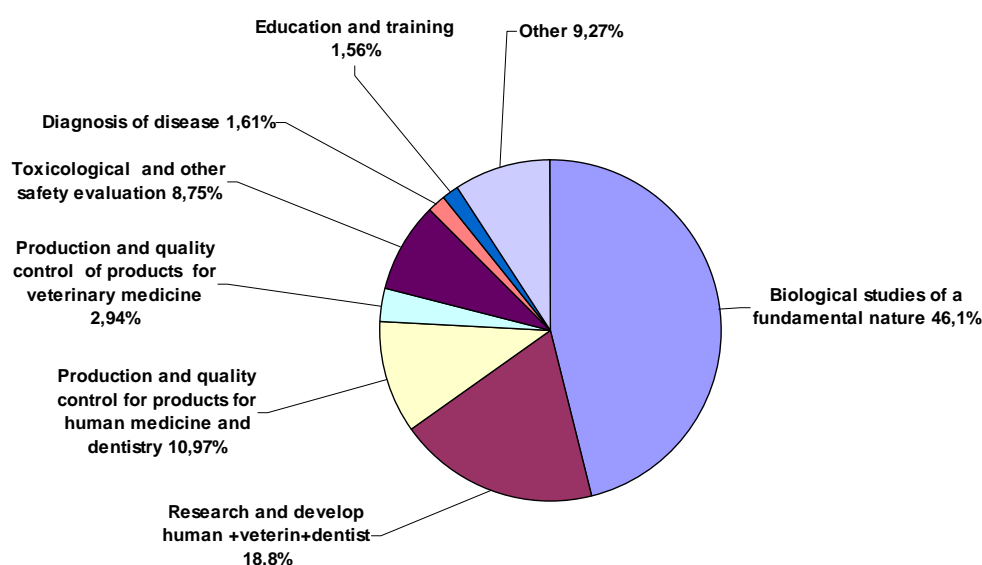
The consolidated data on purposes of the experiments of the 27 Member States are presented in table 2.1 at the end of this chapter.

#### 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 2011. 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 for research and development in the fields of human medicine, veterinary medicine, dentistry and in biological studies of fundamental nature.

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

Toxicological and other safety evaluation represents 8,75% of the total number of animals used for experimental purposes.

Other purposes of procedures represents 9% 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 since 2008 is that the number of animals used for research and development for human medicine, dentistry and veterinary medicine has dropped, as it did between 2005 and 2008. This time the drop is from 22,8% to 18,8% (in terms of animal numbers the decrease is 575 518 animals). There is a reduction of more than



62 000 fish and 41 500 'other birds' whereas the percentage of animals used for fundamental biological research has increased sharply from 38% to 46% (715 519 animals). Both fundamental biological research and research and development in human and veterinary medicine are the areas using by far the highest number of animals in the EU.

The number of animals used for toxicological and other safety evaluation amounts to 8,75% of the total. This represents 1 004 873 animals in this report.

The decrease in the numbers of animals used for toxicological and other safety evaluations since the report of 2008 is modest but represents nevertheless 37 280 animals.

The percentage of animals used for toxicology and safety evaluation was 9.9% in 2002, 8,2% in 2005, 8,7% in 2008 and 8,75% for this report which indicates a trend of stability for this area of use.

The number of animals used for production and quality control of devices for medicine, veterinary medicine and dentistry has gone down by approximately 192 000. In spite of the overall decrease, the use of rabbits has increased by more than 81 000 animals for production and quality control of products and devices for human medicine and dentistry.

Further substantial increases since 2008 have been observed for mice (521 000) and fish (324 000) used in larger numbers for fundamental biological studies. There is also an increase in the use of fish (above 83 000) and birds (above 10 000) for 'other experiments'.

Regarding the increase of mice for biological studies of fundamental nature, Member States indicated that it was due to an increase in developmental assays and research using transgenic mice as specific models for e.g. ocular research, bone metabolism and fertility. The type of studies include LD50, ED50, potency testing and immunogenicity testing, studies in the area of neuroscience, of immunology, studies on physiopathological mechanisms of tumours and research to gain experience for the determination of mechanisms of action of diseases for therapeutic purposes.

The increase use of fish in area of fundamental research was attributed to studies on fish production, genetics, bio-molecular studies, cancer research, physiopathology and diagnosis. Fish have also been used for neurology, cardiovascular studies and in selection according to bioenergetic properties of their cardiac cells.

Fish increase in the category of 'other experiments' was attributed to single testing of biocides and to telemetric monitoring of some common species in the environment. Fish are also exclusively used under this heading by some Member States for vaccine studies.

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

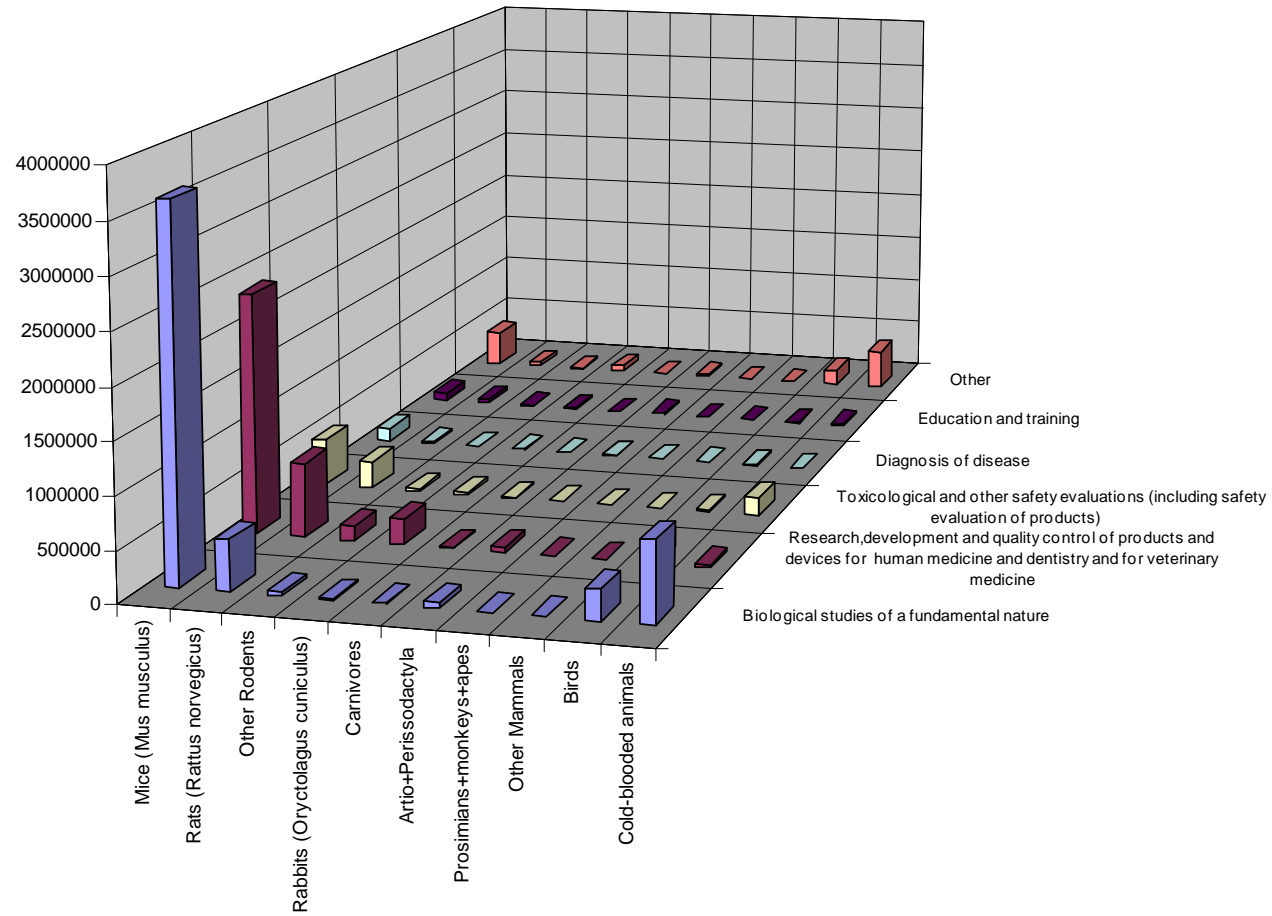
Species	Biological studies of a fundamental nature	Research, development and quality control of products and devices for human medicine and dentistry and for veterinary medicine	Toxicological and other safety evaluations (including safety evaluation of products)	Diagnosis of disease	Education and training	Other	Total
Mice	3602370	2350205	464850	135042	82167	364381	6999015
Rats	491345	725109	272581	18295	48152	47589	1603266
Other rodents	36159	145153	28569	4527	4234	6658	225300
Rabbits	12648	253488	23185	6083	2068	60741	358213
Carnivores	8733	8706	7873	1905	1149	798	29164
Artio+Perissodactyla	51876	48240	5221	7558	14297	19454	146646
Prosimians+monkeys+apes	631	1375	3435	0	209	445	6095

Other mammals	6822	773	179	53	26	35	7888
Birds	294768	191575	17202	7480	3025	161015	675065
Cold-blooded animals	785221	31373	181778	4314	24654	403529	1430869
TOTAL	5290573	3755997	1004873	185257	179981	1064645	11481521

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

The highest number of mice and rats used is attributed to biological studies of a fundamental nature and research, development and quality control of products and devices for medicine, dentistry and veterinary medicine. There has been an increase in the number of cold-blooded animals (essentially fish) used for other purposes and also for biological studies of fundamental nature since 2008.

**Figure 2.2**  
**Species and experimental purposes**



**Table 2.1: Number of animals used in experiments for selected purposes  
Purposes versus species  
data of 2011\***

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> )	3602370	1458291	781514	110400	464850	135042	82167	364381	6999015
1.b. Rats ( <i>Rattus norvegicus</i> )	491345	549341	157145	18623	272581	18295	48152	47589	1603266
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	8426	25777	86142	16350	26722	2067	3293	2807	171584
1.d. Hamsters ( <i>Mesocricetus</i> )	5605	8230	125	5876	1547	408	440	3020	25251
1.e. Other Rodents (other Rodentia)	22128	2653	0	0	300	2052	501	831	28465
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	12648	19434	212043	22011	23185	6083	2068	60741	358213
1.g. Cats ( <i>Felis catus</i> )	855	885	81	223	325	981	169	194	3713
1.h. Dogs ( <i>Canis familiaris</i> )	3715	4671	65	927	7488	458	351	221	17896
1.i. Ferrets ( <i>Mustela putorius furo</i> )	927	1223	86	4	28	9	79	217	2573
1.j. Other Carnivores (other Carnivora)	3236	0	0	541	32	457	550	166	4982
1.k. Horses, donkeys and cross-breds ( <i>Equidae</i> )	1449	868	235	2522	122	902	168	387	6653
1.l. Pigs ( <i>Sus</i> )	24084	20806	839	6841	3537	3067	10022	8084	77280
1.m. Goats ( <i>Capra</i> )	783	535	159	6	8	187	358	871	2907
1.n. Sheep ( <i>Ovis</i> )	9816	2643	4250	2126	746	1854	1206	6251	28892
1.o. Cattle ( <i>Bos</i> )	15744	3228	251	2931	808	1548	2543	3861	30914
1.p. Prosimians ( <i>Prosimia</i> )	83	0	0	0	0	0	0	0	83
1.q. New World Monkeys ( <i>Ceboidea</i> )	244	221	79	0	44	0	0	112	700
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	304	937	138	0	3391	0	209	333	5312
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	6822	531	4	238	179	53	26	35	7888
1.u. Quail ( <i>Coturnix coturnix</i> )	1591	0	0	0	3094	9	80	840	5614
1.v. Other birds (other <i>Aves</i> )	293177	36178	16855	138542	14108	7471	2945	160175	669451
1.w. Reptiles ( <i>Reptilia</i> )	3202	98	0	0	0	412	111	1	3824
1.x. Amphibians ( <i>Amphibia</i> )	16489	946	0	0	2695	5	9127	321	29583
1.y. Fish ( <i>Pisces</i> )	765530	20692	0	9637	179083	3897	15416	403207	1397462
1.z. TOTAL	5290573	2158188	1260011	337798	1004873	185257	179981	1064645	11481521

(\* France is reporting for 2010)

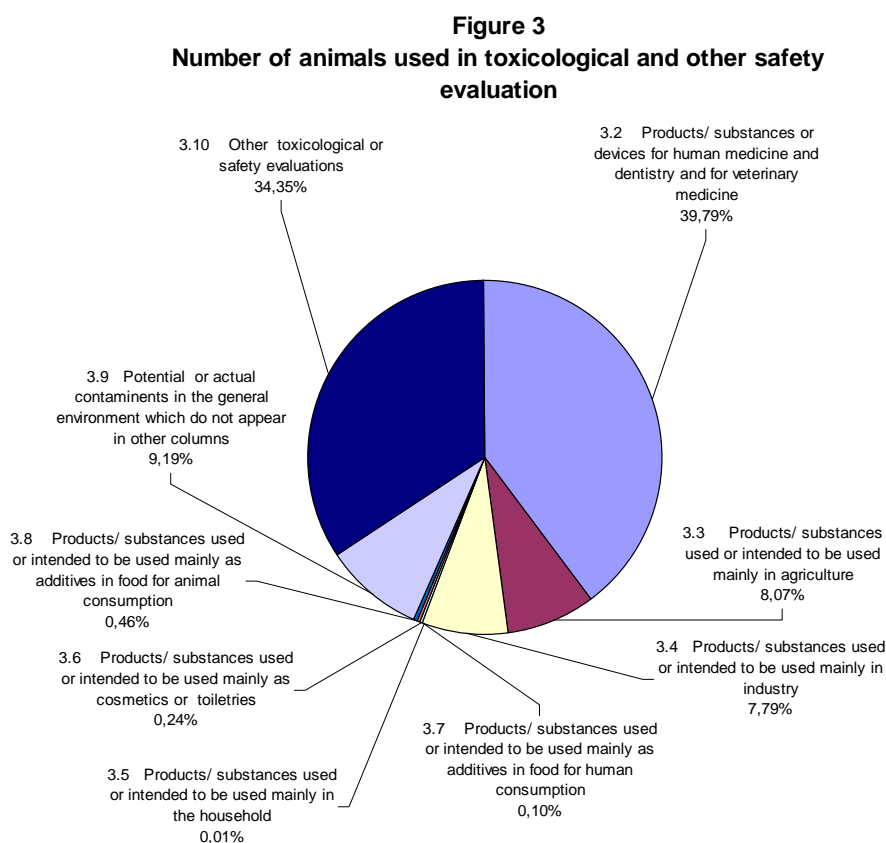
### III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoint

#### 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 2011 is presented in table 3 at the end of this chapter. In this table 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 for testing potential contaminants to the environment amounts to 1 004 873 which represents only 8,75% of the total number of animals used for scientific purposes in 2011 (see table 2.1, column 2.6).

Toxicological or other safety evaluations are split 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 (0,35%) when compared to the other product groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents 39,8% 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 15,9% of the animals for toxicological and other safety evaluations.

There is little change with regard to the number of animals used for toxicological tests for products intended for industry and for agriculture in comparison to 2008, but there is a net increase of the number of animals used for potential contaminants of the environment. The increase is from above 65 000 to approximately 92 000.

A significant decrease has been observed in the number of animals used for testing food for animal consumption in comparison to 2008 from 54 000 to 4 600 which is more than a ten-fold decrease but also for cosmetics and toiletries where the decrease is from 1 960 to 90 animals. This is important to highlight as there is a testing ban in the EU for cosmetics and cosmetic ingredients in place since 2009.

There is, however, a substantial increase in the number of animals used for tests for 'other toxicological or safety evaluations' from 223 000 to 345 000 animals (roughly 122 000 animals which represent an increase of 54%). An increase was also observed in the 2008 report. Member States reported that under this heading, animals are used in metabolic studies and preclinical research, testing substances and products in human and veterinary medicine and in teratology studies on. They are also used in toxicity test to aquatic vertebrates not included in other categories, in LD50, ED50, pyrogen testing, and testing for algae biotoxins and other foodstuff contaminants.

**Table 3: Number of animals used in toxicological and other safety evaluation  
Products versus species**

**Data of 2011\***

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> )	140441	15395	20073	40	40	652	1156	1910	285003	464710
1.b. Rats ( <i>Rattus norvegicus</i> )	146109	35867	47684	804	50	1502	196	4323	36186	272721
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	19132	2180	872	76	0	0	7	0	4455	26722
1.d. Hamsters ( <i>Mesocricetus</i> )	1121	73	151	8	0	0	0	0	194	1547
1.e. Other Rodents (other Rodentia)	70	48	0	0	0	0	0	0	182	300
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	14616	2012	2373	49	0	0	16	4	4115	23185
1.g. Cats ( <i>Felis catus</i> )	325	0	0	0	0	0	0	0	0	325
1.h. Dogs ( <i>Canis familiaris</i> )	6260	247	0	0	0	0	0	0	981	7488
1.i. Ferrets ( <i>Mustela putorius furo</i> )	28	0	0	0	0	0	0	0	0	28
1.j. Other Carnivores (other Carnivore)	32	0	0	0	0	0	0	0	0	32
1.k. Horses, donkeys and cross-breds (Equidae)	122	0	0	0	0	0	0	0	0	122
1.l. Pigs ( <i>Sus</i> )	2589	5	0	0	0	0	196	152	595	3537
1.m. Goats ( <i>Capra</i> )	0	8	0	0	0	0	0	0	0	8
1.n. Sheep ( <i>Ovis</i> )	569	0	0	0	0	0	21	140	16	746
1.o. Cattle ( <i>Bos</i> )	732	19	0	0	0	0	6	0	51	808
1.p. Prosimians (Prosimia)	0	0	0	0	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	38	0	0	0	0	0	0	0	6	44
1.r. Old World Monkeys (Cercopithecoidea)	2589	0	0	0	0	0	0	0	802	3391
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	0	0	0	0
1.u. Quail ( <i>Coturnix coturnix</i> )	0	2859	0	0	0	0	0	0	235	3094
1.v. Other birds (other Aves)	8558	1775	0	0	0	0	3006	64	884	14287
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	336	0	0	0	0	0	2340	19	2695
1.y. Fish (Pisces)	56463	20255	7163	0	0	276	0	83433	11493	179083
1.z. TOTAL	399794	81079	78316	977	90	2430	4604	92366	345217	1004873

(\*) France reporting for 2010

### 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 of 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.

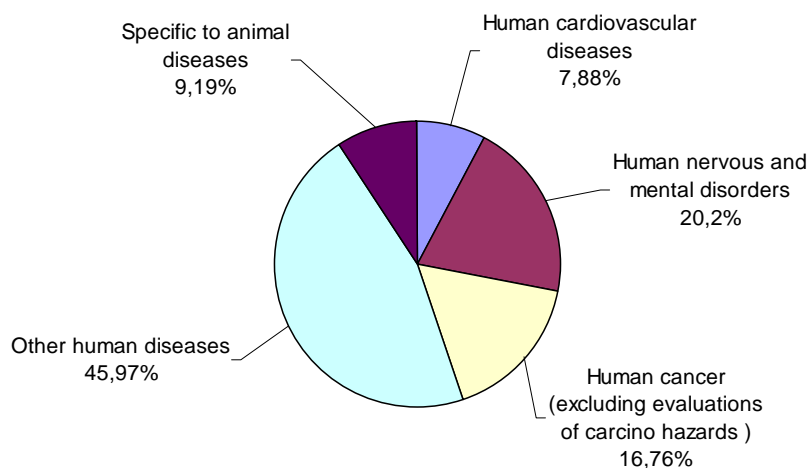
#### III.5.2. Treatment and interpretation of the data

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

In 2011 the number of animals used for the study of both animal and human diseases represented 6 599 320 animals which is more than half (57%) the total number of animals used for scientific purposes in the EU.

Figure 4.1 presents the percentage of animals used in studies per type of disease, 90% of which are used for the study of human diseases.

**Figure 4.1**  
**Proportion of animals used for studies of diseases**



In 2011, the overall number of animals used for studies on human and animal diseases has increased to a little more than 276 000 animals. The use of animals for specific studies on animal diseases in 2011 (which had a decrease of 50% in 2008) is comparatively unchanged from the 2008 report. There is a reduction in the use of cold-blooded animals by just under 22 500.

It is important to note that there has been a net increase of more than 115 000 animals used for studies on cardiovascular diseases, and of more than 250 000 for human cancer studies.

In comparison to 2008, increases of the use of animals have also been observed for dogs, totalling above 1 000; for other carnivores about 500; for other mammals a little above 300 and for other birds above 2 500.

On the other hand, the number of rats used for studies on diseases has decreased by more than 250 000 animals.



**Table 4.1: Number of animals used in experiments for studies on human and animal diseases**  
**Main category of diseases versus species**  
**Data of 2011 \***

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> )	373188	872698	1049177	2106651	303009	4702052
1.b. Rats ( <i>Rattus norvegicus</i> )	118848	409386	36156	438491	5337	1008156
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	2880	1893	44	27472	2373	34662
1.d. Hamsters ( <i>Mesocricetus</i> )	3000	398	779	5517	3269	12963
1.e. Other Rodents (other Rodentia)	1713	912	0	4723	2830	10178
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	5208	825	2852	24023	4523	37424
1.g. Cats ( <i>Felis catus</i> )	2	64	4	217	2026	2313
1.h. Dogs ( <i>Canis familiaris</i> )	860	79	187	3360	6543	11029
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	156	0	2175	55	2386
1.j. Other Carnivores (other Carnivore)	19	0	0	538	1035	1592
1.k. Horses, donkeys and cross-breds ( <i>Equidae</i> )	1	0	0	135	2083	2219
1.l. Pigs ( <i>Sus</i> )	6118	527	227	8743	16278	31893
1.m. Goats ( <i>Capra</i> )	72	15	54	604	281	1026
1.n. Sheep ( <i>Ovis</i> )	897	93	23	10683	3032	14728
1.o. Cattle ( <i>Bos</i> )	220	0	0	2960	6507	9687
1.p. Prosimians ( <i>Prosimia</i> )	0	58	0	25	0	83
1.q. New World Monkeys ( <i>Ceboidea</i> )	15	171	0	385	0	571
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	369	88	61	1746	45	2309
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	0	154	18	833	700	1705
1.u. Quail ( <i>Coturnix coturnix</i> )	0	640	0	244	4	888
1.v. Other birds (other <i>Aves</i> )	1037	2302	100	20365	204069	227873
1.w. Reptiles ( <i>Reptilia</i> )	0	39	0	407	695	1141
1.x. Amphibians ( <i>Amphibia</i> )	549	393	180	6066	949	8137
1.y. Fish ( <i>Pisces</i> )	4814	45004	16059	367640	40788	474305
1.z. TOTAL	519810	1335895	1105921	3034003	606431	6599320

\* France reporting for 2010

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

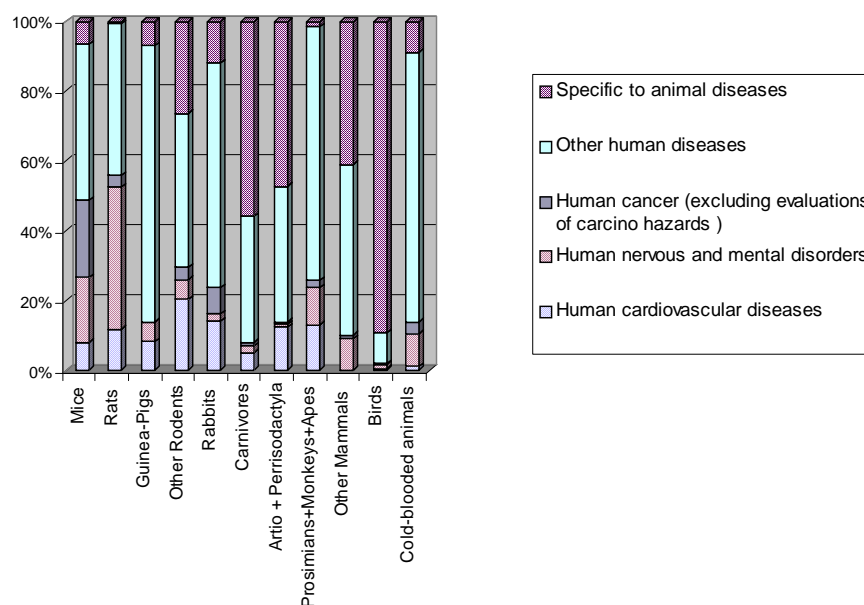
Classes of animals	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino. hazards)	Other human diseases	Specific animal diseases	Total
Mice	373188	872698	1049177	2106651	303009	4702052
Rats	118848	409386	36156	438491	5337	1008156
Guinea-Pigs	2880	1893	44	27472	2373	34662
Other Rodents	4713	1310	779	10240	6099	23141
Rabbits	5208	825	2852	24023	4523	37424
Carnivores	881	299	191	6290	9659	17320
Artio + Perissodactyla	7308	635	304	23125	28181	59553
Prosimians+Monkeys+Apes	384	317	61	2156	45	2963
Other Mammals	0	154	18	833	700	1705
Birds	1037	2942	100	20609	204073	228761
Cold-blooded animals	5363	45436	16239	374113	42432	483583
TOTAL	519810	1335895	1105921	3034003	606431	6599320

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	7,94	18,56	22,31	44,80	6,44	100,00
Rats	11,79	40,61	3,59	43,49	0,53	100,00
Guinea-Pigs	8,31	5,46	0,13	79,26	6,85	100,00
Other Rodents	20,37	5,66	3,37	44,25	26,36	100,00
Rabbits	13,92	2,20	7,62	64,19	12,09	100,00
Carnivores	5,09	1,73	1,10	36,32	55,77	100,00
Artio + Perissodactyla	12,27	1,07	0,51	38,83	47,32	100,00
Prosimians+Monkeys+Apes	12,96	10,70	2,06	72,76	1,52	100,00
Other Mammals	0,00	9,03	1,06	48,86	41,06	100,00
Birds	0,45	1,29	0,04	9,01	89,21	100,00
Cold-blooded animals	1,11	9,40	3,36	77,36	8,77	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 shows 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. For this category a significant decrease in numbers of both *Artiodactyla* and *Perissodactyla*, has been recorded. However, an increase in the numbers of carnivores was observed for the same purpose.

In addition to the year 2011 having been relatively quiet from a zoo-sanitary point of view, and thus the pressure for testing in farm animals relatively low, other reasons indicated by Member States for a decrease in this area include

- reduction of livestock housing capacity;
- move away from large animal-based to more basic laboratory-based bioscience type studies (on tissue culture, cell lines etc. rather than animal type studies);
- as larger animals models are particularly expensive to run, it was suggested that they may have become unsustainable for some laboratories;
- larger animal models are normally used just before going into clinical trials and as such are cyclical.

Regarding the increased use of carnivores Member States indicated that these animals have been used in veterinary clinical trials, studies on genetic diseases, for research and development of products and devices for veterinary medicine and for vaccine studies (e.g. leishmania).

The data on the use of most species for all types of studies on both human and animal diseases show a similarity to the report of 2008. However, there is a substantial decrease in the use of 'other rodents' for studies of human diseases in particular 'human nervous and mental disorders'.

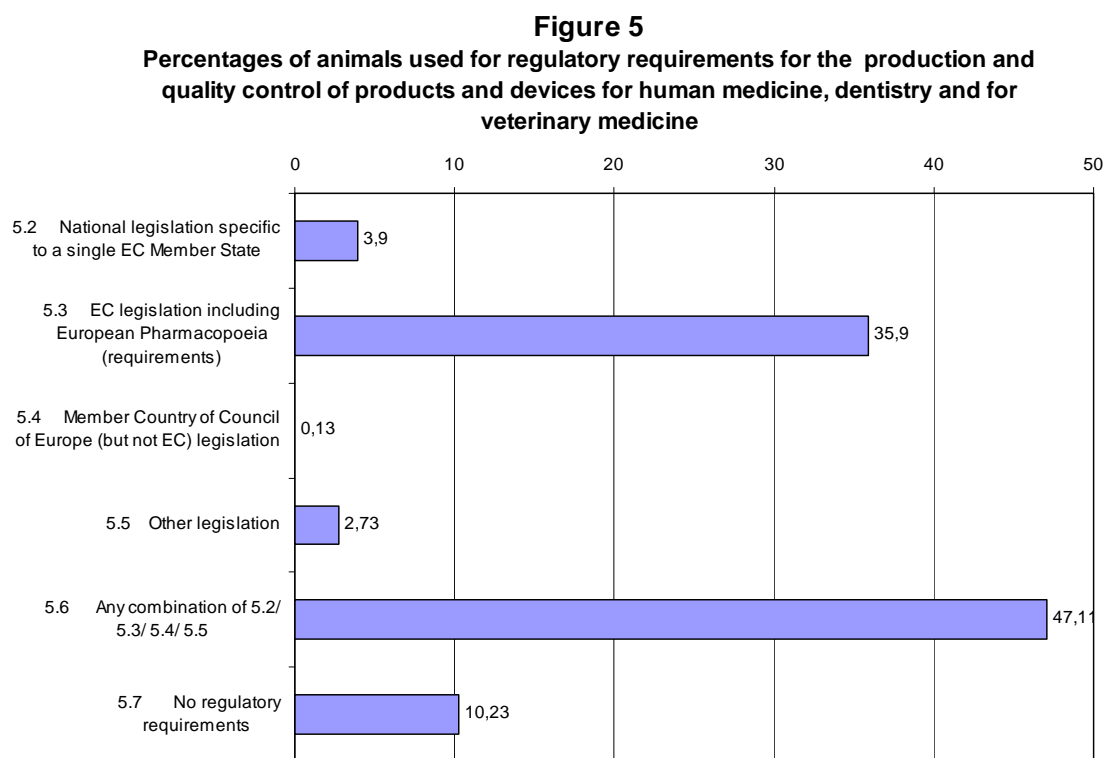
### III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

#### 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 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 13,9% of the total number of animals used for experimental purposes in 2011. 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 simultaneously satisfy requirements from several pieces of legislation emanating from the EU, the Council of Europe, from national legislation and from legislation outside of the EU. The testing carried out to satisfy EU legislation including the European Pharmacopoeia covered 35,9% of the animals used in this area.

In comparison to the report of 2008 it is important to note that there is an increase in the number of animals used for 'no regulatory requirements'.

It should also be noted that, there is a slight increase in the number of animals used to satisfy national legislation, despite the fact that there is a net reduction of the total number of animals used in this sector (192 000).

**Table 5 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 2011 \***

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> )	48385	250338	2162	33046	486522	71461	891914
1.b. Rats ( <i>Rattus norvegicus</i> )	3962	69859	0	4477	93887	3583	175768
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	1406	35856	0	4836	54984	5278	102492
1.d. Hamsters ( <i>Mesocricetus</i> )	0	1667	0	0	4334	0	6001
1.e. Other Rodents (other Rodentia)	0	0	0	0	0	0	0
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	1628	96730	13	880	71826	62757	234054
1.g. Cats ( <i>Felis catus</i> )	0	265	0	0	38	1	304
1.h. Dogs ( <i>Canis familiaris</i> )	118	597	0	0	262	15	992
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	0	0	0	32	58	90
1.j. Other Carnivores (other Carnivore)	19	213	0	0	0	309	541
1.k. Horses, donkeys and cross-breds ( <i>Equidae</i> )	338	231	0	0	105	2083	2757
1.l. Pigs ( <i>Sus</i> )	324	3694	15	0	2465	774	7382
1.m. Goats ( <i>Capra</i> )	0	448	0	0	6	9	463
1.n. Sheep ( <i>Ovis</i> )	109	1651	0	4	691	3901	6376
1.o. Cattle ( <i>Bos</i> )	64	1806	0	4	741	546	3161
1.p. Prosimians ( <i>Prosimia</i> )	0	21	0	0	0	0	21
1.q. New World Monkeys ( <i>Ceboidea</i> )	0	0	0	0	79	0	79
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0	0	0	0	138	0	138
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	0	0	0	0	56	4	60
1.u. Quail ( <i>Coturnix coturnix</i> )	0	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i> )	3811	106761	0	385	36585	8037	155579
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> )	1600	3296	0	0	0	4741	9637
1.z. TOTAL	61764	573433	2190	43632	752751	163557	1597809

(\*) France reporting for 2010

- 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

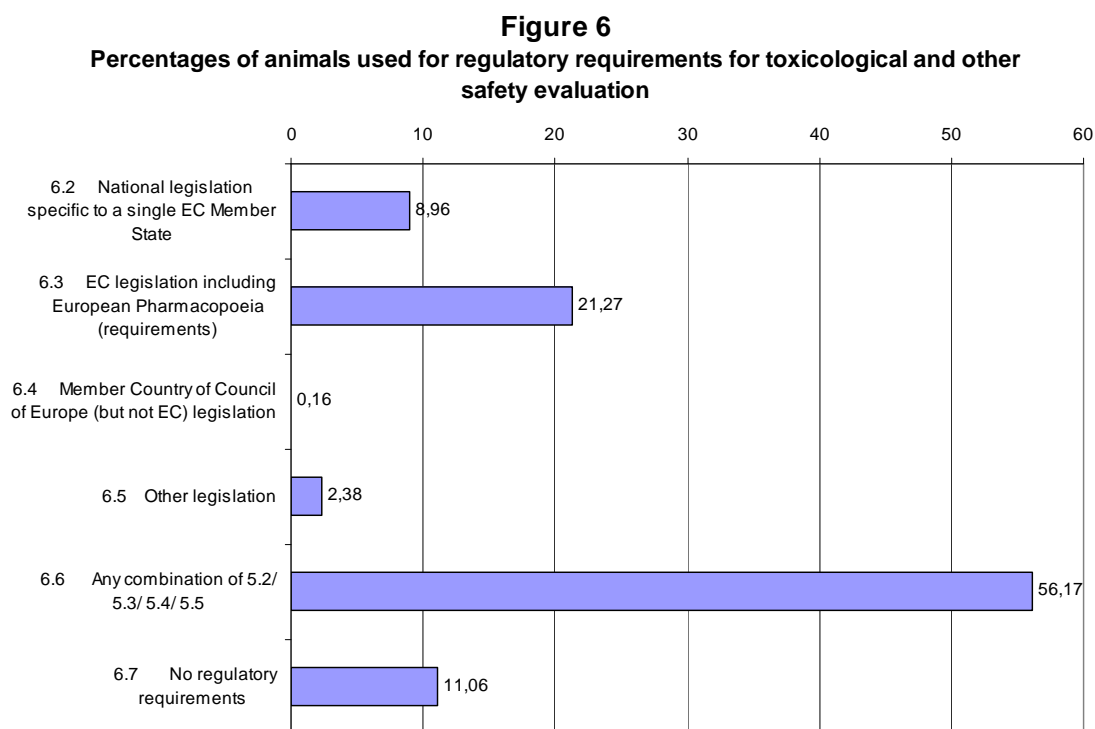
#### III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

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 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 8,75% 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 represent 56% of the animals used in this area. The testing required under EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area, namely 21,27%.

The percentage of the use of animals to satisfy requirements of different legislation has increased from fewer than 50% to more than 56%.

There is also a decrease in the number of animals used for 'no regulatory requirements'.

In addition to the examples of the type of testing reported under 'no regulatory requirements' in the last report (namely those of in-house methods to verify the safety and efficacy of veterinary biologicals and medicinal products carried according to company's or known

international standards), Member States reported preliminary studies for trial of doses, optimisation of numbers and candidates, and probing mechanism of action of toxicities associated with clinically approved drugs or combination studies involving clinically approved drugs.

**Table 6: Number of animals used in toxicological and other safety evaluations  
Regulatory requirements versus species**

**Data of 2011\***

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> )	33212	105801	361	5263	299377	20836	464850
1.b. Rats ( <i>Rattus norvegicus</i> )	17657	44614	924	10481	183446	15459	272581
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	817	14340	37	1466	8503	1559	26722
1.d. Hamsters ( <i>Mesocricetus</i> )	149	278	0	174	946	0	1547
1.e. Other Rodents (other Rodentia)	4	70	0	0	191	35	300
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	1211	8685	257	1481	10796	525	22955
1.g. Cats ( <i>Felis catus</i> )	68	283	0	0	76	16	443
1.h. Dogs ( <i>Canis familiaris</i> )	737	1011	0	603	5024	107	7482
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	118	0	0	20	0	138
1.j. Other Carnivores (other Carnivore)	0	8	0	0	0	0	8
1.k. Horses, donkeys and cross-breeds (Equidae)	60	65	0	0	18	0	143
1.l. Pigs ( <i>Sus</i> )	36	1292	0	307	1691	95	3421
1.m. Goats ( <i>Capra</i> )	0	127	0	0	8	0	135
1.n. Sheep ( <i>Ovis</i> )	320	58	0	69	159	140	746
1.o. Cattle ( <i>Bos</i> )	238	89	0	0	436	24	787
1.p. Prosimians (Prosimia)	0	21	0	0	0	0	21
1.q. New World Monkeys (Ceboidea)	0	11	0	0	20	13	44
1.r. Old World Monkeys (Cercopithecoidea)	221	234	0	348	2558	30	3391
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> )	45	380	0	0	2669	0	3094
1.v. Other birds (other Aves)	591	9654	0	0	3696	346	14287
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0
1.x. Amphibians (Amphibia)	0	0	0	0	1539	1156	2695
1.y. Fish (Pisces)	34625	26566	0	3762	43305	70825	179083
1.z. TOTAL	89991	213705	1579	23954	564478	111166	1004873

(\*) France is reporting for 2010

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

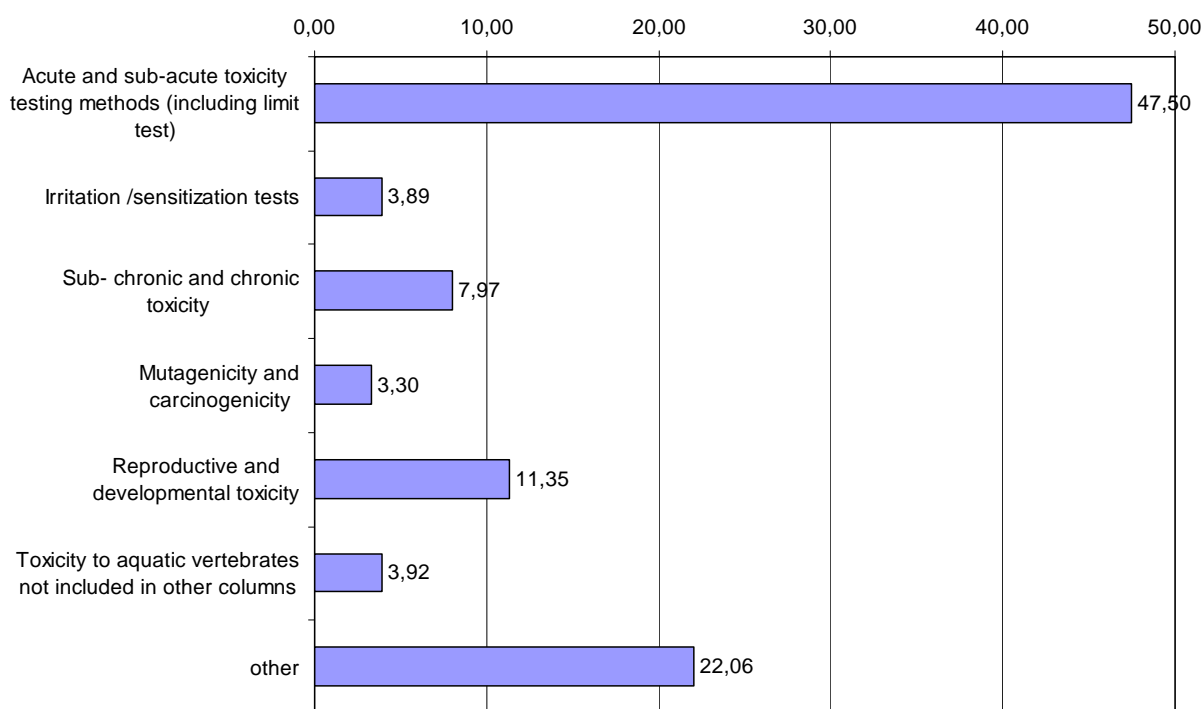
#### III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

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 effects in table 7.2. A graph showing the percentage of animals used per toxicity test groups in 2011 is presented in figure 7.

**Figure 7**  
**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 evaluations represents 8,75% of the total number of animals used for experimental purposes.

In figure 7 the largest percentage (47,5%) of use of animals is due to acute and sub-acute toxicity tests. Taking into account sub-chronic and chronic toxicity, the percentage of animals used in short- and long-term systemic toxicity testing accounts for 55% of the total number of animals used in this area.

Nearly 15% animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction. Another important category of use of animals in 2011 is for 'other tests' with 22%.

In addition to the type of testing reported under 'other toxicological and safety evaluation' in the previous report (namely those of 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), Member States reported that this heading covered also target animal studies carried out on companion animals to different regulatory standards e.g. US EPA, FDA, tests to determine the residues of veterinary medicaments in calves and in broilers, test to determine the non-toxicity and irreversibility of toxins and efficacy of vaccines (blue tongue, clostridium).

By looking both at 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 four reports of the proportion of animals used for acute and sub-acute tests, from 36%, 42%, 45% to 47,5% respectively. This represents in animal numbers an increase of more than 8 400 animals since the last report.

Contrary to the previous three reports where a steady decrease was observed, for 2011 the number of the animals used for reproductive toxicity testing has increased from 9% in 2008 to 11,35%. In terms of animal numbers it means an increase of almost 19 000 animals.

**Table 7.1 Number of animals used in toxicological and other safety evaluations**  
**Type of tests versus species**  
**Data of 2011\***

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> )	220544	51356	43637	64	16846	30	16436	5271	1188	9931	742	0	98796	464841
1.b. Rats ( <i>Rattus norvegicus</i> )	8376	10870	65185	1490	64	0	42274	6445	20189	11278	61209	0	45200	272508
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	773	1847	1546	88	15214	0	1630	110	0	0	254	0	5270	26732
1.d. Hamsters ( <i>Mesocricetus</i> )	0	0	210	11	0	0	489	0	0	50	0	0	857	1617
1.e. Other Rodents (other Rodentia)	182	4	0	0	0	0	0	0	0	0	0	0	274	460
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	15	143	2947	3151	44	2080	634	0	2560	0	2978	0	8515	23067
1.g. Cats ( <i>Felis catus</i> )	0	0	34	0	0	0	12	0	0	0	0	0	285	331
1.h. Dogs ( <i>Canis familiaris</i> )	0	123	2469	0	0	0	2785	0	0	0	95	0	1903	7375
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	0	0	0	0	0	0	0	0	0	0	0	52	52
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0	0	11	11
1.k. Horses, donkeys and cross-breds ( <i>Equidae</i> )	0	0	33	0	0	0	0	0	60	0	0	0	148	241
1.l. Pigs ( <i>Sus</i> )	0	39	807	45	0	0	729	0	22	0	86	0	1682	3410
1.m. Goats ( <i>Capra</i> )	0	0	0	0	0	0	0	0	0	0	0	0	8	8
1.n. Sheep ( <i>Ovis</i> )	0	0	0	0	0	0	30	0	299	0	0	0	438	767
1.o. Cattle ( <i>Bos</i> )	0	0	45	0	0	0	24	0	230	0	0	0	488	787
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	0	0	24	0	0	0	0	0	0	0	0	0	20	44
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	0	0	877	0	0	0	1306	0	266	0	15	0	927	3391
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 Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.u. Quail ( <i>Coturnix coturnix</i> )	329	370	0	0	0	0	45	0	0	0	0	0	2350	3094
1.v. Other birds (other Aves)	423	182	4584	0	0	0	0	50	0	0	556	0	8492	14287
1.w. Reptiles ( <i>Reptilia</i> )	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.x. Amphibians ( <i>Amphibia</i> )	0	0	1660	0	0	0	0	0	500	0	0	516	19	2695
1.y. Fish ( <i>Pisces</i> )	34137	11641	11898	0	0	0	13730	0	16468	29	6381	38890	45909	179083
1.z. TOTAL	264779	76575	135956	4849	32168	2110	80124	11876	41782	21288	72316	39406	221644	1004873

(\*) France reporting for 2010

**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> )	315537	16940	16436	15202	1930	0	98796	464841
1.b. Rats ( <i>Rattus norvegicus</i> )	84431	1554	42274	17723	81398	0	45200	272508
1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )	4166	15302	1630	110	254	0	5270	26732
1.d. Hamsters ( <i>Mesocricetus</i> )	210	11	489	50	0	0	857	1617
1.e. Other Rodents (other Rodentia)	186	0	0	0	0	0	274	460
1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )	3105	5275	634	0	5538	0	8515	23067
1.g. Cats ( <i>Felis catus</i> )	34	0	12	0	0	0	285	331
1.h. Dogs ( <i>Canis familiaris</i> )	2592	0	2785	0	95	0	1903	7375
1.i. Ferrets ( <i>Mustela putorius furo</i> )	0	0	0	0	0	0	52	52
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	11	11
1.k. Horses, donkeys and cross-breeds ( <i>Equidae</i> )	33	0	0	0	60	0	148	241
1.l. Pigs ( <i>Sus</i> )	846	45	729	0	108	0	1682	3410
1.m. Goats ( <i>Capra</i> )	0	0	0	0	0	0	8	8
1.n. Sheep ( <i>Ovis</i> )	0	0	30	0	299	0	438	767
1.o. Cattle ( <i>Bos</i> )	45	0	24	0	230	0	488	787
1.p. Prosimians ( <i>Prosimia</i> )	0	0	0	0	0	0	0	0
1.q. New World Monkeys ( <i>Ceboidea</i> )	24	0	0	0	0	0	20	44
1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )	877	0	1306	0	281	0	927	3391
1.s. Apes ( <i>Hominoidea</i> )	0	0	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i> )	0	0	0	0	0	0	0	0
1.u. Quail ( <i>Coturnix coturnix</i> )	699	0	45	0	0	0	2350	3094
1.v. Other birds (other <i>Aves</i> )	5189	0	0	50	556	0	8492	14287
1.w. Reptiles ( <i>Reptilia</i> )	0	0	0	0	0	0	0	0
1.x. Amphibians ( <i>Amphibia</i> )	1660	0	0	0	500	516	19	2695
1.y. Fish ( <i>Pisces</i> )	57676	0	13730	29	22849	38890	45909	179083
1.z. TOTAL	477310	39127	80124	33164	114098	39406	221644	1004873

### 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.

#### III.9.2. Treatment and interpretation of the data

As pointed out earlier, animals used in toxicological and other safety evaluation represent 8,75% 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. 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.

Figure 8 gives the proportion of animals used for toxicity and other safety evaluation by types of products.

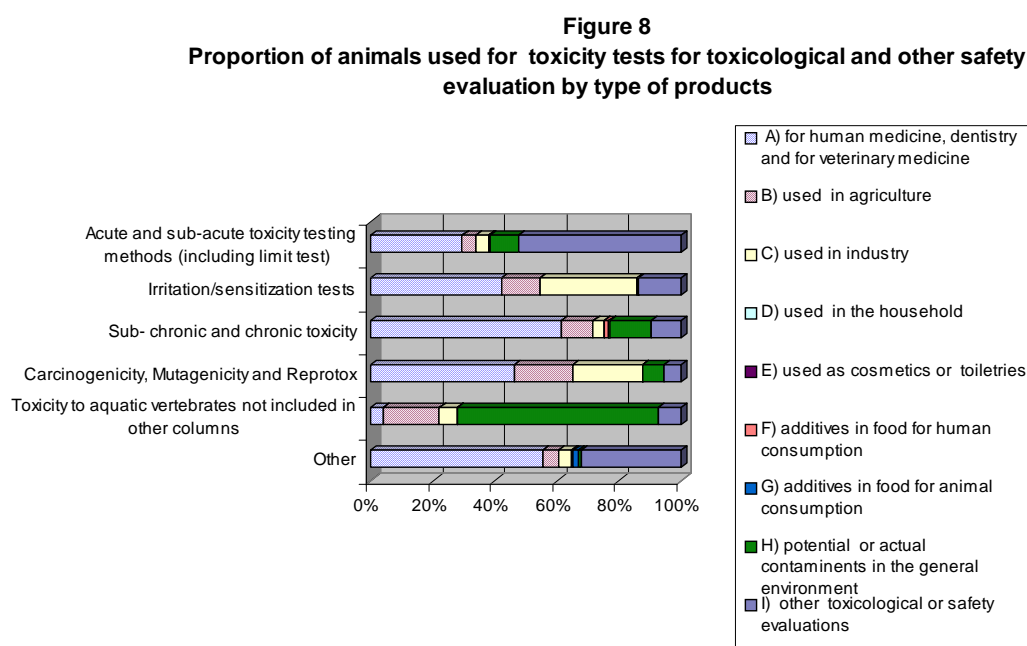


Figure 8 shows that the majority of animals tested in acute/sub-acute toxicity are intended for the purpose of 'human medicine, dentistry and veterinary medicine' and for 'other toxicological and safety evaluation'. For irritation/sensitization properties and for carcinogenicity/mutagenicity and reprotox the three categories of uses; human medicine, agriculture and industrial products show a similar pattern of use of animals. Whereas the largest number of animals used in sub-chronic and chronic toxicity test are carried out mainly for human medicine, dentistry and veterinary medicine.

In Figure 8 it is difficult to show the numbers of animals used for testing, for example, household products and additives for human consumption because they are much lower than

in the other categories e.g. for household products only 800 animals were used whereas for products for human medicine, dentistry and veterinary medicine almost 400 000 animals were used.

Overall products intended for medicine, dentistry and veterinary medicine required the highest proportion of animals for the different types of tests i.e. approximately 39%. In comparison to 2008 the amount of animals used in 2011 has been reduced by more than 130 000.

The next highest proportion is for 'other' toxicological evaluations, above 34%, (22% in 2008) this means an increase of use of 122 000 animals. The third type of test using the largest number of animals is that used for potential and actual contaminants in the general environment with 92 000 animals or 9%.

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

**Data of 2011\***

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	40400	13904	86828	1772	14410	336	49351	6087	15247	10796	35906	1671	122646	399354
8.b. Products/ substances used or intended to be used mainly in agriculture	6079	7825	7479	992	3047	801	8200	4884	8335	2255	12359	7089	11634	80979
8.c. Products/ substances used or intended to be used mainly in industry	3635	1690	13974	1461	10200	613	2691	4	11493	6805	14682	2208	9564	79020
8.d. Products/ substances used or intended to be used mainly in the household	40	119	79	47	76	2	80	0	0	0	46	0	348	837
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	25	25	40	0	0	0	0	0	0	0	0	0	0	90
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	25	131	57	0	24	0	1300	0	0	152	0	0	741	2430
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	53	928	0	0	0	0	100	0	0	54	0	0	3469	4604
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	27673	9521	6620	2	0	0	10759	664	5264	28	4439	25529	1867	92366
8.i. Other toxicological or safety evaluations	186849	42432	20879	575	4411	358	7643	237	1443	1198	4884	2909	71375	345193
8.j. TOTAL	264779	76575	135956	4849	32168	2110	80124	11876	41782	21288	72316	39406	221644	1004873

(\* France reporting for 2010)

**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	141132	16518	49351	68036	1671	122646	399354
8.b. Products/ substances used or intended to be used mainly in agriculture	21383	4840	8200	27833	7089	11634	80979
8.c. Products/ substances used or intended to be used mainly in industry	19299	12274	2691	32984	2208	9564	79020
8.d. Products/ substances used or intended to be used mainly in the household	238	125	80	46	0	348	837
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	90	0	0	0	0	0	90
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	213	24	1300	152	0	741	2430
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	981	0	100	54	0	3469	4604
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	43814	2	10759	10395	25529	1867	92366
8.i. Other toxicological or safety evaluations	250160	5344	7643	7762	2909	71375	345193
8.j. TOTAL	477310	39127	80124	147262	39406	221644	1004873