

Animals used under § 7 (2) of the Animal Protection Act by species

1. Animals used by species

Table 1: In total animals used by species (excludes re-use)

Animal Species	Number of Animals	Percentage
Mice	1.405.079	65,30%
Rats	191.925	8,92%
Guinea-Pigs	9.655	0,45%
Hamsters (Syrian)	1.054	0,05%
Hamsters (Chinese)	0	0,00%
Mongolian gerbil	2.785	0,13%
Other rodents	13.857	0,64%
Rabbits	90.876	4,22%
Cats	680	0,03%
Dogs	1.678	0,08%
Ferrets	122	0,01%
Other carnivores	301	0,01%
Horses, donkeys and cross-breeds	519	0,02%
Pigs	18.792	0,87%
Goats	409	0,02%
Sheep	4.695	0,22%
Cattle	5.886	0,27%
Prosimians	85	0,00%
Marmoset and tamarins	135	0,01%
Cynomolgus monkey	2.385	0,11%
Rhesus monkey	51	0,00%
Vervets (Chlorocebus spp.)	0	0,00%
Baboons	6	0,00%
Squirrel monkey	0	0,00%
Other species of Old World Monkeys (Cercopithecoidea)	0	0,00%
Other species of New World Monkeys (Ceboidea)	0	0,00%
Apes	0	0,00%
Other mammals	1.919	0,09%
Domestic fowl	24.567	1,14%
Other birds	10.402	0,48%
Reptiles	85	0,00%
Rana	381	0,02%
Xenopus	12.220	0,57%
Other amphibians	5.479	0,25%
Zebra fish	142.391	6,62%
Other fish	203.369	9,45%
Cephalopods	17	0,00%
Total uses	2.151.805	100,00%

Figure 1: Animals used by species groups (excludes re-use)

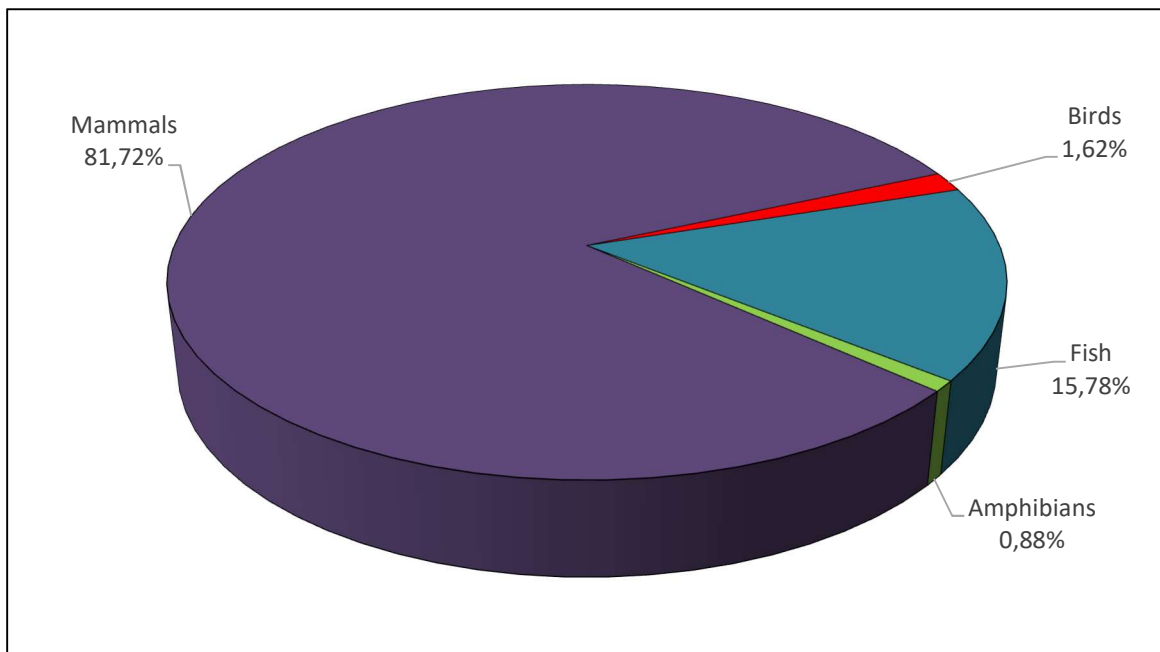


Table 2: Animals used by species groups (excludes re-use)

Species grouping Level 1	Number of Animals
Warm-blooded vertebrates	1.787.863
Invertebrates	17
Cold-blooded vertebrates	363.952
Total uses	2.151.805

Mammals	Number of Animals
Rodents	1.624.355
Rabbits	90.876
Carnivores	2.781
Equidae	519
Artiodactyla	29.782
Non-human primates	2.662
Other mammals	1.919
Total uses	1.752.894

Species grouping Level 2	Number of Animals
Mammals	1.752.894
Birds	34.969
Fish	345.760
Amphibians	18.080
Reptiles	85
Cephalopods	17
Total uses	2.151.805

Non-human primates	Number of Animals
Prosimians	85
New World Monkeys	135
Old World Monkeys	2.442
Total uses	2.662

2. Origin of used Animals

Table 3: Origin of used animals in total (excludes re-use)

Animal Species	Animals born in				Total
	the EU at a registered breeder	the EU but not at a registered breeder	rest of Europe	rest of the world	
Mice	1.390.296	7.392	404	6.987	1.405.079
Rats	189.821	643	0	1.461	191.925
Guinea-Pigs	9.526	129	0	0	9.655
Hamsters (Syrian)	886	0	0	168	1.054
Hamsters (Chinese)	0	0	0	0	0
Mongolian gerbil	2.533	252	0	0	2.785
Other rodents	1.066	12.774	0	17	13.857
Rabbits	90.238	638	0	0	90.876
Cats	191	382	0	107	680
Dogs	178	642	0	858	1.678
Ferrets	84	35	0	3	122
Other carnivores	277	22	2	0	301
Horses, donkeys and cross-breeds	214	305	0	0	519
Pigs	10.190	8.572	0	30	18.792
Goats	313	96	0	0	409
Sheep	3.707	988	0	0	4.695
Cattle	3.917	1.969	0	0	5.886
Prosimians	85	0	0	0	85
Marmoset and tamarins	135	0	0	0	135
Cynomolgus monkey	105	0	0	2.280	2.385

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Rhesus monkey	36	0	0	15	51
Vervets (Chlorocebus spp.)	0	0	0	0	0
Baboons	6	0	0	0	6
Squirrel monkey	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	0	0	0
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0
Apes	0	0	0	0	0
Other mammals	97	1.751	51	20	1.919
Domestic fowl	17.756	6.811	0	0	24.567
Other birds	2.928	7.161	229	84	10.402
Reptiles	8	67	0	10	85
Rana	0	381	0	0	381
Xenopus	3.877	6.800	0	1.543	12.220
Other amphibians	2.169	3.310	0	0	5.479
Zebra fish	131.439	10.952	0	0	142.391
Other fish	181.999	19.179	899	1.292	203.369
Cephalopods	17	0	0	0	17
Total uses	2.044.094	91.251	1.585	14.875	2.151.805

Table 4 – 6: Origin of used animals by species groups (excludes re-use)

Species grouping Level 1	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of the world	Total
Warm-blooded vertebrates	1.724.585	50.562	686	12.030	1.787.863
Cold-blooded vertebrates	319.492	40.689	899	2.845	363.925
Invertebrates	17	0	0	0	17
Total uses	2.044.094	91.251	1.585	14.875	2.151.805

Species grouping Level 2	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of the world	Total
Mammals	1.703.901	36.590	457	11.946	1.752.894
Birds	20.684	13.972	229	84	34.969
Fish	313.438	30.131	899	1.292	345.760
Amphibians	6.046	10.491	0	1.543	18.080
Reptiles	8	67	0	10	85
Cephalopods	17	0	0	0	17
Total uses	2.044.094	91.251	1.585	14.875	2.151.805

Mammals	Animals born in the EU at a registered breeder	Animals born in the EU but not at a registered breeder	Animals born in rest of Europe	Animals born in rest of the world	Total
Rodents	1.594.128	21.190	404	8.633	1.624.355
Rabbits	90.238	638	0	0	90.876
Carnivores	730	1.081	2	968	2.781
Equidae	214	305	0	0	519
Artiodactyla	18.127	11.625	0	30	29.782
Non-human primates	367	0	0	2.295	2.662
Other mammals	97	1.751	51	20	1.919
Total uses	1.703.901	36.590	457	11.946	1.752.894

3. Non-Human Primates by source and generation

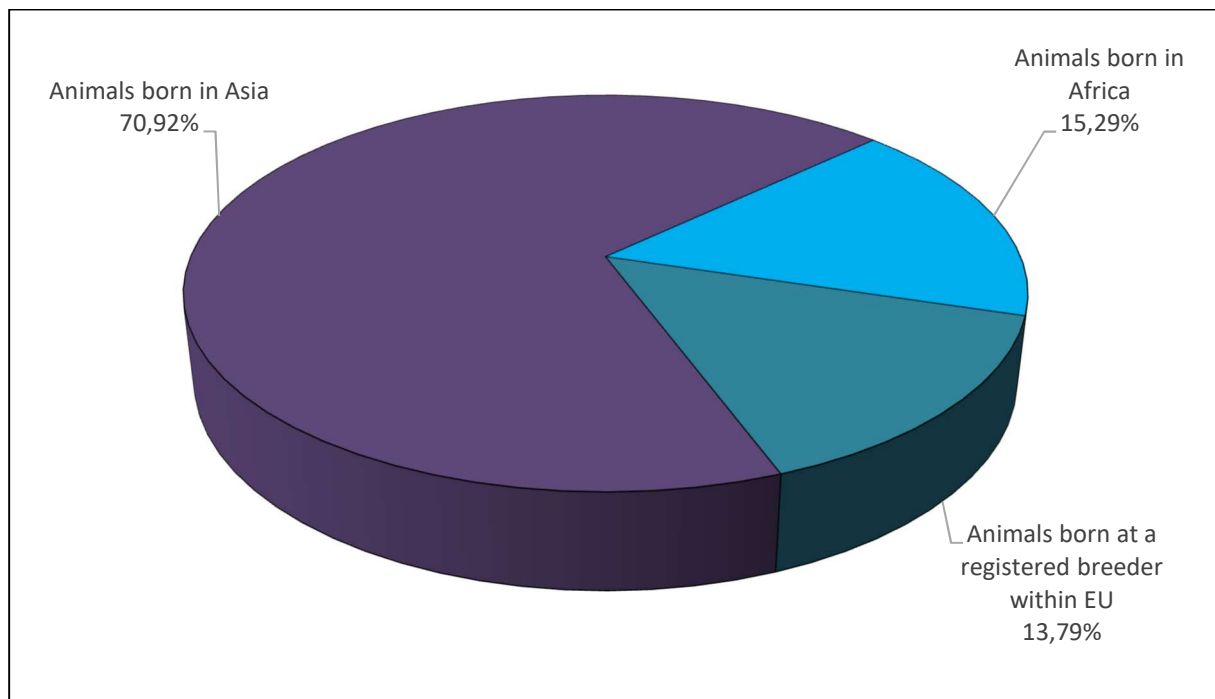
Table 7: Generation of non-human primates (excludes re-use)

NHP Generation	Number of Animals
F0	0
F1	135
F2 or greater	1.576
Self-sustaining colony	951
Total uses	2.662

Table 8: Origin of non-human primates (excludes re-use)

NHP Source (origin)	Number of Animals
Animals born at a registered breeder within EU	367
Animals born in rest of Europe	0
Animals born in Asia	1.888
Animals born in America	0
Animals born in Africa	407
Animals born elsewhere	0
Total uses	2.662

Figure 2: Origin of non-human primates (excludes re-use)



4. Use of species in procedures by purposes

Table 9: Use of species in procedures by purposes

Animal Species	Basic Research	Translational and applied research	Regulatory use and Routine production	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Preservation of species	Higher education or training for the acquisition, maintenance or improvement of vocational skills	Maintenance of colonies of established genetically altered animals, not used in other procedures	Total
Mice	809.679	221.623	172.224	2	2.444	35.557	196.807	1.438.336
Rats	29.755	18.746	136.570	258	0	9.589	2.055	196.973
Guinea-Pigs	797	419	8.361	0	0	294	0	9.871
Hamsters (Syrian)	422	408	202	0	0	22	0	1.054
Hamsters (Chinese)	0	0	0	0	0	0	0	0
Mongolian gerbil	902	1.733	109	0	0	49	0	2.793
Other rodents	3.303	493	9.943	0	0	122	0	13.861
Rabbits	1.226	1.049	91.701	0	0	264	0	94.240
Cats	221	296	397	0	0	40	0	954
Dogs	443	559	1.766	0	0	751	0	3.519
Ferrets	67	46	0	0	0	11	0	124
Other carnivores	0	0	291	7	3	0	0	301
Horses, donkeys and cross-breeds	417	242	32	0	0	82	0	773
Pigs	6.292	9.291	2.561	368	9	1.405	0	19.926
Goats	282	92	19	0	0	36	0	429
Sheep	2.839	1.021	787	90	0	108	0	4.845
Cattle	3.112	1.477	826	149	0	1.059	0	6.623

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Prosimians	140	0	0	0	0	0	0	0	140
Marmoset and tamarins	69	30	44	0	0	0	0	0	143
Cynomolgus monkey	9	154	2.717	0	0	0	0	0	2.880
Rhesus monkey	47	39	0	0	0	0	0	0	86
Vervets (Chlorocebus spp.)	0	8	0	0	0	0	0	0	8
Baboons	0	6	0	0	0	0	0	0	6
Squirrel monkey	0	0	0	0	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	13	0	0	0	0	0	0	13
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0
Apes	0	0	0	0	0	0	0	0	0
Other mammals	1.459	223	14	27	34	185	0	0	1.942
Domestic fowl	10.050	6.467	7.763	384	0	272	0	0	24.936
Other birds	8.493	1.049	205	576	232	227	0	0	10.782
Reptiles	84	0	0	0	0	11	0	0	95
Rana	91	0	0	0	0	290	0	0	381
Xenopus	5.137	0	8.160	0	0	222	0	0	13.519
Other amphibians	1.956	0	0	2.400	0	1.123	0	0	5.479
Zebra fish	112.789	1.699	20.320	2.942	0	1.536	3.258	0	142.544
Other fish	27.923	9.148	9.890	4.365	152.212	550	911	0	204.999
Cephalopods	17	0	0	0	0	0	0	0	17
Total uses	1.028.021	276.331	474.902	11.568	154.934	53.805	203.031	0	2.202.592

Figure 3: Use of animals in procedures by purposes

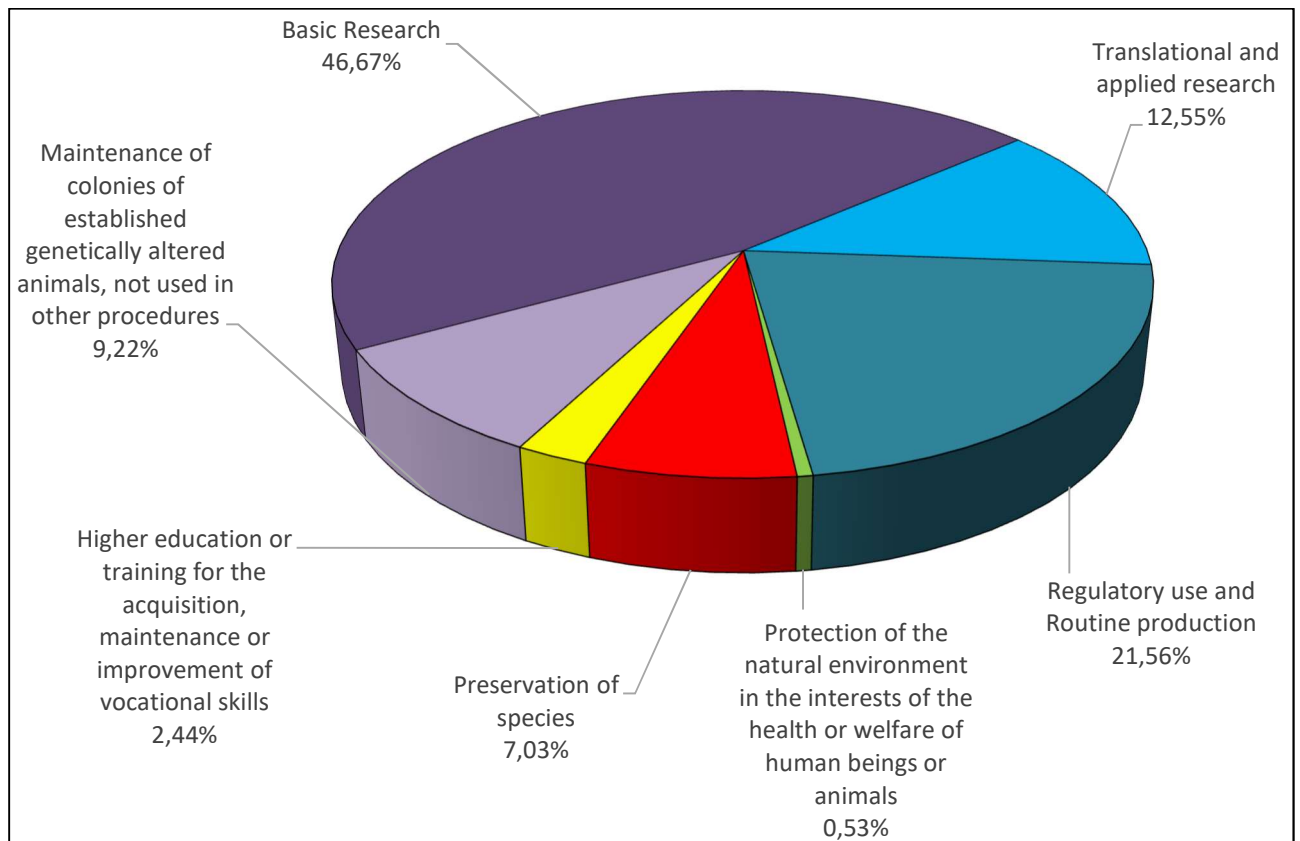


Table 10: Use of species in basic research purposes

Animal Species	Oncology	Cardio-vascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/Metabolism	Multisystemic	Ethology / Animal Behaviour /Animal Biology	Other basic research	Total
Mice	101.757	66.682	149.040	16.860	30.184	12.308	174.382	19.314	19.520	40.401	92.999	868	85.364	809.679
Rats	355	3.694	15.401	824	1.841	1.004	2.865	219	417	778	1.281	596	480	29.755
Guinea-Pigs	34	0	12	0	0	0	15	3	276	95	254	97	11	797
Hamsters (Syrian)	1	331	90	0	0	0	0	0	0	0	0	0	0	422
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mongolian gerbil	0	0	315	0	0	0	172	0	316	0	99	0	0	902
Other rodents	61	0	160	0	0	4	432	0	16	0	216	1.525	889	3.303
Rabbits	6	114	0	0	4	56	21	1	120	0	30	0	874	1.226
Cats	4	0	2	0	0	0	70	31	1	23	79	11	0	221
Dogs	32	68	0	86	26	46	121	35	0	0	29	0	0	443
Ferrets	0	0	38	0	0	0	0	0	0	0	12	0	17	67
Other carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Horses, donkeys and cross-breeds	0	0	0	0	0	8	156	4	14	51	170	12	2	417
Pigs	8	534	46	73	243	156	187	43	0	0	2.930	577	1.495	6.292
Goats	0	0	0	0	0	0	0	0	0	0	28	78	176	282
Sheep	0	12	3	2	14	33	32	0	0	12	2.685	6	40	2.839
Cattle	0	0	0	0	82	0	106	546	0	868	147	137	1.226	3.112
Prosimians	0	0	0	0	0	0	0	0	0	0	0	140	0	140
Marmoset and tamarins	0	0	5	0	0	0	0	36	0	9	19	0	0	69
Cynomolgus	0	0	8	0	0	0	0	0	0	1	0	0	0	9

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monkey															
Rhesus monkey	0	0	47	0	0	0	0	0	0	0	0	0	0	0	47
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other mammals	0	0	23	0	0	0	2	16	2	0	24	1.130	262		1.459
Domestic fowl	0	58	16	0	2.353	0	293	0	123	380	744	2.629	3.454		10.050
Other birds	0	0	115	0	0	0	0	0	12	0	5	7.740	621		8.493
Reptiles	0	0	45	36	0	3	0	0	0	0	0	0	0		84
Rana	0	0	0	0	0	0	0	0	0	0	0	0	91		91
Xenopus	13	29	717	20	0	0	0	1.899	0	10	479	0	1.970		5.137
Other amphibians	0	0	25	0	0	310	0	0	0	0	347	250	1.024		1.956
Zebra fish	186	31.307	35.996	0	0	3.622	5.358	8.882	3.598	2.488	5.174	1.201	14.977		112.789
Other fish	0	25	861	0	0	0	824	191	2.445	0	1.153	16.036	6.388		27.923
Cephalopods	0	0	17	0	0	0	0	0	0	0	0	0	0		17
Total uses	102.457	102.854	202.982	17.901	34.747	17.550	185.036	31.220	26.860	45.116	108.904	33.033	119.361		1.028.021
%	9,97%	10,01%	19,74%	1,74%	3,38%	1,71%	18,00%	3,04%	2,61%	4,39%	10,59%	3,21%	11,61%		100,00%

Table 11: Use of species in translational and applied research purposes

Animal Species	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Human Nervous and Mental Disorders	Human Respiratory Disorders	Human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders	Human Urogenital/Reproductive Disorders	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non-regulatory toxicology and ecotoxicology	Total
Mice	109.716	21.346	9.244	24.280	7.219	6.718	973	16.199	1.483	1.911	15.023	3.030	992	320	716	62	2.391	221.623
Rats	1.143	60	1.239	5.010	616	1.094	973	679	800	1.748	3.094	593	290	0	162	0	1.245	18.746
Guinea-Pigs	0	33	157	0	21	0	0	40	0	108	3	8	49	0	0	0	0	419
Hamsters (Syrian)	0	9	0	399	0	0	0	0	0	0	0	0	0	0	0	0	0	408
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mongolian gerbil	0	1.115	0	0	0	0	0	0	0	0	0	0	618	0	0	0	0	1.733
Other rodents	0	199	0	0	0	0	0	0	0	0	0	0	294	0	0	0	0	493
Rabbits	56	82	269	0	0	7	151	12	0	50	0	0	367	0	17	38	0	1.049
Cats	0	0	0	0	0	0	0	0	0	0	0	0	284	0	12	0	0	296
Dogs	31	0	9	89	45	0	0	2	0	17	26	0	340	0	0	0	0	559
Ferrets	0	20	0	0	0	0	0	0	0	0	0	0	7	0	19	0	0	46
Other carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	10	0	0	232	0	0	0	0	242
Pigs	202	44	359	68	107	90	289	16	26	26	111	76	4.105	3.701	37	0	34	9.291
Goats	0	14	8	0	0	0	0	0	0	0	0	0	42	0	15	0	13	92
Sheep	6	36	63	0	0	0	60	0	0	4	0	4	270	0	574	0	4	1.021
Cattle	0	27	0	0	0	0	0	0	0	0	0	0	847	591	4	0	8	1.477
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Marmoset and tamarins	0	0	0	26	0	0	0	0	0	4	0	0	0	0	0	0	0	30

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Cynomolgus monkey	3	7	4	68	6	0	0	0	0	28	6	32	0	0	0	0	0	154
Rhesus monkey	4	10	9	0	0	0	0	0	0	0	0	16	0	0	0	0	0	39
Vervets (Chlorocebus spp.)	0	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
Baboons	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other mammals	7	0	2	0	0	0	0	0	0	0	0	0	162	52	0	0	0	223
Domestic fowl	0	67	0	0	0	0	0	0	0	0	0	0	4.298	1.849	253	0	0	6.467
Other birds	0	1	0	0	0	0	0	0	0	0	0	0	523	456	69	0	0	1.049
Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rana	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Zebra fish	0	0	900	0	0	0	0	0	0	475	190	0	0	0	0	0	134	1.699
Other fish	0	0	0	0	0	0	0	0	0	0	0	0	4.688	1.260	0	0	3.200	9.148
Cephalopods	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total uses	111.168	23.091	12.269	29.940	8.014	7.909	2.446	16.948	2.309	4.381	18.453	3.759	18.408	8.229	1.878	100	7.029	276.331
%	40,23%	8,36%	4,44%	10,83%	2,90%	2,86%	0,89%	6,13%	0,84%	1,59%	6,68%	1,36%	6,66%	2,98%	0,68%	0,04%	2,54%	100,00%

Table 12: Regulatory use of animals and routine production purposes

Animal Species	Quality control (incl. batch safety and potency testing)	Other efficacy and tolerance testing	Toxicity and other safety testing including pharmacology	Routine production	Total
Mice	89.273	15.212	65.552	2.187	172.224
Rats	62.800	445	72.300	1.025	136.570
Guinea-Pigs	6.358	0	1.884	119	8.361
Hamsters (Syrian)	155	0	47	0	202
Hamsters (Chinese)	0	0	0	0	0
Mongolian gerbil	0	0	50	59	109
Other rodents	0	80	9.863		9.943
Rabbits	8.394	447	7.534	75.326	91.701
Cats	13	82	283	19	397
Dogs	0	20	1.715	31	1.766
Ferrets	0	0	0	0	0
Other carnivores	151	140	0	0	291
Horses, donkeys and cross-breeds	0	0	32	0	32
Pigs	240	969	1.336	16	2.561
Goats	0	0	14	5	19
Sheep	57	11	70	649	787
Cattle	289	152	295	90	826
Prosimians	0	0	0	0	0
Marmoset and tamarins	0	0	44	0	44
Cynomolgus monkey	0	0	2.589	128	2.717
Rhesus monkey	0	0	0	0	0
Vervets (Chlorocebus spp.)	0	0	0	0	0
Baboons	0	0	0	0	0
Squirrel monkey	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	0	0	0
Other species of New World Monkeys (Ceboidae)	0	0	0	0	0
Apes	0	0	0	0	0
Other mammals	0	0	0	14	14
Domestic fowl	2.794	2.784	1.611	574	7.763
Other birds	0	0	202	3	205
Reptiles	0	0	0	0	0
Rana	0	0	0	0	0
Xenopus	0	0	8.160	0	8.160
Other amphibians	0	0	0	0	0
Zebra fish	0	0	20.320		20.320
Other fish	0	0	8.490	1.400	9.890
Cephalopods	0	0	0	0	0
Total uses	170.524	20.342	202.391	81.645	474.902
%	35,91%	4,28%	42,62%	17,19%	100,00%

Table 13: Use of animals in quality control purposes

Animal Species	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Total
Mice	20.092	0	69.181	0	89.273
Rats	304	0	62.496	0	62.800
Guinea-Pigs	1.473	0	4.885	0	6.358
Hamsters (Syrian)	0	0	155	0	155
Rabbits	81	6.457	1.838	18	8.394
Cats	13	0	0	0	13
Other carnivores	0	0	151		151
Pigs	240	0	0	0	240
Sheep	38	0	0	19	57
Cattle	46	0	243	0	289
Domestic fowl	2.726	0	68	0	2.794
Total uses	25.013	6.457	139.017	37	170.524
%	14,67%	3,79%	81,52%	0,02%	100,00%

Table 14: Use of animals in routine production purposes

Animal Species	Blood based products	Monoclonal antibody	Other product types	Total
Mice	585	1.456	146	2.187
Rats	706	0	319	1.025
Guinea-Pigs	117	0	2	119
Mongolian gerbil	0	0	59	59
Rabbits	74.520	0	806	75.326
Cats	4	0	15	19
Dogs	14	0	17	31
Pigs	0	0	16	16
Goats	5	0	0	5
Sheep	630	0	19	649
Cattle	59	0	31	90
Cynomolgus monkey	0	0	128	128
Other mammals	0	0	14	14
Domestic fowl	3	0	571	574
Other birds	3	0	0	3
Other fish	0	0	1.400	1.400
Total uses	76.646	1.456	3.543	81.645
%	93,88%	1,78%	4,34%	100,00%

Table 15: Use of animals in toxicity and other safety testing by test type purposes

Animal Species	Acute and sub-acute	Skin irritation/corrosion	Skin sensitisation	Repeated dose toxicity	Carcinogenicity	Genotoxicity	Reproductive toxicity	Developmental toxicity	Kinetics	Pharmacodynamics (incl. safety pharmacology)	Ecotoxicity	Safety testing in food and feed area	Target animal safety	Eye irritation/corrosion	Other toxicity/safety testing	Total
Mice	4.029		4.085	2.892	500	1.118			13.149	39.200			356		223	65.552
Rats	2.232	24		14.213	710	1.413	16.895	12.276	6.366	17.845					326	72.300
Guinea-Pigs	20		1.773	10					9	72						1.884
Hamsters (Syrian)		29	18													47
Mongolian gerbil										50						50
Other rodents													767		9.096	9.863
Rabbits	69	307	124	192			459	5.237	62	849				23	212	7.534
Cats									199	67			17			283
Dogs	65			666					492	421			44		27	1.715
Horses, donkeys and cross-breeds												32				32
Pigs	4	6		130					119	299		120	633		25	1.336
Goats									14							14
Sheep									64						6	70
Cattle									132	61		43	54		5	295
Marmoset and tamarins				36											8	44
Cynomolgus monkey				1.648				260	399	11					271	2.589
Domestic fowl									20	103		1.488				1.611
Other birds											202					202
Xenopus											8.160					8.160
Zebra fish	52										20.268					20.320
Other fish	90							320			8.080					8.490
Total uses	6.561	366	6.000	19.787	1.210	2.531	17.354	18.093	21.025	58.978	36.710	1.683	1.871	23	10.199	202.391

Table 16: Use of animals in repeated dose toxicity testing methods

Animal Species	up to 28 days	29 - 90 days	> 90 days	Total
Mice	2.722	170	0	2.892
Rats	8.995	4.604	614	14.213
Guinea-Pigs	10	0	0	10
Rabbits	176	16	0	192
Dogs	484	126	56	666
Pigs	130	0	0	130
Marmoset and tamarins	36	0	0	36
Cynomolgus monkey	218	619	811	1.648
Total uses	12.771	5.535	1.481	19.787
%	64,54%	27,97%	7,48%	100,00%

Table 17: Use of animals in acute and subacute toxicity testing methods

Animal Species	LD50, LC50	Other lethal methods	Non lethal methods	Total
Mice	0	14	4.015	4.029
Rats	799	216	1.217	2.232
Guinea-Pigs	0	0	20	20
Rabbits	0	0	69	69
Dogs	0	0	65	65
Pigs	0	0	4	4
Zebra fish	0	0	52	52
Other fish	90	0	0	90
Total uses	889	230	5.442	6.561
%	13,55%	3,51%	82,94%	100,00%

Table 18: Use of animals in ecotoxicity testing methods

Animal Species	Acute toxicity	Chronic toxicity	Reproductive ecotoxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total
Other birds	138	10	0	0	0	54	202
Xenopus	0	0	0	8.160	0	0	8.160
Zebra fish	2.359	15.683	224	312	1.403	287	20.268
Other fish	1.745	3.931	0	312	2.068	24	8.080
Total uses	4.242	19.624	224	8.784	3.471	365	36.710
%	11,56%	53,46%	0,61%	23,93%	9,46%	0,99%	100,00%

5. Use of species and severity

Table 19: Use of species and severity in total

Animal Species	Non-recovery	%	Mild [up to and including]	%	Moderate	%	Severe	%	Total
Mice	84.320	5,86%	850.414	59,12%	417.465	29,02%	86.137	5,99%	1.438.336
Rats	9.753	4,95%	124.997	63,46%	58.728	29,82%	3.495	1,77%	196.973
Guinea-Pigs	262	2,65%	5.995	60,73%	871	8,82%	2.743	27,79%	9.871
Hamsters (Syrian)	6	0,57%	601	57,02%	447	42,41%	0	0	1.054
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0
Mongolian gerbil	123	4,40%	1.044	37,38%	1.593	57,04%	33	1,18%	2.793
Other rodents	117	0,84%	13.529	97,60%	166	1,20%	49	0,35%	13.861
Rabbits	28.662	30,41%	64.321	68,25%	1.144	1,21%	113	0,12%	94.240
Cats	16	1,68%	857	89,83%	81	8,49%	0	0	954
Dogs	94	2,67%	3.008	85,48%	411	11,68%	6	0,17%	3.519
Ferrets	0	0	50	40,32%	72	58,06%	2	1,61%	124
Other carnivores	0	0	60	19,93%	241	80,07%	0	0	301
Horses, donkeys and cross-breeds	17	2,20%	755	97,67%	1	0,13%	0	0	773
Pigs	2.620	13,15%	14.293	71,73%	2.385	11,97%	628	3,15%	19.926
Goats	0	0	390	90,91%	39	9,09%	0	0	429
Sheep	81	1,67%	3.943	81,38%	790	16,31%	31	0,64%	4.845
Cattle	3	0,05%	5.731	86,53%	889	13,42%	0	0	6.623
Prosimians	0	0	140	100,00%	0	0	0	0	140
Marmoset and tamarins	0	0	81	56,64%	61	42,66%	1	0,70%	143
Cynomolgus monkey	0	0	1.283	44,55%	1.597	55,45%	0	0	2.880
Rhesus monkey	0	0	38	44,19%	48	55,81%	0	0	86
Vervets (Chlorocebus spp.)	0	0	8	100,00%	0	0	0	0	8
Baboons	0	0	0	0	0	0	6	100,00%	6
Squirrel monkey	0	0	0	0	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	13	100,00%	0	0	0	0	13

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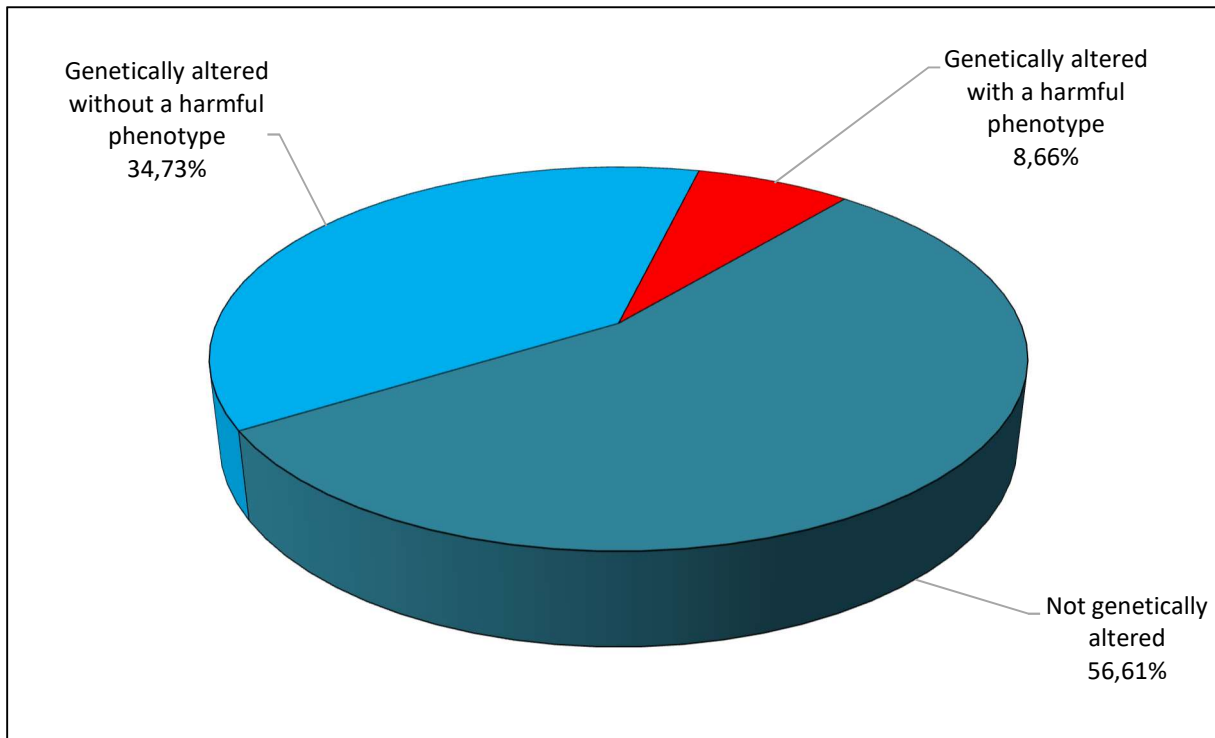
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0
Apes	0	0	0	0	0	0	0	0	0
Other mammals	12	0,62%	1.866	96,09%	33	1,70%	31	1,60%	1.942
Domestic fowl	1.539	6,17%	19.457	78,03%	3.000	12,03%	940	3,77%	24.936
Other birds	443	4,11%	8.810	81,71%	1.248	11,57%	281	2,61%	10.782
Reptiles	0	0	55	57,89%	38	40,00%	2	2,11%	95
Rana	0	0	381	100,00%	0	0	0	0	381
Xenopus	358	2,65%	6.064	44,86%	271	2,00%	6.826	50,49%	13.519
Other amphibians	2.433	44,41%	2.629	47,98%	417	7,61%	0	0	5.479
Zebra fish	1.348	0,95%	111.254	78,05%	21.297	14,94%	8.645	6,06%	142.544
Other fish	4.670	2,28%	192.393	93,85%	6.309	3,08%	1.627	0,79%	204.999
Cephalopods	0	0	15	88,24%	2	11,76%	0	0	17
Total uses	136.877	6,21%	1.434.475	65,13%	519.644	23,59%	111.596	5,07%	2.202.592

6. Use of species and genetic status

Table 20: Use of species and genetic status in total

Animal Species	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total
Mice	591.794	664.407	182.135	1.438.336
Rats	187.974	5.552	3.447	196.973
Guinea-Pigs	9.871	0	0	9.871
Hamsters (Syrian)	663	0	391	1.054
Hamsters (Chinese)	0	0	0	0
Mongolian gerbil	2.793	0	0	2.793
Other rodents	13.820	41	0	13.861
Rabbits	94.186	27	27	94.240
Cats	954	0	0	954
Dogs	3.519	0	0	3.519
Ferrets	114	10		124
Other carnivores	301	0	0	301
Horses, donkeys and cross-breeds	773	0	0	773
Pigs	19.470	317	139	19.926
Goats	429	0	0	429
Sheep	4.845	0	0	4.845
Cattle	6.623	0	0	6.623
Prosimians	140	0	0	140
Marmoset and tamarins	111	32	0	143
Cynomolgus monkey	2.880	0	0	2.880
Rhesus monkey	86	0	0	86
Vervets (Chlorocebus spp.)	8	0	0	8
Baboons	6	0	0	6
Squirrel monkey	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	13	0	0	13
Other species of New World Monkeys (Ceboidea)	0	0	0	0
Apes	0	0	0	0
Other mammals	1.942	0	0	1.942
Domestic fowl	24.655	281	0	24.936
Other birds	10.778	4	0	10.782
Reptiles	95	0	0	95
Rana	381	0	0	381
Xenopus	11.746	114	1.659	13.519
Other amphibians	4.343	880	256	5.479
Zebra fish	49.896	90.116	2.532	142.544
Other fish	201.664	3.176	159	204.999
Cephalopods	17	0	0	17
Total uses	1.246.890	764.957	190.745	2.202.592
%	56,61%	34,73%	8,66%	100,00%

Figure 4: Use of animals: genetic status



7. Use of Species and re-use

Table 21: Use of species and re-use in total

Animal Species	First use	Re-uses	Total
Mice	1.405.079	33.257	1.438.336
Rats	191.925	5.048	196.973
Guinea-Pigs	9.655	216	9.871
Hamsters (Syrian)	1.054	0	1.054
Hamsters (Chinese)	0	0	0
Mongolian gerbil	2.785	8	2.793
Other rodents	13.857	4	13.861
Rabbits	90.876	3.364	94.240
Cats	680	274	954
Dogs	1.678	1.841	3.519
Ferrets	122	2	124
Other carnivores	301		301
Horses, donkeys and cross-breeds	519	254	773
Pigs	18.792	1.134	19.926
Goats	409	20	429
Sheep	4.695	150	4.845
Cattle	5.886	737	6.623
Prosimians	85	55	140
Marmoset and tamarins	135	8	143
Cynomolgus monkey	2.385	495	2.880
Rhesus monkey	51	35	86
Vervets (Chlorocebus spp.)	0	8	8
Baboons	6	0	6
Squirrel monkey	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	13	13
Other species of New World Monkeys (Ceboidea)	0	0	0
Apes	0	0	0
Other mammals	1.919	23	1.942
Domestic fowl	24.567	369	24.936
Other birds	10.402	380	10.782
Reptiles	85	10	95
Rana	381	0	381
Xenopus	12.220	1.299	13.519
Other amphibians	5.479	0	5.479
Zebra fish	142.391	153	142.544
Other fish	203.369	1.630	204.999
Cephalopods	17	0	17
Total uses	2.151.805	50.787	2.202.592

Figure 5: Use of species groups and re-use

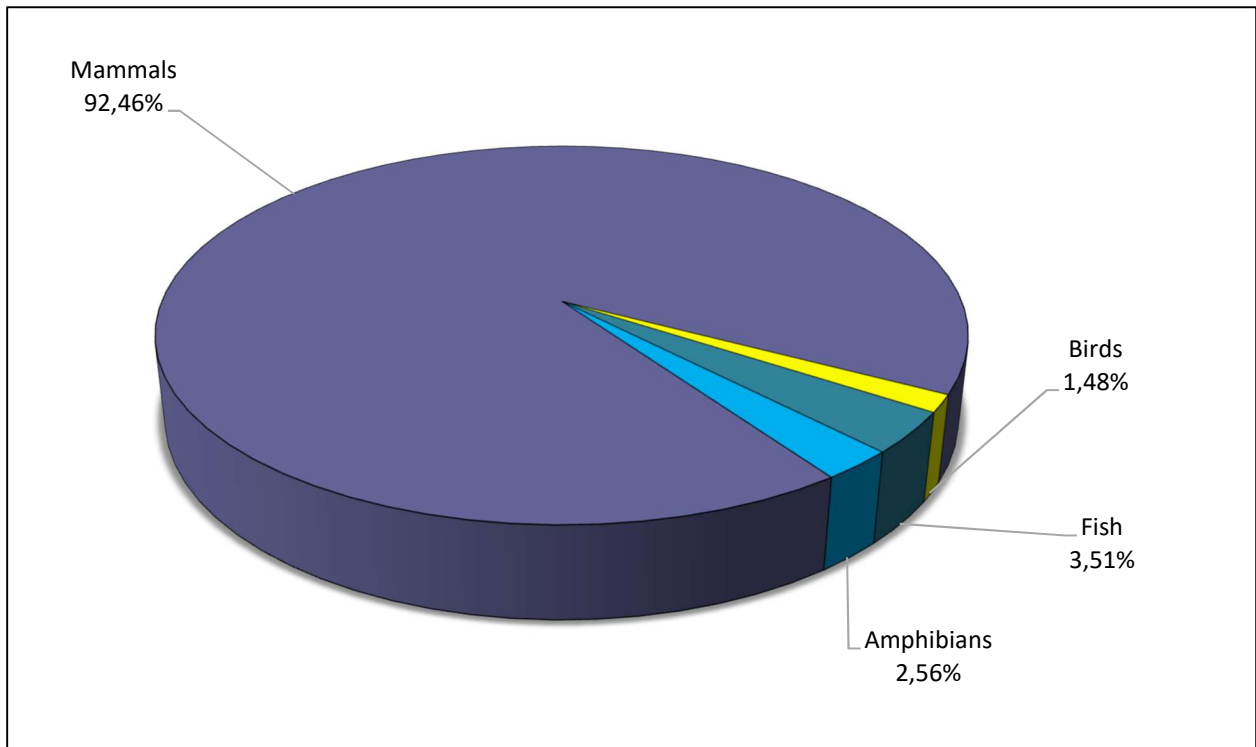
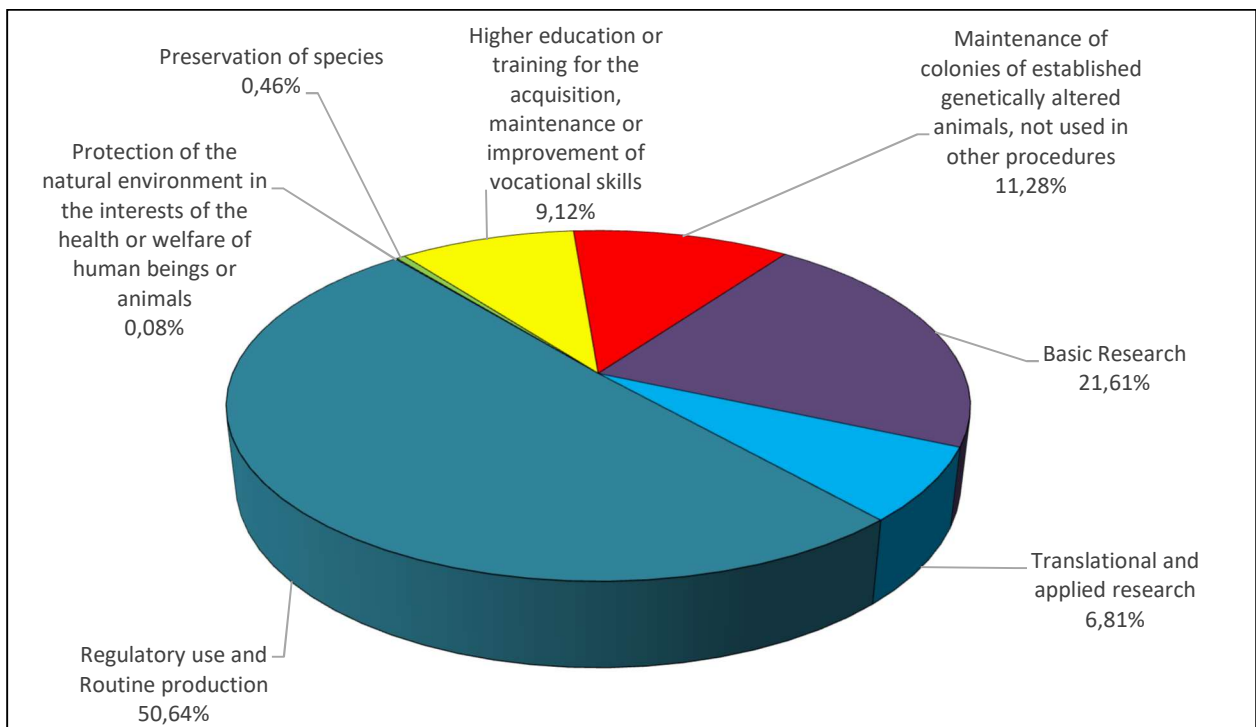


Figure 6: Primary purpose and re-use



8. Purposes and severity

Table 22: Purpose and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Basic Research	76.539	651.695	277.829	21.958	1.028.021
Translational and applied research	13.191	123.290	133.461	6.389	276.331
Regulatory use and Routine production	33.567	290.578	81.968	68.789	474.902
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3.120	7.966	155	327	11.568
Preservation of species	718	153.111	1.082	23	154.934
Higher education or training for the acquisition, maintenance or improvement of vocational skills	9.726	30.762	13.193	124	53.805
Maintenance of colonies of established genetically altered animals, not used in other procedures	16	177.073	11.956	13.986	203.031
Total uses	136.877	1.434.475	519.644	111.596	2.202.592
%	6,21%	65,13%	23,59%	5,07%	100,00%

Table 23: Basic research purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Oncology	3.987	39.407	57.382	1.681	102.457
Cardiovascular Blood and Lymphatic System	5.881	61.384	33.666	1.923	102.854
Nervous System	19.693	109.894	67.190	6.205	202.982
Respiratory System	3.755	9.613	3.870	663	17.901
Gastrointestinal System including Liver	4.767	15.569	13.700	711	34.747
Musculoskeletal System	1.200	10.248	5.763	339	17.550
Immune System	10.195	121.968	48.685	4.188	185.036
Urogenital/Reproductive System	5.854	22.058	3.199	109	31.220
Sensory Organs (skin, eyes and ears)	5.681	15.713	4.489	977	26.860
Endocrine System/Metabolism	2.610	28.940	12.948	618	45.116
Multisystemic	4.229	92.512	11.236	927	108.904
Ethology / Animal Behaviour /Animal Biology	2.718	28.811	1.461	43	33.033
Other basic research	5.969	95.578	14.240	3.574	119.361
Total uses	76.539	651.695	277.829	21.958	1.028.021
%	7,45%	63,39%	27,03%	2,14%	100,00%

Table 24: Basic research: species and severity

Animal Species	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Mice	68.026	478.645	245.498	17.510	809.679
Rats	3.128	14.688	10.476	1.463	29.755
Guinea-Pigs	98	416	276	7	797
Hamsters (Syrian)	0	337	85	0	422
Hamsters (Chinese)	0	0	0	0	0
Mongolian gerbil	119	225	558	0	902
Other rodents	81	3.102	119	1	3.303
Rabbits	27	1.045	153	1	1.226
Cats	3	190	28	0	221
Dogs	0	425	18	0	443
Ferrets	0	13	52	2	67
Other carnivores	0	0	0	0	0
Horses, donkeys and cross-breeds	0	416	1	0	417
Pigs	578	5.197	475	42	6.292
Goats	0	282	0	0	282
Sheep	5	2.760	74	0	2.839
Cattle	0	2.391	721	0	3.112
Prosimians	0	140	0	0	140
Marmoset and tamarins	0	50	19	0	69
Cynomolgus monkey	0	2	7	0	9
Rhesus monkey	0	11	36	0	47
Vervets (Chlorocebus spp.)	0	0	0	0	0
Baboons	0	0	0	0	0
Squirrel monkey	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	0	0	0
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0
Apes	0	0	0	0	0
Other mammals	0	1.408	27	24	1.459
Domestic fowl	221	9.420	27	382	10.050
Other birds	80	7.131	1.070	212	8.493
Reptiles	0	44	38	2	84
Rana	0	91	0	0	91
Xenopus	333	4.568	230	6	5.137
Other amphibians	15	1.527	414	0	1.956
Zebra fish	900	92.700	16.905	2.284	112.789
Other fish	2.925	24.456	520	22	27.923
Cephalopods	0	15	2	0	17
Total uses:	76.539	651.695	277.829	21.958	1.028.021

Table 25: Translational and applied research: purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Human Cancer	2.098	30.426	76.634	2.010	111.168
Human Infectious Disorders	463	11.752	10.353	523	23.091
Human Cardiovascular Disorders	2.574	6.940	2.306	449	12.269
Human Nervous and Mental Disorders	1.960	12.834	14.586	560	29.940
Human Respiratory Disorders	2.114	4.209	1.520	171	8.014
Human Gastrointestinal Disorders including Liver	202	2.205	5.331	171	7.909
Human Musculoskeletal Disorders	260	594	1.554	38	2.446
Human Immune Disorders	1.348	7.354	7.061	1.185	16.948
Human Urogenital/Reproductive Disorders	572	766	967	4	2.309
Human Sensory Organ Disorders (skin, eyes and ears)	76	2.634	1.595	76	4.381
Human Endocrine/Metabolism Disorders	185	16.184	2.039	45	18.453
Other Human Disorders	183	1.824	1.685	67	3.759
Animal Diseases and Disorders	765	14.004	3.119	520	18.408
Animal Welfare	94	7.846	277	12	8.229
Diagnosis of diseases	60	511	752	555	1.878
Plant diseases	0	100	0	0	100
Non-regulatory toxicology and ecotoxicology	237	3.107	3.682	3	7.029
Total uses	13.191	123.290	133.461	6.389	276.331
%	4,77%	44,62%	48,30%	2,31%	100,00%

Table 26: Translational and applied research: species and severity

Animal Species	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Mice	9.435	86.185	120.789	5.214	221.623
Rats	2.005	10.171	6.391	179	18.746
Guinea-Pigs	78	103	118	120	419
Hamsters (Syrian)	0	46	362	0	408
Hamsters (Chinese)	0	0	0	0	0
Mongolian gerbil	0	674	1.026	33	1.733
Other rodents	0	449	20	24	493
Rabbits	210	454	381	4	1.049
Cats	0	264	32	0	296
Dogs	0	551	8	0	559
Ferrets	0	26	20	0	46
Other carnivores	0	0	0	0	0
Horses, donkeys and cross-breeds	16	226	0	0	242
Pigs	649	7.520	894	228	9.291
Goats	0	55	37	0	92
Sheep	35	274	689	23	1.021
Cattle	0	1.325	152	0	1.477
Prosimians	0	0	0	0	0
Marmoset and tamarins	0	23	6	1	30
Cynomolgus monkey	0	97	57	0	154
Rhesus monkey	0	27	12	0	39
Vervets (Chlorocebus spp.)	0	8	0	0	8
Baboons	0	0	0	6	6
Squirrel monkey	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	13	0	0	13
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0
Apes	0	0	0	0	0
Other mammals	12	208	0	3	223
Domestic fowl	5	5.439	538	485	6.467
Other birds	0	917	63	69	1.049
Reptiles	0	0	0	0	0
Rana	0	0	0	0	0
Xenopus	0	0	0	0	0
Other amphibians	0	0	0	0	0
Zebra fish	0	1.565	134	0	1.699
Other fish	746	6.670	1.732	0	9.148
Cephalopods	0	0	0	0	0
Total uses	13.191	123.290	133.461	6.389	276.331

Table 27: Regulatory use/routine production purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Routine production	28.213	53.380	48	4	81.645
Quality control (incl. batch safety and potency testing)	237	90.985	27.614	51.688	170.524
Other efficacy and tolerance testing	843	8.054	10.305	1.140	20.342
Toxicity and other safety testing including pharmacology	4.274	138.159	44.001	15.957	202.391
Total uses	33.567	290.578	81.968	68.789	474.902
%	7,07%	61,19%	17,26%	14,48%	100,00%

Table 28: Regulatory use/routine production: species and severity

Animal Species	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Mice	1.840	92.239	28.180	49.965	172.224
Rats	1.941	93.602	39.912	1.115	136.570
Guinea-Pigs	3	5.266	476	2.616	8.361
Hamsters (Syrian)	0	202	0	0	202
Hamsters (Chinese)	0	0	0	0	0
Mongolian gerbil	0	106	3	0	109
Other rodents	36	9.856	27	24	9.943
Rabbits	28.391	62.624	578	108	91.701
Cats	13	363	21	0	397
Dogs	94	1.282	384	6	1.766
Ferrets	0	0	0	0	0
Other carnivores	0	50	241	0	291
Horses, donkeys and cross-breeds	0	32	0	0	32
Pigs	300	972	931	358	2.561
Goats	0	17	2	0	19
Sheep	0	761	18	8	787
Cattle	0	810	16	0	826
Prosimians	0	0	0	0	0
Marmoset and tamarins	0	8	36	0	44
Cynomolgus monkey	0	1.184	1.533	0	2.717
Rhesus monkey	0	0	0	0	0
Vervets (Chlorocebus spp.)	0	0	0	0	0
Baboons	0	0	0	0	0
Squirrel monkey	0	0	0	0	0
Other species of Old World Monkeys (Cercopithecoidea)	0	0	0	0	0
Other species of New World Monkeys (Ceboidea)	0	0	0	0	0
Apes	0	0	0	0	0
Other mammals	0	4	6	4	14
Domestic fowl	765	4.503	2.422	73	7.763
Other birds	0	205	0	0	205

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Reptiles	0	0	0	0	0
Rana	0	0	0	0	0
Xenopus	0	1.300	40	6.820	8.160
Other amphibians	0	0	0	0	0
Zebra fish	184	9.517	4.258	6.361	20.320
Other fish	0	5.675	2.884	1.331	9.890
Cephalopods	0	0	0	0	0
Total uses	33.567	290.578	81.968	68.789	474.902

Table 29: Quality control purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Batch safety testing	237	21.016	3.758	2	25.013
Pyrogenicity testing	0	6.433	24	0	6.457
Batch potency testing	0	63.535	23.796	51.686	139.017
Other quality controls	0	1	36	0	37
Total uses	237	90.985	27.614	51.688	170.524
%	0,14%	53,36%	16,19%	30,31%	100,00%

Table 30: Routine production purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Blood based products	28.069	48.576	1	0	76.646
Monoclonal antibody	7	1.424	25	0	1.456
Other product types	137	3.380	22	4	3.543
Total uses	28.213	53.380	48	4	81.645
%	34,56%	65,38%	0,06%	0,00%	100,00%

Table 31: Toxicity and other safer testing by test type purposes and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Acute and sub-acute	0	5.251	892	418	6.561
Skin irritation/corrosion	0	298	68		366
Skin sensitisation	0	5.184	812	4	6.000
Eye irritation/corrosion	0	12	11		23
Repeated dose toxicity	0	11.575	8.081	131	19.787
Carcinogenicity	0	846	217	147	1.210
Genotoxicity	0	2.255	224	52	2.531
Reproductive toxicity	0	16.376	945	33	17.354
Developmental toxicity	0	17.488	548	57	18.093
Neurotoxicity	0	0	0	0	0
Kinetics	59	17.262	3.655	49	21.025
Pharmaco-dynamics (incl.	3.987	34.022	20.333	636	58.978

safety pharmacology)					
Phototoxicity	0	0	0	0	0
Ecotoxicity	184	14.914	7.182	14.430	36.710
Safety testing in food and feed area	0	1.382	301	0	1.683
Target animal safety	0	1.421	450	0	1.871
Other toxicity/safety testing	44	9.873	282	0	10.199
Total uses	4.274	138.159	44.001	15.957	202.391
%	2,11%	68,26%	21,74%	7,88%	100,00%

Table 32: Repeated dose toxicity testing methods and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
up to 28 days	0	7.899	4.767	105	12.771
29 - 90 days	0	3.170	2.342	23	5.535
> 90 days	0	506	972	3	1.481
Total uses	0	11.575	8.081	131	19.787
%	0,00%	58,50%	40,84%	0,66%	100,00%

Table 33: Acute and subacute toxicity testing methods and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
LD50. LC50	0	223	392	274	889
Other lethal methods	0	2	146	82	230
Non lethal methods	0	5.026	354	62	5.442
Total uses	0	5.251	892	418	6.561
%	0,00%	80,03%	13,60%	6,37%	100,00%

Table 34: Ecotoxicity testing methods and severity

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total
Acute toxicity	28	1.930	180	2.104	4.242
Chronic toxicity	0	7.992	6.290	5.342	19.624
Reproductive ecotoxicity	156	0	0	68	224
Endocrine activity	0	1.924	40	6.820	8.784
Bioaccumulation	0	2.813	658	0	3.471
Other ecotoxicity	0	255	14	96	365
Total uses	184	14.914	7.182	14.430	36.710
%	0,50%	40,63%	19,56%	39,31%	100,00%

9. Purposes and testing by type of legislation

Table 35: Regulatory use and routine production purposes: type of legislation

	Quality control (incl. batch safety and potency testing)	Other efficacy and tolerance testing	Toxicity and other safety testing including pharmacology	Routine production	Total
Legislation on medicinal products for human use	162.267	15.298	104.486	28.926	310.977
Legislation on medicinal products for veterinary use and their residues	8.032	1.580	3.540	893	14.045
Medical devices legislation	118	210	6.052	47.598	53.978
Industrial chemicals legislation	0	0	39.600	326	39.926
Plant protection product legislation	0	0	45.183	299	45.482
Biocides legislation	0	350	62	71	483
Food legislation including food contact material	0	0	206	21	227
Feed legislation including legislation for the safety of target animals, workers and environment	19	2.748	1.645	1.400	5.812
Cosmetics legislation	0	0	0	0	0
Other legislation	88	156	1.617	2.111	3.972
Total uses	170.524	20.342	202.391	81.645	474.902

Table 36: Quality control purposes: type of legislation

	Batch potency testing	Batch safety testing	Other quality controls	Pyrogenicity testing	Total
Legislation on medicinal products for human use	134.543	21.343	18	6.363	162.267
Legislation on medicinal products for veterinary use and their residues	4.459	3.569	0	4	8.032
Medical devices legislation	0	28	0	90	118
Industrial chemicals legislation	0	0	0	0	0
Plant protection product legislation	0	0	0	0	0
Biocides legislation	0	0	0	0	0
Food legislation including food contact material	0	0	0	0	0
Feed legislation including legislation for the safety of target animals, workers and environment	0	0	19	0	19
Cosmetics legislation	0	0	0	0	0
Other legislation	15	73	0	0	88
Total uses	139.017	25.013	37	6.457	170.524

Table 37: Routine production purposes: type of legislation

	Blood based products	Monoclonal antibody	Other product types	Total
Legislation on medicinal products for human use	28.699	0	227	28.926
Legislation on medicinal products for veterinary use and their residues	0	332	561	893
Medical devices legislation	47.518	76	4	47.598
Industrial chemicals legislation	0	326	0	326
Plant protection product legislation	0	0	299	299
Biocides legislation	0	0	71	71
Food legislation including food contact material	5	0	16	21
Feed legislation including legislation for the safety of target animals, workers and environment	0	0	1.400	1.400
Cosmetics legislation	0	0	0	0
Other legislation	424	722	965	2.111
Total uses	76.646	1.456	3.543	81.645

Table 38: Toxicity and other safety testing by test type purposes: type of legislation

	Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Cosmetics legislation	Other legislation	Total
Acute and sub-acute	3.487	0	1.576	907	532	0	14	0	0	45	6.561
Skin irritation/ corrosion	24	0	241	89	12	0	0	0	0	0	366
Skin sensitisation	1.080	0	2.936	1.595	389	0	0	0	0	0	6.000
Eye irritation/ corrosion	0	0	3	11	9	0	0	0	0	0	23
Repeated dose toxicity	12.459	194	116	5.807	1.211	0	0	0	0	0	19.787
Carcinogenicity	110	0	0	0	1.100	0	0	0	0	0	1.210
Genotoxicity	688	126	0	552	1.165	0	0	0	0	0	2.531
Reproductive toxicity	1.159	0	0	11.509	4.494	0	192	0	0	0	17.354
Developmental toxicity	356	0	0	10.979	6.758	0	0	0	0	0	18.093
Neurotoxicity	0	0	0	0	0	0	0	0	0	0	0
Kinetics	19.577	1.011	27	172	238	0	0	0	0	0	21.025
Pharmaco-dynamics (incl. safety pharmacology)	58.179	727	2	0	0	0	0	0	0	70	58.978
Phototoxicity	0	0	0	0	0	0	0	0	0	0	0
Ecotoxicity	6.828	313	881	7.979	19.377	62	0	0	0	1.270	36.710
Safety testing in food and feed area	0	8	0	0	35	0	0	1.640	0	0	1.683
Target animal safety	0	1.104	0	0	767	0	0	0	0	0	1.871
Other toxicity/safety testing	539	57	270	0	9.096	0	0	5	0	232	10.199
Total uses	104.486	3.540	6.052	39.600	45.183	62	206	1.645	0	1.617	202.391

Table 39: Repeated dose toxicity purposes: type of legislation

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation on medicinal products for human use	8.768	2.355	1.336	12.459
Legislation on medicinal products for veterinary use and their residues	194	0	0	194
Medical devices legislation	56	60	0	116
Industrial chemicals legislation	2.792	2.870	145	5.807
Plant protection product legislation	961	250	0	1.211
Biocides legislation	0	0	0	0
Food legislation including food contact material	0	0	0	0
Feed legislation including legislation for the safety of target animals, workers and environment	0	0	0	0
Cosmetics legislation	0	0	0	0
Other legislation	0	0	0	0
Total uses	12.771	5.535	1.481	19.787

Table 40: Acute and subacute toxicity testing methods: type of legislation

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation on medicinal products for human use	0	0	3.487	3.487
Legislation on medicinal products for veterinary use and their residues	0	0	0	0
Medical devices legislation	0	0	1.576	1.576
Industrial chemicals legislation	573	0	334	907
Plant protection product legislation	316	216	0	532
Biocides legislation	0	0	0	0
Food legislation including food contact material	0	14	0	14
Feed legislation including legislation for the safety of target animals, workers and environment	0	0	0	0
Cosmetics legislation	0	0	0	0
Other legislation	0	0	45	45
Total uses	889	230	5.442	6.561

Table 41: Ecotoxicity purposes: type of legislation

	Acute toxicity	Chronic toxicity	Reproductive ecotoxicity	Endocrine activity	Bioaccumulation	Other ecotoxicity	Total
Legislation on medicinal products for human use	42	6.356	0	0	430	0	6.828
Legislation on medicinal products for veterinary use and their residues	88	0	0	0	225	0	313
Medical devices legislation	0	480	0	0	401	0	881
Industrial chemicals legislation	1.273	5.079	224	50	1.056	297	7.979
Plant protection product legislation	1.507	7.709	0	8.734	1.359	68	19.377
Biocides legislation	62	0	0	0	0	0	62
Food legislation including food contact material	0	0	0	0	0	0	0
Feed legislation including legislation for the safety of target animals, workers and environment	0	0	0	0	0	0	0
Cosmetics legislation	0	0	0	0	0	0	0
Other legislation	1.270	0	0	0	0	0	1.270
Total uses	4.242	19.624	224	8.784	3.471	365	36.710

10. Purposes and origin of legislative requirement

Table 42: Regulatory use and routine production: origin of legislative requirement

	Quality control (incl. batch safety and potency testing)	Other efficacy and tolerance testing	Toxicity and other safety testing including pharma- cology	Routine production	Total
Legislation satisfying EU requirements	163.326	20.181	197.781	51.027	432.315
Legislation satisfying national requirements only [within EU]	402	161	1.692	30.618	32.873
Legislation satisfying Non-EU requirements only	6.796	0	2.918	0	9.714
Total uses	170.524	20.342	202.391	81.645	474.902

Table 43: Toxicity and other safety testing: origin of legislative requirement

	Legislation satisfying EU requirements	Legislation satisfying national require- ments only [within EU]	Legislation satisfying Non-EU requirements only	Total
Acute and sub-acute	6.444	59	58	6.561
Skin irritation/corrosion	299	0	67	366
Skin sensitisation	5.490	0	510	6.000
Eye irritation/corrosion	11	0	12	23
Repeated dose toxicity	18.977	0	810	19.787
Carcinogenicity	1.210	0	0	1.210
Genotoxicity	2.531	0	0	2.531
Reproductive toxicity	16.811	0	543	17.354
Developmental toxicity	18.093	0	0	18.093
Neurotoxicity	0	0	0	0
Kinetics	21.014	0	11	21.025
Pharmaco-dynamics (incl. safety pharmacology)	58.292	166	520	58.978
Phototoxicity	0	0	0	0
Ecotoxicity	35.018	1.462	230	36.710
Safety testing in food and feed area	1.683	0	0	1.683
Target animal safety	1.741	0	130	1.871
Other toxicity/safety testing	10.167	5	27	10.199
Total uses	197.781	1.692	2.918	202.391

Table 44: Repeated dose toxicity: origin of legislative requirement

	up to 28 days	29 - 90 days	> 90 days	Total
Legislation satisfying EU requirements	12.731	4.765	1.481	18.977
Legislation satisfying national requirements only [within EU]	0	0	0	0
Legislation satisfying Non-EU requirements only	40	770	0	810
Total uses	12.771	5.535	1.481	19.787

Table 45: Acute and subacute toxicity testing: origin of legislative requirement

	LD50, LC50	Other lethal methods	Non lethal methods	Total
Legislation satisfying EU requirements	889	216	5.339	6.444
Legislation satisfying national requirements only [within EU]	0	14	45	59
Legislation satisfying Non-EU requirements only	0	0	58	58
Total uses	889	230	5.442	6.561

Table 46: Ecotoxicity testing: origin of legislative requirement

	Acute toxicity	Chronic toxicity	Endocrine activity	Reproductive ecotoxicity	Bioaccumulation	Other ecotoxicity	Total
Legislation satisfying EU requirements	2.560	19.624	8.784	224	3.471	355	35.018
Legislation satisfying national requirements only [within EU]	1.452	0	0	0	0	10	1.462
Legislation satisfying Non-EU requirements only	230	0	0	0	0	0	230
Total uses	4.242	19.624	8.784	224	3.471	365	36.710

11. Animals used under § 4 (3) of the Animal Protection Act by speciesTable 47: Animals used by species

Animal Species	Number of Animals	%
Mice	562.973	80,44
Rats	73.154	10,44
Guinea-Pigs	441	0,06
Hamsters (Syrian)	82	0,01
Hamsters (Chinese)	0	0,00
Mongolian gerbil	1.021	0,15
Other rodents	3.578	0,51
Rabbits	439	0,06
Cats	0	0,00
Dogs	8	0,01
Ferrets	3	0,01
Other carnivores	0	0,00
Horses, donkeys & cross-breeds	17	0,01
Pigs	1.073	0,15
Goats	55	0,01
Sheep	11	0,01
Cattle	0	0,00
Prosimians	0	0,00
Marmoset and tamarins	25	0,01
Cynomolgus monkey	132	0,02
Rhesus monkey	10	0,01
Vervets (Chlorocebus spp.)	0	0,00
Baboons	0	0,00
Squirrel monkey	0	0,00
Other species of Old World Monkeys (Cercopithecoidea)	0	0,00
Other species of New World Monkeys (Ceboidea)	0	0,00
Apes	0	0,00
Other mammals	287	0,04
Domestic fowl	7.618	1,08
Other birds	447	0,06
Reptiles	108	0,02
Rana	6	0,01
Xenopus	1.475	0,20
Other amphibians	139	0,02
Zebra fish	37.297	5,33
Other fish	9.275	1,32
Cephalopods	82	0,01
Total uses	699.756	100,00