EUROPEAN
COMMISSION

Brussels, 5.2.2020
SWD(2020) 10 final

PART 3/5

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

SECTION C: MEMBER STATE DATA BETWEEN 2015 AND 2017

V. Member State narratives and data submissions 2015-2017

V.1. Introduction

Member States submitted statistical data to the Commission between 2015 and 2017 using the main categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU. The accompanying Member State narratives make reference to the numbers in these submissions.

However, the numbers contained in the Member State submission do not directly correlate with the compiled EU data.

Drawing from the Member State submissions, the EU report is based on a revised, improved, categorisation of data:

- **Numbers of animals** used for purposes of research, testing, routine production and education (including training) – Part 1 (III.1)
- **Details of all uses** (first and any subsequent reuse) of animals for the purposes of research, testing, routine production and education (including training) - Part 2 (III.2)
- Numbers and uses of animals for the **creation and maintenance of genetically altered animals** in the EU – Part 3 (III.3)

This has allowed for the presentation of a much clearer and precise picture of the numbers of animals and purposes for which animals are used in the EU.

To provide a possibility to refer back to the Member State data in a similar manner, the part V.3. of this Section C presents recalculation of the Member State data, for the year 2017, divided into the three categories above.

V.2. Member State narratives and data submissions 2015-2017

Member States annual submissions between years 2015 and 2017 are listed by Member State, first providing the Member State narrative for the respective year followed by the related data tables.

As stated above, these numbers do not directly correlate with numbers in the EU report in Part A but have been left here so that accurate presentation of the Member State submissions is provided, including correspondence with the related annual narratives.

Austria

Austria: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Austria already collected statistical data on animals used in 2013 in the new format. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the years before 2013 can only be made with caution. The overall number of animals used in 2015 was 227.317 (2014: 209.183), this constitutes an increase of 8,7%, in comparison to 2013 this is an increase of 9%.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Significant increases in animal use were reported for translational research on infectious diseases and regulatory pyrogenicity testing. Significant decrease in animal use was observed for translational research in oncology and regulatory batch potency testing.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The percentages of actual severities were
Non-recovery: 4% (2014: 3%)
Mild: 60% (2014: 57%)
Moderate: 24% (2014: 30%)
Severe: 12% (2014: 10%)
These changes could not be considered as significant.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all the steps of the authorization processes, so that even with an increase in research activities the overall numbers of animals used have remained fairly constant.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Only small, not significant proportions were reported under the category “other”.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were observed or reported.

Austria: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	187413	82.45%
Rats	5162	2.27%
Guinea-Pigs	1858	0.82%
Hamsters (Syrian)	602	0.26%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	99	0.04%
Rabbits	15910	7%
Cats	34	0.01%
Dogs	111	0.05%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	94	0.04%
Pigs	1762	0.78%
Goats	7	0%
Sheep	115	0.05%
Cattle	632	0.28%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	515	0.23%
Domestic fowl	1623	0.71%
Other birds	465	0.2%
Reptiles		
Rana		
Xenopus	121	0.05%
Other Amphibians	616	0.27%
Zebra fish	9411	4.14%
Other Fish	767	0.34%
Cephalopods		
Total	**227317**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	216341	96.04%
Animals born in the EU but not at a registered breeder	4188	1.86%
Animals born in rest of Europe	61	0.03%
Animals born in rest of world	4678	2.08%
Total	**225268**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	89479	39.36%
Translational and applied research	74146	32.62%
Regulatory use and Routine production	31789	13.98%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	551	0.24%
Preservation of species	67	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1925	0.85%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	29360	12.92%
Total	**227317**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	15691	17.54%
Cardiovascular Blood and Lymphatic System	10313	11.53%
Nervous System	12922	14.44%
Respiratory System	739	0.83%
Gastrointestinal System including Liver	2525	2.82%
Musculoskeletal System	1816	2.03%
Immune System	19514	21.81%
Urogenital/Reproductive System	553	0.62%
Sensory Organs (skin, eyes and ears)	420	0.47%
Endocrine System/Metabolism	2055	2.3%
Multisystemic	8104	9.06%
Ethology / Animal Behaviour /Animal Biology	1343	1.5%
Other basic research	13484	15.07%
Total	**89479**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13389	18.06%
Human Infectious Disorders	42653	57.53%
Human Cardiovascular Disorders	7030	9.48%
Human Nervous and Mental Disorders	3885	5.24%
Human Respiratory Disorders	91	0.12%
Human Gastrointestinal Disorders including Liver	471	0.64%
Human Musculoskeletal Disorders	595	0.8%
Human Immune Disorders	2396	3.23%
Human Urogenital/Reproductive Disorders	167	0.23%
Human Sensory Organ Disorders (skin, eyes and ears)	262	0.35%
Human Endocrine/Metabolism Disorders	263	0.35%
Other Human Disorders	20	0.03%
Animal Diseases and Disorders	2874	3.88%
Animal Welfare		
Diagnosis of diseases	15	0.02%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	35	0.05%
Total	**74146**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	31413	98.82%
Other efficacy and tolerance testing	44	0.14%
Toxicity and other safety testing including pharmacology	151	0.48%
Routine production	181	0.57%
Total	**31789**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4708	14.99%
Pyrogenicity testing	14794	47.1%
Batch potency testing	11461	36.48%
Other quality controls	450	1.43%
Total	**31413**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	6	3.97%
Neurotoxicity	88	58.28%
Kinetics	48	31.79%
Safety testing in food and feed area	9	5.96%
Total	**151**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	6	100%
> 90 days		
Total	**6**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	181	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**181**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	31642	99.54%
Legislation on medicinal products for veterinary use and their residues	44	0.14%
Medical devices legislation	6	0.02%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material		

Testing by Legislation	Number of uses	Percentage
Feed legislation including legislation for the safety of target animals, workers and environment	9	0.03%
Cosmetics legislation		
Other legislation	88	0.28%
Total	**31789**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	27929	87.86%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	3860	12.14%
Total	**31789**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225268	99.1%
Yes	2049	0.9%
Total	**227317**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	8782	3.86%
Mild [up to and including]	136602	60.09%
Moderate	54896	24.15%
Severe	27037	11.89%
Total	**227317**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	215627	94.86%
Yes	11690	5.14%
Total	**227317**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	135911	59.79%
Genetically altered without a harmful phenotype	73220	32.21%
Genetically altered with a harmful phenotype	18186	8%
Total	**227317**	**100.00%**

Austria: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In Austria the total number of animals used for scientific purposes in 2016 is 236.459 (2015: 227.317), which is an increase of 4.0% or in absolute numbers 9.142 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats. However, the overall numbers between 2013 and 2016 remained within the range of the last 10 years.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

A marked increase is observed in “Basic Research, Immune System” (from 19.514 animals to 29.555 animals). On the other hand, there is a decline in “Maintenance of colonies of established genetically altered animals, not used in other procedures” (from 29.360 animals to 18.905 animals).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of severity "severe" decreased from 12% to 7% compared to the previous year (also in absolute numbers: from 27.037 to 17.272). One possible reason for this could be the case-specific application of humane endpoints.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints. Thus, even with an increase in research activities the numbers of animals used have remained fairly constant, while at the same time the proportion of animals with “severe” suffering declined.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

“Other rodents” include i.a. the wood mouse (not Mus musculus), the edible dormouse and garden dormouse; “Other mammals” include i.a. llamas, “Other birds” i.a. turkeys, great tits and Eurasian blackcaps; “Other fish” mainly trouts and medaka.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as the production of antibodies.

6. Details on cases where the “severe” classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why “severe” classification was exceeded.

Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

Austria: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	191896	81.15%
Rats	6344	2.68%
Guinea-Pigs	1785	0.75%
Hamsters (Syrian)	277	0.12%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	276	0.12%
Rabbits	14684	6.21%
Cats	12	0.01%
Dogs	177	0.07%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	43	0.02%
Pigs	4901	2.07%
Goats	2	0%
Sheep	423	0.18%
Cattle	386	0.16%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	150	0.06%
Domestic fowl	3307	1.4%
Other birds	1208	0.51%
Reptiles		
Rana		
Xenopus	148	0.06%
Other Amphibians	4	0%
Zebra fish	7960	3.37%
Other Fish	2476	1.05%
Cephalopods		
Total	**236459**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	224314	95.23%
Animals born in the EU but not at a registered breeder	7403	3.14%
Animals born in rest of Europe		

Place of birth	Number of animals	Percentage
Animals born in rest of world	3843	1.63%
Total	**235560**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	103605	43.82%
Translational and applied research	74336	31.44%
Regulatory use and Routine production	36202	15.31%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	191	0.08%
Preservation of species	563	0.24%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2657	1.12%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	18905	8%
Total	**236459**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	17191	16.59%
Cardiovascular Blood and Lymphatic System	11179	10.79%
Nervous System	9439	9.11%
Respiratory System	399	0.39%
Gastrointestinal System including Liver	1761	1.7%
Musculoskeletal System	2566	2.48%
Immune System	29555	28.53%
Urogenital/Reproductive System	469	0.45%
Sensory Organs (skin, eyes and ears)	1158	1.12%
Endocrine System/Metabolism	2033	1.96%
Multisystemic	10967	10.59%
Ethology / Animal Behaviour /Animal Biology	2842	2.74%
Other basic research	14046	13.56%

Basic Research	Number of uses	Percentage
Total	**103605**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	15369	20.68%
Human Infectious Disorders	35473	47.72%
Human Cardiovascular Disorders	7850	10.56%
Human Nervous and Mental Disorders	4748	6.39%
Human Respiratory Disorders	64	0.09%
Human Gastrointestinal Disorders including Liver	832	1.12%
Human Musculoskeletal Disorders	351	0.47%
Human Immune Disorders	1437	1.93%
Human Urogenital/Reproductive Disorders	8	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	47	0.06%
Human Endocrine/Metabolism Disorders	769	1.03%
Other Human Disorders	897	1.21%
Animal Diseases and Disorders	2637	3.55%
Animal Welfare	3848	5.18%
Diagnosis of diseases	6	0.01%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**74336**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	35884	99.12%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	72	0.2%
Routine production	246	0.68%
Total	**36202**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4228	11.78%
Pyrogenicity testing	13157	36.67%
Batch potency testing	17604	49.06%
Other quality controls	895	2.49%
Total	**35884**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Neurotoxicity	22	30.56%
Target animal safety	50	69.44%
Total	**72**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	246	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**246**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	36103	99.73%
Legislation on medicinal products for veterinary use and their residues	50	0.14%
Medical devices legislation	27	0.07%

Testing by Legislation	Number of uses	Percentage
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	22	0.06%
Total	**36202**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	31134	86%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	5068	14%
Total	**36202**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235560	99.62%
Yes	899	0.38%
Total	**236459**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	5815	2.46%
Mild [up to and including]	148333	62.73%
Moderate	65039	27.51%
Severe	17272	7.3%
Total	**236459**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	222857	94.25%
Yes	13602	5.75%
Total	**236459**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	138680	58.65%
Genetically altered without a harmful phenotype	80249	33.94%
Genetically altered with a harmful phenotype	17530	7.41%
Total	**236459**	**100.00%**

Austria: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In Austria the total number of animals used for scientific purposes in 2017 is 264.071 (2016: 236.459), which is an increase of 11.7% or in absolute numbers 27.612 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The total number of fish (zebra fish and other fish) used for scientific purposes in 2017 is 20.927 (2016: 10.436). Zebra fish were mainly used for the purpose “Basic Research, Other” in particular cell and developmental biology.

With regard to the categories of purposes, a marked increase is observed in “Basic Research, Oncology” (from 17.191 animals to 25.406 animals used in 2017). For Maintenance of colonies of established genetically altered animals, not used in other procedures” a decrease was reported in 2016, whereas for 2017 an increase is observed in this category (from 18.905 animals to 29.360 animals).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

No significant changes are observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

“Other rodents” include i.a. the common vole and the wood mouse; “Other mammals” include i.a. the brown hare and wild boar, “Other birds” i.a. reed buntings and Eurasian blackcaps; “Other fish” include i.a. trouts.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as cell and developmental biology and imaging.

6. Details on cases where the “severe” classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why “severe” classification was exceeded.

Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

Austria: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	212913	80.63%
Rats	6038	2.29%
Guinea-Pigs	1154	0.44%
Hamsters (Syrian)	8	0%
Hamsters (Chinese)		
Mongolian gerbil	41	0.02%
Other Rodents	998	0.38%
Rabbits	10388	3.93%
Cats	61	0.02%
Dogs	203	0.08%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	521	0.2%
Pigs	2040	0.77%
Goats	22	0.01%
Sheep	149	0.06%
Cattle	908	0.34%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	102	0.04%
Domestic fowl	3895	1.47%
Other birds	1819	0.69%
Reptiles		
Rana		
Xenopus	972	0.37%
Other Amphibians	912	0.35%
Zebra fish	16297	6.17%
Other Fish	4630	1.75%
Cephalopods		
Total	**264071**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	247185	93.95%
Animals born in the EU but not at a registered breeder	11909	4.53%
Animals born in rest of Europe	99	0.04%

Place of birth	Number of animals	Percentage
Animals born in rest of world	3902	1.48%
Total	**263095**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	127667	48.35%
Translational and applied research	77138	29.21%
Regulatory use and Routine production	26569	10.06%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	198	0.07%
Preservation of species	30	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3108	1.18%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	29361	11.12%
Total	**264071**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	25406	19.9%
Cardiovascular Blood and Lymphatic System	10272	8.05%
Nervous System	16591	13%
Respiratory System	316	0.25%
Gastrointestinal System including Liver	2229	1.75%
Musculoskeletal System	4947	3.87%
Immune System	25283	19.8%
Urogenital/Reproductive System	1128	0.88%
Sensory Organs (skin, eyes and ears)	1208	0.95%
Endocrine System/Metabolism	1694	1.33%
Multisystemic	12805	10.03%
Ethology / Animal Behaviour /Animal Biology	5799	4.54%
Other basic research	19989	15.66%

Basic Research	Number of uses	Percentage
Total	**127667**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14506	18.81%
Human Infectious Disorders	42202	54.71%
Human Cardiovascular Disorders	5109	6.62%
Human Nervous and Mental Disorders	5487	7.11%
Human Respiratory Disorders	285	0.37%
Human Gastrointestinal Disorders including Liver	151	0.2%
Human Musculoskeletal Disorders	260	0.34%
Human Immune Disorders	785	1.02%
Human Urogenital/Reproductive Disorders	201	0.26%
Human Sensory Organ Disorders (skin, eyes and ears)	300	0.39%
Human Endocrine/Metabolism Disorders	1138	1.48%
Other Human Disorders	576	0.75%
Animal Diseases and Disorders	4816	6.24%
Animal Welfare	542	0.7%
Diagnosis of diseases	715	0.93%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	65	0.08%
Total	**77138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25823	97.19%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	740	2.79%
Routine production	6	0.02%
Total	**26569**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2700	10.46%
Pyrogenicity testing	9125	35.34%
Batch potency testing	13554	52.49%
Other quality controls	444	1.72%
Total	**25823**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	43	5.81%
Neurotoxicity	32	4.32%
Target animal safety	665	89.86%
Total	**740**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	43	100%
> 90 days		
Total	**43**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	6	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**6**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25870	97.37%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation	2	0.01%

Testing by Legislation	Number of uses	Percentage
Industrial chemicals legislation		
Plant protection product legislation	665	2.5%
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	32	0.12%
Total	**26569**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23037	86.71%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	3532	13.29%
Total	**26569**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	263095	99.63%
Yes	976	0.37%
Total	**264071**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	5153	1.95%
Mild [up to and including]	175022	66.28%
Moderate	62516	23.67%
Severe	21380	8.1%
Total	**264071**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	241513	91.46%
Yes	22558	8.54%
Total	**264071**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	145931	55.26%
Genetically altered without a harmful phenotype	82509	31.25%
Genetically altered with a harmful phenotype	35631	13.49%
Total	**264071**	**100.00%**

Belgium

Belgium: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2014 (660.261 animals used), there is a decrease of 14,95 % in the number of animals used for scientific purposes in 2015 (561.551 animals used).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The use of animals in the specific areas is similar to the figures of 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 more animals were reported in the 'severe' category [2014: severe (14.82%), moderate (28.23%), mild (53.02%) and non-recovery (3.93%); 2015: severe (16.68%), moderate (22.14%), mild (56.69%) and non-recovery (4.49%)]. This trend is mostly due to a better reporting of the actual severities by the users and stricter controls by the ethical committees and the government.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests
- Collaboration with the university board to promote the development and promotion of alternative methods.
- Collaboration between the different regions and other member states to promote the 3R principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

40.67% of the fishes are reported under the "other" category. They are mostly *Clarias gariepinus* and *Dicentrarchus labrax.* 36.67% of the amphibians reported under the "other" category are *Salamandridae* (in order of importance: *Lissotriton helveticus*, *Ichthyosaura alpestris*, *Salamandra salamandra*) and *Ranidae* (in order of importance: *Lithobates catesbeianus*, *Litoria caerulea*, *Alytes obstetricans*). 18.10% of the birds are reported under the "other" category. They are mostly *Paridae, Fringillidae, Passeridae, Coturnix, Meleagrididae, Estrildida* and *Laridae*.

19.73% of the regulatory routine production – toxicity and safety testing is reported as "other" toxicity and safety testing. This concerns mostly immunogenicity and psychopharmacology tests.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no exceeding of the 'severe' classification reported in 2015.

Belgium: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	331692	59.07%
Rats	33686	6%
Guinea-Pigs	17363	3.09%
Hamsters (Syrian)	2246	0.4%
Hamsters (Chinese)		
Mongolian gerbil	111	0.02%
Other Rodents	200	0.04%
Rabbits	43304	7.71%
Cats	82	0.01%
Dogs	1850	0.33%
Ferrets	5	0%
Other carnivores		
Horses, donkeys and cross-breeds	115	0.02%
Pigs	3391	0.6%
Goats	96	0.02%
Sheep	417	0.07%
Cattle	598	0.11%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	5	0%
Rhesus monkey	41	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	131	0.02%
Domestic fowl	18350	3.27%
Other birds	4055	0.72%
Reptiles	133	0.02%
Rana		
Xenopus	855	0.15%
Other Amphibians	495	0.09%
Zebra fish	60711	10.81%
Other Fish	41619	7.41%
Cephalopods		
Total	**561551**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	496746	91.89%
Animals born in the EU but not at a registered breeder	36621	6.77%
Animals born in rest of Europe	2693	0.5%
Animals born in rest of world	4501	0.83%
Total	**540561**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	5	50%
Animals born in rest of Europe		
Animals born in Asia	5	50%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**10**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	10	100%
Self-sustaining colony		
Total	**10**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	309245	55.07%
Translational and applied research	94736	16.87%
Regulatory use and Routine production	146804	26.14%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	377	0.07%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8426	1.5%
Forensic enquiries	36	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1927	0.34%
Total	**561551**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	42541	13.76%
Cardiovascular Blood and Lymphatic System	19624	6.35%
Nervous System	48985	15.84%
Respiratory System	7410	2.4%
Gastrointestinal System including Liver	15356	4.97%
Musculoskeletal System	18962	6.13%
Immune System	59121	19.12%
Urogenital/Reproductive System	20248	6.55%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	4820	1.56%
Endocrine System/Metabolism	30242	9.78%
Multisystemic	15254	4.93%
Ethology / Animal Behaviour /Animal Biology	17519	5.67%
Other basic research	9163	2.96%
Total	**309245**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	16760	17.69%
Human Infectious Disorders	21894	23.11%
Human Cardiovascular Disorders	1085	1.15%
Human Nervous and Mental Disorders	17936	18.93%
Human Respiratory Disorders	4176	4.41%
Human Gastrointestinal Disorders including Liver	971	1.02%
Human Musculoskeletal Disorders	181	0.19%
Human Immune Disorders	2558	2.7%
Human Urogenital/Reproductive Disorders	433	0.46%
Human Sensory Organ Disorders (skin, eyes and ears)	2880	3.04%
Human Endocrine/Metabolism Disorders	1359	1.43%
Other Human Disorders	62	0.07%
Animal Diseases and Disorders	6235	6.58%
Animal Welfare	165	0.17%
Diagnosis of diseases	7256	7.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	10785	11.38%
Total	**94736**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	89897	61.24%
Other efficacy and tolerance testing	7066	4.81%
Toxicity and other safety testing including pharmacology	9705	6.61%
Routine production	40136	27.34%
Total	**146804**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	13136	14.61%
Pyrogenicity testing		
Batch potency testing	74356	82.71%
Other quality controls	2405	2.68%
Total	**89897**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	990	10.2%
Skin irritation/corrosion	158	1.63%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Phototoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Repeated dose toxicity	1380	14.22%
Genotoxicity	126	1.3%
Reproductive toxicity	349	3.6%
Neurotoxicity	183	1.89%
Kinetics	671	6.91%
Pharmaco-dynamics (incl safety pharmacology)	1548	15.95%
Ecotoxicity	871	8.97%
Safety testing in food and feed area	1506	15.52%
Target animal safety	8	0.08%
Other toxicity/safety testing	1915	19.73%
Total	**9705**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	990	100%
Total	**990**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1380	100%
29 - 90 days		
> 90 days		
Total	**1380**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	871	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**871**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	39961	99.56%
Monoclonal antibody by mouse ascites method		
Other product types	175	0.44%
Total	**40136**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	120283	81.93%
Legislation on medicinal products for veterinary use and their residues	18724	12.75%
Medical devices legislation	552	0.38%
Industrial chemicals legislation		
Plant protection product legislation	136	0.09%
Biocides legislation		
Food legislation including food contact material	1336	0.91%
Feed legislation including legislation for the safety of target animals, workers and environment	332	0.23%
Cosmetics legislation		
Other legislation	5441	3.71%
Total	**146804**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	130212	88.7%
Legislation satisfying national requirements only [within EU]	871	0.59%
Legislation satisfying Non-EU requirements only	15721	10.71%
Total	**146804**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	540571	96.26%
Yes	20980	3.74%
Total	**561551**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	25221	4.49%
Mild [up to and including]	318327	56.69%
Moderate	124343	22.14%
Severe	93660	16.68%
Total	**561551**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	539762	96.12%
Yes	21789	3.88%
Total	**561551**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	424438	75.58%
Genetically altered without a harmful phenotype	124304	22.14%
Genetically altered with a harmful phenotype	12809	2.28%
Total	**561551**	**100.00%**

Belgium: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2015 (561.551 animals used), there is a decrease of 4.75 % in the number of animals used for scientific purposes in 2016 (534.854 animals used).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The use of animals in the specific areas is similar to the figures of 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There were no significant changes in actual severities.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests.
- Collaboration with the university board to promote the development and promotion of alternative methods.
- Collaboration between the different regions and other member states to promote the 3R principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

40.12% of the fishes are reported under the “other” category. They are mostly Cyprinidae, Cichlidae, Salmonidae, Percidae, Soleidae, Pleuronectidae and Aplocheilidae.

37,28% of the amphibians reported under the “other” category are mostly Ranidae (Lithobates catesbeianus), Salamandridae (in order of importance: Lissotriton helveticus, Pleurodeles waltl, Ichthyosaura alpestris) and Bombinatoridae (Bombina orientalis).

14.65% of the birds are reported under the “other” category. They are Paridae, Fringillidae, Meleagrididae, Phasianidae, Passeridae, Pycnonotidae, Estrildida, Laridae, Columbidae and Psittacidae.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the ‘severe’ classification was exceeded.

Belgium: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	336052	62.83%
Rats	30337	5.67%
Guinea-Pigs	16223	3.03%
Hamsters (Syrian)	1880	0.35%
Hamsters (Chinese)		
Mongolian gerbil	118	0.02%
Other Rodents	175	0.03%
Rabbits	48036	8.98%
Cats	123	0.02%
Dogs	1529	0.29%
Ferrets	13	0%
Other carnivores		
Horses, donkeys and cross-breeds	231	0.04%
Pigs	3630	0.68%
Goats	101	0.02%
Sheep	581	0.11%
Cattle	1279	0.24%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	40	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	153	0.03%
Domestic fowl	26230	4.9%
Other birds	4504	0.84%
Reptiles	172	0.03%
Rana		
Xenopus	769	0.14%
Other Amphibians	457	0.09%
Zebra fish	37256	6.97%
Other Fish	24965	4.67%
Cephalopods		
Total	**534854**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	494820	93.94%
Animals born in the EU but not at a registered breeder	26817	5.09%
Animals born in rest of Europe	48	0.01%
Animals born in rest of world	5034	0.96%
Total	**526719**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	4	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**4**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	4	100%
Self-sustaining colony		
Total	**4**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	283739	53.05%
Translational and applied research	105760	19.77%
Regulatory use and Routine production	132925	24.85%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1006	0.19%
Preservation of species	6	0%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8819	1.65%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2599	0.49%
Total	**534854**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	54616	19.25%
Cardiovascular Blood and Lymphatic System	14443	5.09%
Nervous System	56699	19.98%
Respiratory System	6121	2.16%
Gastrointestinal System including Liver	19837	6.99%
Musculoskeletal System	5877	2.07%
Immune System	50140	17.67%
Urogenital/Reproductive System	11536	4.07%
Sensory Organs (skin, eyes and ears)	3772	1.33%
Endocrine System/Metabolism	18300	6.45%
Multisystemic	10342	3.64%
Ethology / Animal Behaviour /Animal Biology	19464	6.86%
Other basic research	12592	4.44%
Total	**283739**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	18857	17.83%
Human Infectious Disorders	18443	17.44%
Human Cardiovascular Disorders	920	0.87%
Human Nervous and Mental Disorders	22383	21.16%
Human Respiratory Disorders	3243	3.07%
Human Gastrointestinal Disorders including Liver	1328	1.26%
Human Musculoskeletal Disorders	1047	0.99%
Human Immune Disorders	2329	2.2%
Human Urogenital/Reproductive Disorders	284	0.27%
Human Sensory Organ Disorders (skin, eyes and ears)	3290	3.11%
Human Endocrine/Metabolism Disorders	2634	2.49%
Other Human Disorders	232	0.22%
Animal Diseases and Disorders	12467	11.79%
Animal Welfare	1514	1.43%
Diagnosis of diseases	6481	6.13%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	10308	9.75%
Total	**105760**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	82222	61.86%
Other efficacy and tolerance testing	3345	2.52%
Toxicity and other safety testing including pharmacology	5467	4.11%
Routine production	41891	31.51%
Total	**132925**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	12844	15.62%
Pyrogenicity testing		
Batch potency testing	66345	80.69%
Other quality controls	3033	3.69%
Total	**82222**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	392	7.17%
Carcinogenicity		
Eye irritation/corrosion		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	964	17.63%
Genotoxicity	83	1.52%
Developmental toxicity	1697	31.04%
Neurotoxicity	30	0.55%
Kinetics	465	8.51%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	358	6.55%
Safety testing in food and feed area	1451	26.54%
Target animal safety	8	0.15%
Other toxicity/safety testing	19	0.35%
Total	**5467**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	392	100%
Total	**392**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	864	89.63%
29 - 90 days	92	9.54%
> 90 days	8	0.83%
Total	**964**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	262	73.18%
Chronic toxicity	96	26.82%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**358**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	41781	99.74%
Monoclonal antibody by mouse ascites method		
Other product types	110	0.26%
Total	**41891**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	115307	86.75%
Legislation on medicinal products for veterinary use and their residues	15187	11.43%
Medical devices legislation	1299	0.98%
Industrial chemicals legislation	195	0.15%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	668	0.5%
Feed legislation including legislation for the safety of target animals, workers and environment	159	0.12%
Cosmetics legislation		
Other legislation	110	0.08%
Total	**132925**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	118429	89.09%
Legislation satisfying national requirements only [within EU]	19	0.01%
Legislation satisfying Non-EU requirements only	14477	10.89%
Total	**132925**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	526723	98.48%
Yes	8131	1.52%
Total	**534854**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21229	3.97%
Mild [up to and including]	297600	55.64%
Moderate	119243	22.29%
Severe	96782	18.1%
Total	**534854**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	513065	95.93%
Yes	21789	4.07%
Total	**534854**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	408773	76.43%
Genetically altered without a harmful phenotype	108899	20.36%
Genetically altered with a harmful phenotype	17182	3.21%
Total	**534854**	**100.00%**

Belgium: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2016 (534.854 animals used), there is an increase of 1.54% in the number of animals used for scientific purposes in 2017 (543.074 animals used) but still a decrease of 3.29% compared to 2015 (561.551 animals used). The increase in 2017 is the result of an increased use of poultry merely in translational and applied research (animal diseases and disorders) and for forensic enquiries.

Number of use in 2017	Number of use in 2016	Number of use in 2015
543074	534854	561551

Since 2015 the numbers of re-used animals continues to decline: 3.74% of all uses in 2015, 1.52% in 2016 and 0.93% in 2017.

Re-Use	Number of use in 2017	Number of use in 2016	Number of use in 2015
No	538043	526723	540571
Yes	5031	8131	20980
Total uses	**543074**	**534854**	**561551**

There is a significant increase in the use of birds (108.94% compared with the use of birds in 2015). This is due to an increase in the area of Animal Diseases and Disorders and Regulatory use and Routine production (Legislation on medicinal products for veterinary use and their residues). The fish decreased with 48,73% compared to 2015. No apparent reason was noted.

Species	Number of use in 2017	Number of use in 2016	Number of use in 2015
Mammals	442378	440501	435333
Birds	46812	30734	22405
Fish	52462	62221	102330
Amphibians	1241	1226	1350
Reptiles	181	172	133
Cephalopods	0	0	0

Total uses	**543074**	**534854**	**561551**

In the mammals the use of rabbits and Artiodactyla increased. The use of rabbits has increased in the Legislation on medicinal products for human use area. This is reflected in an increase of 33.68% compared to 2015. The use of Artiodactyla augmented (61.53% more Artiodactyla used compared to 2015). This is due to an increase in Basic research (this was caused by zootechnics (selection)), Translational and applied research (Animal Diseases and Disorders) and Protection of the natural environment in the interests of the health or welfare of human beings or animals. The use of all other species remained unchanged.

Mammals	Number of use in 2017	Number of use in 2016	Number of use in 2015
Rodents	374857	384785	385298
Rabbits	57888	48036	43304
Carnivores	1943	1665	1937
Equidae	234	231	115
Artiodactyla	7272	5591	4502
Non-human primates	44	40	46
Other mammals	140	153	131
Total uses	**442378**	**440501**	**435333**

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Between 2015 and 2017, basic research diminished with 11,79%. This was in particular due to decreases in the area of Musculoskeletal System, Urogenital/Reproductive System, Multisystemic research, Endocrine System/Metabolism and Respiratory System. However, the research in the domain of the Immune System and Oncology significantly increased between 2015 and 2017.
During the same time period Translational and applied research augmented with 23.77%. We noted a significant increase in Animal Welfare (3,525 animals in 2017 compared to 165 in 2015), Animal Diseases and Disorders, Human Endocrine/Metabolism Disorders, Human Sensory Organ Disorders (skin, eyes and ears), Human Nervous and Mental Disorders and Non-regulatory toxicology and ecotoxicology. A decrease was noted in Diagnosis of diseases and Human Infectious Disorders.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Within the actual severities classification we note that the category "severe" decreased from 18.10% in 2016 to 15.61% in 2017.
This is due to a diminution of quality control research (incl. batch safety and potency testing). This percentage is still higher than the European average of 10% but in Belgium a lot of basic research was done with in particular research in the field of Oncology, Immune system and Nervous system. Another important area in the research concerns Translational and applied research with again Human Nervous and Mental Disorders, Human Infectious Disorders and Human Cancer as the most important domains. Since, according to the legislation, tumours leading to metastases, tumours that lead to cachexia, invasive bone tumours, ulcerating tumours, loss of immunity, etc. (research that is often done in Belgium) should be classified as "severe", this can lead to an increase in this category.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- Funding of research projects for the development of alternative toxicity tests:
  - Thyroid hormone disruptors: There is a wide-variety of environmental contaminants that have the potential to cause thyroid hormone disruption[1]. Exposure to specific environmental toxins, including polychlorinated biphenyls, dioxins, phthalates, polybrominated diphenyl ethers (PBDEs), and other halogenated compounds, has been shown to interfere with the production, transportation, and/or metabolism of thyroid hormones by a variety of mechanisms. Some chemicals, with structural similarity to thyroid hormones, have been shown to bind to thyroid receptors with both agonist and antagonist effects on thyroid hormone signalling. Thyroid hormone disruption can therefore cause severe adverse effects on *e.g*. brain development, growth and metabolism.

    Validated and internationally recognised tests methods are essential in assessing the potential of chemicals to interact with the hormonal system and cause adverse effects. Non-animal test methods are needed for efficient testing and screening of substances. In 2014, OECD published a scoping document on *in vitro* and *ex vivo* assays for the identification of modulators of thyroid hormone signalling (OECD, 2014). Several key biological mechanisms of thyroid system disruption were reviewed and the corresponding methods evaluated for their state of readiness as candidates to enter the validation process. Relevant *in vitro* and *ex vivo* methods were identified and recommendations were given for their development/use. Eighteen methods were reported that cover the possible sites of action in the hypothalamic-pituitary-thyroid (HPT) axis. The research is carried out by EU-Netval facilities. By funding this research we enable our EU NETVAL facility to take part of this study.

[1] http://www.oecd.org/chemicalsafety/oecd-encourages-development-of-non-animal-test-methods-for-detection-of-thyroid-disruptors.htm

- Differentiation of human skin-derived stem cells towards hepatic cells: new source for the "in vitro study" of liver toxicity of drugs. Liver toxicity is one of the most important research elements in drug development. In addition, liver toxicity is the main reason for withdrawing medicines from the market. Presently, pre-clinical drug safety tests are carried out by "in vivo studies", i.e. studies on laboratory animals. In addition to the ethical concerns and the high costs associated with these in vivo studies, it is important to note the relatively low correlation between the results of animals on humans (less than 60% of the results of tests on animals apply to humans). By funding the project, we contribute to research that will lead in the long term to the reduction of the number of laboratory animals that are used in the context of drug development.

- Collaboration with the university board to promote the development and promotion of alternative methods (for example, WALCOPA project in Wallonia).

- Collaboration between the different regions and other member states to promote the 3R principle.

- Establishment of RE-place: The RE-Place project will create a database that brings together all existing expertise on alternative methods for animal testing in the Flemish and Brussels regions. The RE-Place website will be expanded in a next phase into a platform where researchers can find more information about alternative methods for animal testing and share their research methodology with the rest of the research community. By charting and making known generally the available and developing alternative methods for animal testing, not only researchers but also the general public and the political world will be better informed about the expertise in their own region. In the long term, all collected information will be integrated at European level.

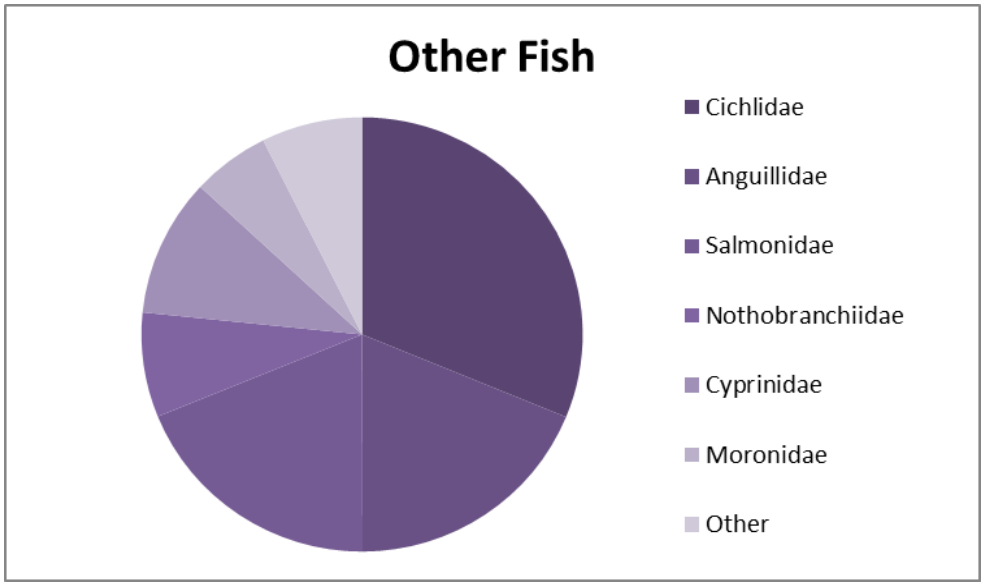
5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

1. Other fish
   45.80% of the fishes are reported under the “other” category.
   They are mostly Cichlidae (*Oreochromis niloticus*) (31.21% of other fish), Salmonidae (*Salmo salar and Oncorhynchus mykiss*) (18.85% of other fish), Anguillidae (*Anguilla anguilla*) (18.75% of other fish), Cyprinidae (*Cyprinus carpio carpio and Cyprinus carpio*) (10.27% of other fish), Nothobranchiidae (*Nothobranchius furzeri*) (7.79% of other fish) and Moronidae (*Dicentrarchus labrax*) (5.70% of other fish).

Other Fish	Number of uses
Oreochromis niloticus	7499
Anguilla anguilla	4506
Salmo salar	2012

Oncorhynchus mykiss	2522
Nothobranchius furzeri	1871
Cyprinus carpio carpio	1814
Dicentrarchus labrax	1370
Cyprinus carpio	654
Scortum barcoo	648
Poecilia reticulata	300
Pleuronectes platessa	229
Lota lota	144
Gasterosteus aculeatus	82
Clarias gariepinus	50
Kryptolebias marmoratus	50
Limanda limanda	48
Gadus morhua	47
Pseudotropheus saulosi	25
Synodontis grandiops	20
Microsynodontis batesii	12
Myloplus schomburgkii	8
Catoprion mento	7
Metynnis hypsauchen	7
Pseudotropheus estherae	7
Pygopristis denticulata	7
Serrasalmus spilopleura	7
Ophthalmotilapia ventralis	6
Synodontis nigriventris	6
Maylandia zebra	5
Mochokiella paynei	5
Pygocentrus cariba	5
Pygocentrus nattereri	5
Pygocentrus piraya	5
Botia morleti	3
Myloplus rubripinnis	3
Pantodon buchholzi	3
Piaractus brachypomus	3
Synodontis acanthomias	3
Synodontis brichardi	3
Synodontis contractus	3
Synodontis elongatus	3
Synodontis flavitaeniatus	3
Synodontis lucipinnis	3
Synodontis notatus	3
Botia modesta	2
Serrasalmus manueli	2

Colossoma macropomum	1
Malapterurus electricus	1
Metynnis lippincottianus	1
Ophthalmotilapia nasuta	1
Platydoras hancockii	1
Synodontis eupterus	1
Synodontis schall	1
Total uses:	**24027**

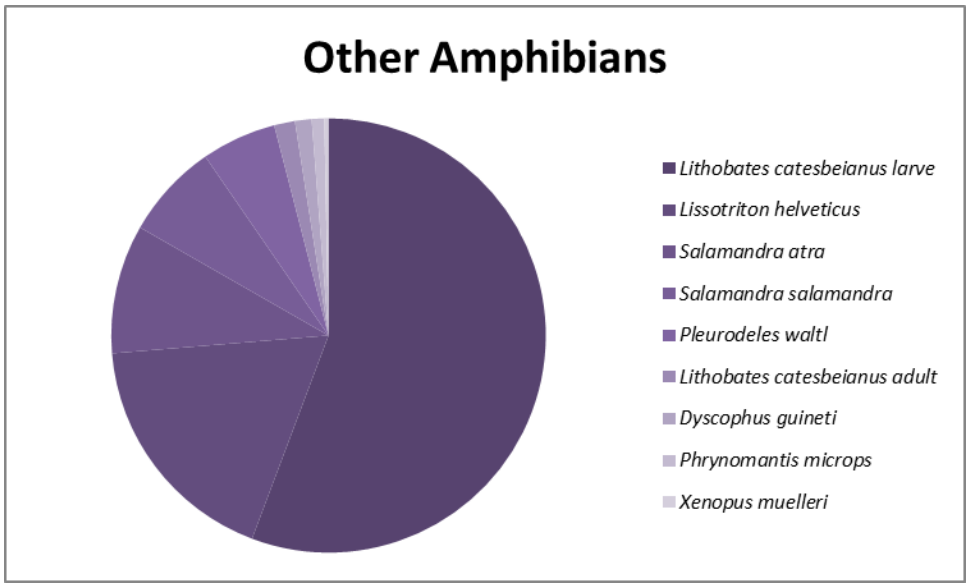


2. Other amphibians

   26.03% of the amphibians are reported under the "other" category.

   They are mostly Ranidae (*Lithobates catesbeianus larva + adult*) (57.27% of other amphibians) and Salamandridae (in order of importance: *Lissotriton helveticus, Salamandra atra, Salamandra salamandra, Pleurodeles waltl*) (40.24% of other amphibians).

Other Amphibians	Number of uses
Lithobates catesbeianus larve	180
Lissotriton helveticus	58
Salamandra atra	31
Salamandra salamandra	23
Pleurodeles waltl	18
Lithobates catesbeianus adult	5
Dyscophus guineti	4
Phrynomantis microps	3
Xenopus muelleri	1
Total uses:	**323**



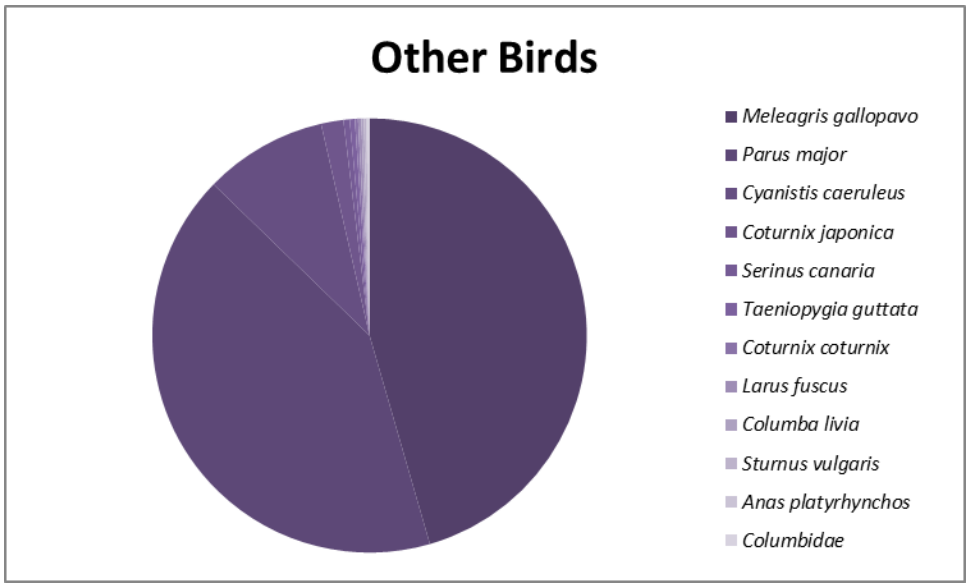
3. Other birds

   15.25% of the birds are reported under the "other" category.

   They are mostly Paridae (*Parus major and Cyanistis caeruleus*) (50.89% of other birds) and Phasianidae (*Meleagris gallopavo, Coturnix japonica, Coturnix coturnix*) (47.42% of other birds).

   The other birds are members of Fringillidae (*Serinus canaria*), Estrildidae (*Taeniopygia guttata*), Laridae (*Larus fuscus*), Columbidae (Columba livia), Sturnidae (Sturnus vulgaris) and the Anatidae (*Anas platyrhynchos*).

Other Birds	Number of uses
Meleagris gallopavo	3249
Parus major	2979
Cyanistis caeruleus	654
Coturnix japonica	119
Serinus canaria	33
Taeniopygia guttata	27
Coturnix coturnix	17
Larus fuscus	17
Columba livia	14
Sturnus vulgaris	13
Anas platyrhynchos	8
Columbidae	8
Total uses:	**7138**



6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

As in previous years, there were no cases in which the 'severe' classification was exceeded.

Belgium: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	334054	61.51%
Rats	23826	4.39%
Guinea-Pigs	15541	2.86%
Hamsters (Syrian)	1147	0.21%
Hamsters (Chinese)		
Mongolian gerbil	174	0.03%
Other Rodents	115	0.02%
Rabbits	57888	10.66%
Cats	61	0.01%
Dogs	1856	0.34%
Ferrets	26	0%
Other carnivores		
Horses, donkeys and cross-breeds	234	0.04%
Pigs	4970	0.92%
Goats	78	0.01%
Sheep	666	0.12%
Cattle	1558	0.29%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	44	0.01%

Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	140	0.03%
Domestic fowl	39674	7.31%
Other birds	7138	1.31%
Reptiles	181	0.03%
Rana		
Xenopus	918	0.17%
Other Amphibians	323	0.06%
Zebra fish	28435	5.24%
Other Fish	24027	4.42%
Cephalopods		
Total	**543074**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	511268	95.03%
Animals born in the EU but not at a registered breeder	22269	4.14%
Animals born in rest of Europe	903	0.17%
Animals born in rest of world	3594	0.67%
Total	**538034**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	9	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**9**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	9	100%
Self-sustaining colony		
Total	**9**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	272795	50.23%
Translational and applied research	117258	21.59%
Regulatory use and Routine production	141853	26.12%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	706	0.13%
Preservation of species	151	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8051	1.48%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2260	0.42%
Total	**543074**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	58087	21.29%
Cardiovascular Blood and Lymphatic System	13462	4.93%
Nervous System	42974	15.75%
Respiratory System	3583	1.31%
Gastrointestinal System including Liver	16775	6.15%
Musculoskeletal System	4967	1.82%
Immune System	70105	25.7%
Urogenital/Reproductive System	5852	2.15%
Sensory Organs (skin, eyes and ears)	4785	1.75%
Endocrine System/Metabolism	14861	5.45%
Multisystemic	5600	2.05%
Ethology / Animal Behaviour /Animal Biology	14701	5.39%
Other basic research	17043	6.25%
Total	**272795**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	12720	10.85%
Human Infectious Disorders	15691	13.38%
Human Cardiovascular Disorders	1573	1.34%
Human Nervous and Mental Disorders	28936	24.68%
Human Respiratory Disorders	5945	5.07%
Human Gastrointestinal Disorders including Liver	977	0.83%
Human Musculoskeletal Disorders	783	0.67%
Human Immune Disorders	2039	1.74%
Human Urogenital/Reproductive Disorders	503	0.43%
Human Sensory Organ Disorders (skin, eyes and ears)	5441	4.64%
Human Endocrine/Metabolism Disorders	3722	3.17%
Other Human Disorders	40	0.03%
Animal Diseases and Disorders	17960	15.32%
Animal Welfare	3525	3.01%
Diagnosis of diseases	4292	3.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	13111	11.18%
Total	**117258**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68615	48.37%
Other efficacy and tolerance testing	17201	12.13%
Toxicity and other safety testing including pharmacology	4133	2.91%
Routine production	51904	36.59%
Total	**141853**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	8016	11.68%
Pyrogenicity testing		
Batch potency testing	57716	84.12%
Other quality controls	2883	4.2%
Total	**68615**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1037	25.09%
Carcinogenicity		
Eye irritation/corrosion		
Genotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation		
Repeated dose toxicity	672	16.26%
Reproductive toxicity	290	7.02%
Developmental toxicity	11	0.27%
Neurotoxicity	20	0.48%
Kinetics	399	9.65%
Ecotoxicity	1418	34.31%
Safety testing in food and feed area	150	3.63%
Target animal safety	136	3.29%
Total	**4133**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	4.82%
Other lethal methods		
Non lethal methods	987	95.18%
Total	**1037**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	505	75.15%
29 - 90 days	42	6.25%
> 90 days	125	18.6%
Total	**672**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1202	84.77%
Chronic toxicity	216	15.23%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1418**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	51804	99.81%
Monoclonal antibody by mouse ascites method		
Other product types	100	0.19%
Total	**51904**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	113897	80.29%
Legislation on medicinal products for veterinary use and their residues	25559	18.02%
Medical devices legislation	779	0.55%
Industrial chemicals legislation	216	0.15%
Plant protection product legislation	52	0.04%
Biocides legislation		
Food legislation including food contact material	74	0.05%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1276	0.9%
Total	**141853**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	128208	90.38%
Legislation satisfying national requirements only [within EU]	50	0.04%
Legislation satisfying Non-EU requirements only	13595	9.58%
Total	**141853**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	538043	99.07%
Yes	5031	0.93%
Total	**543074**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	26546	4.89%
Mild [up to and including]	297189	54.72%
Moderate	134577	24.78%
Severe	84762	15.61%
Total	**543074**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	513454	94.55%
Yes	29620	5.45%
Total	**543074**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	402289	74.08%
Genetically altered without a harmful phenotype	118326	21.79%
Genetically altered with a harmful phenotype	22459	4.14%
Total	**543074**	**100.00%**

Bulgaria

Bulgaria: Narrative 2015 - no narrative submitted

No narrative submitted by the Member State

Bulgaria : Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2381	25.17%
Rats	1753	18.53%
Guinea-Pigs	105	1.11%
Hamsters (Syrian)	404	4.27%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	365	3.86%
Cats	46	0.49%
Dogs	10	0.11%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	4	0.04%
Pigs	50	0.53%
Goats	7	0.07%
Sheep	320	3.38%
Cattle	26	0.27%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	1025	10.84%
Other birds	24	0.25%
Reptiles		
Rana	2920	30.87%
Xenopus		
Other Amphibians	20	0.21%
Zebra fish		
Other Fish		
Cephalopods		
Total	**9460**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	8850	99.55%
Animals born in the EU but not at a registered breeder	40	0.45%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**8890**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	4930	52.11%
Translational and applied research	322	3.4%
Regulatory use and Routine production	1000	10.57%
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	3208	33.91%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9460**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1480	30.02%
Cardiovascular Blood and Lymphatic System	20	0.41%
Nervous System	950	19.27%
Respiratory System		
Gastrointestinal System including Liver	242	4.91%
Musculoskeletal System		
Immune System	1	0.02%
Urogenital/Reproductive System	3	0.06%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	84	1.7%
Endocrine System/Metabolism	284	5.76%
Multisystemic	624	12.66%
Ethology / Animal Behaviour /Animal Biology	1204	24.42%
Other basic research	38	0.77%
Total	**4930**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	100	31.06%
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	4	1.24%
Animal Welfare		
Diagnosis of diseases	218	67.7%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**322**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	850	85%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	150	15%
Total	**1000**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	700	82.35%
Pyrogenicity testing	150	17.65%
Batch potency testing		
Other quality controls		
Total	**850**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	33.33%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Neurotoxicity	100	66.67%
Total	**150**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	100%
Other lethal methods		
Non lethal methods		
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	900	90%
Legislation on medicinal products for veterinary use and their residues	100	10%
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	**1000**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1000	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**1000**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	8890	93.97%
Yes	570	6.03%
Total	**9460**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	815	8.62%
Mild [up to and including]	3933	41.58%
Moderate	2508	26.51%
Severe	2204	23.3%
Total	**9460**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9460	100%
Yes		
Total	**9460**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	9460	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**9460**	**100.00%**

Bulgaria: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

Bulgaria: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2015	21.19%
Rats	2047	21.53%
Guinea-Pigs	1860	19.56%
Hamsters (Syrian)	30	0.32%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	689	7.25%
Cats		
Dogs	60	0.63%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	300	3.16%
Cattle	6	0.06%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	100	1.05%
Other birds		
Reptiles		
Rana	2400	25.24%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**9507**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	9267	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**9267**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	6033	63.46%
Translational and applied research	691	7.27%
Regulatory use and Routine production	180	1.89%
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	2603	27.38%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9507**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	30	0.5%
Cardiovascular Blood and Lymphatic System		
Nervous System	1529	25.34%
Respiratory System	60	0.99%
Gastrointestinal System including Liver	572	9.48%
Musculoskeletal System	5	0.08%
Immune System	2936	48.67%
Urogenital/Reproductive System	40	0.66%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	10	0.17%
Endocrine System/Metabolism	270	4.48%
Multisystemic	563	9.33%
Ethology / Animal Behaviour /Animal Biology		
Other basic research	18	0.3%
Total	**6033**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	331	47.9%
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	30	4.34%
Other Human Disorders	74	10.71%
Animal Diseases and Disorders	256	37.05%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**691**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	130	72.22%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	50	27.78%
Total	**180**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	130	100%
Total	**130**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	100%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	50	100%
Other lethal methods		
Non lethal methods		
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	180	100%
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	**180**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	180	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**180**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	9267	97.48%
Yes	240	2.52%
Total	**9507**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1474	15.5%
Mild [up to and including]	4016	42.24%
Moderate	1762	18.53%
Severe	2255	23.72%
Total	**9507**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9507	100%
Yes		
Total	**9507**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	9507	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**9507**	**100.00%**

Bulgaria: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

Bulgaria: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	989	11.39%
Rats	1892	21.79%
Guinea-Pigs	1841	21.21%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	568	6.54%
Cats	30	0.35%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	20	0.23%
Goats		
Sheep	340	3.92%
Cattle	15	0.17%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	680	7.83%
Other birds		
Reptiles		
Rana	2306	26.56%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**8681**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	8651	99.65%
Animals born in the EU but not at a registered breeder	30	0.35%

Place of birth	Number of animals	Percentage
Animals born in rest of Europe		
Animals born in rest of world		
Total	**8681**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2246	25.87%
Translational and applied research	19	0.22%
Regulatory use and Routine production	4126	47.53%
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	2290	26.38%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**8681**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	1651	73.51%
Respiratory System		
Gastrointestinal System including Liver	11	0.49%
Musculoskeletal System	74	3.29%
Immune System	42	1.87%
Urogenital/Reproductive System	45	2%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	56	2.49%
Multisystemic	62	2.76%
Ethology / Animal Behaviour /Animal Biology	235	10.46%

Basic Research	Number of uses	Percentage
Other basic research	70	3.12%
Total	**2246**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	19	100%
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	**19**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2843	68.9%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	238	5.77%
Routine production	1045	25.33%
Total	**4126**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2843	100%
Batch potency testing		
Other quality controls		
Pyrogenicity testing		
Total	**2843**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	38	15.97%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Pharmaco-dynamics (incl safety pharmacology)	150	63.03%
Ecotoxicity	50	21.01%
Total	**238**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	38	100%
Other lethal methods		
Non lethal methods		
Total	**38**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	50	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**50**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	1045	100%
Total	**1045**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3081	74.67%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		

Testing by Legislation	Number of uses	Percentage
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	1045	25.33%
Total	**4126**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4126	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**4126**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	8681	100%
Yes		
Total	**8681**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	4547	52.38%
Moderate	3869	44.57%
Severe	265	3.05%
Total	**8681**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	8681	100%
Yes		
Total	**8681**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	8681	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**8681**	**100.00%**

Croatia

Croatia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

There is an overall decrease in the total number of uses but increase in the use of not genetically altered animals, increase of uses in basic research and decrease in uses for regulatory and routine production. The number of uses for higher education or training for the acquisition, maintenance or improvement of vocational skills is less in number even though it is higher in percentage. There is a significant decrease in testing by legislation and regulatory use and routine production but slightly increase in basic research.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is decrease in 2015 in:

- uses (7,53% (1958)) in 2015 when we compare data from 2015 with the data from 2014:
    - Testing by legislation – decrease in total – 45,99% (3899)
        - Legislation on medicinal products for human use – 52,73% (1760)
        - Food legislation including food contact material – from 32,87 % in 2014 to 8,40% in 2015
    - Regulatory use and production – decrease in total 45,99 % (3899):
        - Quality control (incl. batch safety and potency testing) – 60,67% (1876)
        - Toxicity and other safety testing including pharmacology – 2091 uses less
        - Other quality controls uses (they are specified as a use for Registration purpose (use of European viper venom antiserum, Equine on dogs), as a method of validation and use of cock RBCs) in number of uses and also in percentage in 2015 – 33,89% (1993)

There is increase in 2015 in:

- Regulatory use and Routine production:
    - Routine production - 68 uses in 2015 (in 2014 such uses were not reported)
    - Toxicity and other safety testing including pharmacology:
        - Repeated dose toxicity – 80 uses (in 2014 such uses were not reported)

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Severity of procedures	**2014**		**2015**	
	number	**%**	**number**	**%**
Non-recovery	6543	25,17	3714	16,13

Mild (up to and including)	13 915	53,52	9 273	40,26
Moderate	4 551	17,51	7 994	34,71
Severe	989	3,80	2 051	8,91
Total number	25 998	100	23 032	100

In 2015 (when we compare with 2014) there is:

- an increase of Non-recovery procedures in Basic research but in total it is decrease of Non-recovery procedures (in 2014 it was reported 2659 uses in Basic research, 3445 in Regulatory use and Routine production, 359 in education and 60 in Translation and applied research and in 2015 it was reported 3236 uses in Basic research, nothing in Regulatory use and Routine production, 361 in education and 117 in Translation and applied research)
- an decrease of mild procedures in total
- an increase of moderate procedures in Basic research mainly and in total and
- an increase of severe procedures in Regulatory use and Routine production (in 2014 it was reported 903 uses in Basic research, nothing in Regulatory use and Routine production, 78 in Translation and applied research and 8 in education and in 2015 it was reported 908 uses in Basic research, 1078 in Regulatory use and Routine production and 67 in Translation and applied research)

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- 22 October 2015, 2nd Workshop of the Croatian Society for Laboratory Animal Science, international participation, Implementation of 3R principles, Zagreb, Croatia - for users, breeders, suppliers
- 10th October 2015, 2nd Symposium of Croatian Society for the Science of Laboratory Animals 'Experimental Animals in Scientific Research", Zagreb, Croatia - for users, breeders, suppliers
- 25th March 2015, Scientific Forum, Application and evaluation of projects and experiments using animal models for scientific purposes, Zagreb - for users, breeders, suppliers

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

See point 2.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The exceeded 'severe' classification was not authorised and also not reported.

Croatia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	16197	70.32%
Rats	5374	23.33%
Guinea-Pigs	264	1.15%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	472	2.05%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	26	0.11%
Pigs	1	0%
Goats		
Sheep	44	0.19%
Cattle	28	0.12%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	626	2.72%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**23032**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	22347	97.65%
Animals born in the EU but not at a registered breeder	538	2.35%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**22885**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	18073	78.47%
Translational and applied research	421	1.83%
Regulatory use and Routine production	3321	14.42%
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	1217	5.28%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**23032**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	447	2.47%
Cardiovascular Blood and Lymphatic System	412	2.28%
Nervous System	1619	8.96%
Respiratory System	4426	24.49%
Gastrointestinal System including Liver	565	3.13%
Musculoskeletal System	217	1.2%
Immune System	4177	23.11%
Urogenital/Reproductive System	424	2.35%
Sensory Organs (skin, eyes and ears)	431	2.38%
Endocrine System/Metabolism	873	4.83%
Multisystemic	2223	12.3%
Ethology / Animal Behaviour /Animal Biology	28	0.15%
Other basic research	2231	12.34%
Total	**18073**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	92	21.85%
Human Nervous and Mental Disorders	108	25.65%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	185	43.94%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1	0.24%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	35	8.31%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**421**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2894	87.14%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	359	10.81%
Routine production	68	2.05%
Total	**3321**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	569	19.66%
Pyrogenicity testing	63	2.18%
Batch potency testing	1236	42.71%
Other quality controls	1026	35.45%
Total	**2894**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Skin irritation/corrosion		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	80	22.28%
Safety testing in food and feed area	279	77.72%
Total	**359**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	80	100%
29 - 90 days		
> 90 days		
Total	**80**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	68	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**68**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1964	59.14%
Legislation on medicinal products for veterinary use and their residues	1078	32.46%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	279	8.4%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**3321**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3321	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**3321**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	22885	99.36%
Yes	147	0.64%
Total	**23032**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3714	16.13%
Mild [up to and including]	9273	40.26%
Moderate	7994	34.71%
Severe	2051	8.91%
Total	**23032**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	23032	100%
Yes		
Total	**23032**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	21756	94.46%
Genetically altered without a harmful phenotype	1143	4.96%
Genetically altered with a harmful phenotype	133	0.58%
Total	**23032**	**100.00%**

Croatia: Narrative 2016

This report shows statistical data on the number of animals used for scientific purposes during the year 2016. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

1. General information on any changes in trends observed since the previous reporting period.
Data for 2016, in comparison with data from 2014 and 2015:

Purpose	**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**
Total number of animals used for scientific purposes	21,901	100	23,032	100	25,998	100
Basic research	19,183	87.59	18,073	78.47	15,024	57.79
Testing by legislation	988	4.51	3,321	14.42	7,220	27.77
Number of genetically altered animals with a harmful phenotype	129	0.59	133	0.58	3,930	15.12

Compared to the data for 2014 and 2015, the data for 2016 shows:

- an overall decrease in the total number of animals used for scientific purposes
- an increase in number of animals used for basic research and
- a decrease in number of genetically altered animals with a harmful phenotype used for scientific purposes.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

When data from 2016 are compared with data from 2015 and 2014, the following is apparent:

- a significant decrease in number of animals used for regulatory use and routine production
- a significant decrease in number of animals used for testing by legislation
- a decrease in number of animals used in non-recovery and mild procedures and significant decrease in number of animals used in severe procedures while the number of animals used in moderate procedures is significantly higher.
- a significant decrease in number of animals used for regulatory use and routine production (Quality control including batch safety and potency testing).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof. Compared to the data for 2014 and 2015, the data for 2016 shows:

Severity of procedures	**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**
Non-recovery	3,220	14.70	3,714	16.13	6,543	25.17
Mild (up to and including)	6,875	31.31	9,273	40.26	13,915	53.52
Moderate	11,394	52.03	7,994	34.71	4,551	17.51
Severe	430	1.96	2,051	8.91	989	3.80
Total number	21,901	100	23,032	100	25,998	100

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- 26 – 29th October 2016, Implementation of legislation on the protection of animals used for scientific purposes, Croatian Veterinary Days 2016, Croatia, Scientific – Proffesional conference with International participation – for veterinary inspectors
- 24th October 2016, Workshop "Best practice and alternatives to animal experiments in education and training", Co-organisers Ministry of Agriculture, Animal Friends Croatia and InterNICHE, Zagreb – for users, breeders, suppliers
- 4th October 2016, Training "Implementation of legislation on the protection of animals in experiments", Medicin School of the University of Rijeka, Croatia - for users, breeders, suppliers
- 3 May 2016, Presentation on education and training in implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes, Zagreb - for users, breeders, suppliers
- Workshop "Animal Experiment Design" organised by *Croatian Laboratory Animal Science Association (CroLASA)*.

5. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The exceeded 'severe' classification was not authorised and also not reported.

Croatia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	14976	68.38%
Rats	5762	26.31%
Guinea-Pigs	71	0.32%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	704	3.21%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	27	0.12%
Pigs	2	0.01%
Goats		
Sheep	49	0.22%
Cattle	50	0.23%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	260	1.19%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**21901**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	21701	99.59%
Animals born in the EU but not at a registered breeder	89	0.41%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**21790**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	19183	87.59%
Translational and applied research	456	2.08%
Regulatory use and Routine production	988	4.51%
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	1203	5.49%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	71	0.32%
Total	**21901**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	708	3.69%
Cardiovascular Blood and Lymphatic System	510	2.66%
Nervous System	1613	8.41%
Respiratory System	4564	23.79%
Gastrointestinal System including Liver	663	3.46%
Musculoskeletal System	122	0.64%
Immune System	3861	20.13%
Urogenital/Reproductive System	146	0.76%
Sensory Organs (skin, eyes and ears)	1652	8.61%
Endocrine System/Metabolism	397	2.07%
Multisystemic	2673	13.93%
Ethology / Animal Behaviour /Animal Biology	88	0.46%
Other basic research	2186	11.4%
Total	**19183**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	70	15.35%
Human Infectious Disorders		
Human Cardiovascular Disorders	119	26.1%
Human Nervous and Mental Disorders	60	13.16%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	37	8.11%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	120	26.32%
Other Human Disorders		
Animal Diseases and Disorders	50	10.96%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**456**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	831	84.11%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	98	9.92%
Routine production	59	5.97%
Total	**988**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	210	25.27%
Pyrogenicity testing	67	8.06%
Batch potency testing	194	23.35%
Other quality controls	360	43.32%
Total	**831**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	88	89.8%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	4	4.08%
Kinetics	6	6.12%
Total	**98**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	88	100%
Total	**88**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4	100%
29 - 90 days		
> 90 days		
Total	**4**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	59	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**59**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	618	62.55%
Legislation on medicinal products for veterinary use and their residues	364	36.84%
Medical devices legislation	6	0.61%
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	**988**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	988	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**988**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	21790	99.49%
Yes	111	0.51%
Total	**21901**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3220	14.7%
Mild [up to and including]	6857	31.31%
Moderate	11394	52.03%
Severe	430	1.96%
Total	**21901**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	21901	100%
Yes		
Total	**21901**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19422	88.68%
Genetically altered without a harmful phenotype	2350	10.73%
Genetically altered with a harmful phenotype	129	0.59%
Total	**21901**	**100.00%**

Croatia: Narrative 2017

This report shows statistical data on the number of animals used for scientific purposes during the year 2017. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

1. General information on any changes in trends observed since the previous reporting periods.

1) Animal Species used for scientific procedures

Data for 2017, 2016, 2015 and 2014:

Animal Species	**2017**		**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**	**number**	**%**
Mice	19,806	69.41	14,976	68.38	16,197	70.32	19,427	74.72
Rats	7,700	26.99	5,762	26.31	5,374	23.33	4,962	19.09
Guinea Pigs	21	0.07	71	0.32	264	1.15	488	1.88
Rabbits	426	1,49	704	3.21	472	2.05	331	1.27
Horses, donkeys and cross-breeds	25	0.09	27	0.12	26	0.11	0	0
Pigs	2	0.01	2	0.01	1	0.00	0	0
Sheep	39	0.14	49	0.22	44	0.19	18	0.07
Cattle	30	0.11	50	0.23	28	0.12	0	0
Domestic fowl	255	0.89	260	1.19	626	2.72	772	2.97
Zebra fish	230	0.81	0	0	0	0	0	0
SUMMARY	28,534	100	21,901	100	23,032	100	25,998	100

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

- an overall decrease in the total number of animals used for scientific purposes and most in mice and rats
- Zebra fish as new animal model has been reported

2) Information on any changes in trends in Purpose

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

Purpose	**2017**		**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**	**number**	**%**
Total number of animals used for scientific purposes	28,534	100	21,901	100	23,032	100	25,998	100

Basic research	22,067	77.36	19,183	87.59	18,073	78.47	15,024	57.79
Translational and applied research	2,761	9,68	456	2,08	421	1.83	671	2.58
Regulatory use and routine production	2,182	7.65	988	4.51	3,321	14.42	7,220	27.77
Higher education or training for acquisition, maintenance or improvement of vocational skills	1,428	5,01	1,203	5,49	1,217	5.28	0	0
Maintenance of colonies of established genetically altered animals, not used in other procedures	96	0,34	71	0,32	0	0	0	0

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

- an increase in the total number of animals used for basic and translational/applied research and regulatory use and routine production
- in 2017 and 2016 the data for maintenance of colonies of established genetically altered animals, not used in other procedures have been reported.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

When data from 2017 are compared with the data from 2016, 2015 and 2014, the following is apparent:

- a significant increase in the total number of animals used for translational/applied research and regulatory use and routine production
- an overall decrease in the total number of rabbits and domestic fowl used for scientific purposes
- increase of number of animals not used for creation of new GL
- for the first time use of animals for use for creation of new GL reported
- increase of number of not genetically altered animals and genetically altered animals without a harmful phenotype
- decrease of number of animals genetically altered with a harmful phenotype
- no animals in pyrogenicity testing are reported

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

Severity of procedures	**2017**		**2016**		**2015**		**2014**	
	number	**%**	**number**	**%**	**number**	**%**	**number**	**%**
Non-recovery	3,005	10.53	3,220	14.70	3,714	16.13	6,543	25.17
Mild (up to and including)	8,338	29.22	6,875	31.31	9,273	40.26	13,915	53.52
Moderate	11,593	40.63	11,394	52.03	7,994	34.71	4,551	17.51
Severe	5,598	19.62	430	1.96	2,051	8.91	989	3.80
Total number	28,534	100	21,901	100	23,032	100	25,998	100

- an increase in number of animals used in mild and severe procedures but in percentage there is a decrease in all categories except in “severe” where the significant increase is reported

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   - 2nd Workshop “Animal Experiment Design” organised by *Croatian Laboratory Animal Science Association (CroLASA), 19-20 October 2017*

   - Workshop "How to submit an experiment on animals for approval", 2017

5. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

The exceeded 'severe' classification was not authorised and also not reported.

Croatia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	19806	69.41%
Rats	7700	26.99%
Guinea-Pigs	21	0.07%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	426	1.49%
Cats		

Animal Species	Number of animals	Percentage
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	25	0.09%
Pigs	2	0.01%
Goats		
Sheep	39	0.14%
Cattle	30	0.11%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	255	0.89%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	230	0.81%
Other Fish		
Cephalopods		
Total	**28534**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	28292	99.51%
Animals born in the EU but not at a registered breeder	60	0.21%
Animals born in rest of Europe		
Animals born in rest of world	79	0.28%
Total	**28431**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	22067	77.34%
Translational and applied research	2761	9.68%
Regulatory use and Routine production	2182	7.65%
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	1428	5%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	96	0.34%
Total	**28534**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1345	6.1%
Cardiovascular Blood and Lymphatic System	378	1.71%
Nervous System	1428	6.47%
Respiratory System	5721	25.93%
Gastrointestinal System including Liver	2069	9.38%
Musculoskeletal System	30	0.14%
Immune System	3764	17.06%
Urogenital/Reproductive System	234	1.06%
Sensory Organs (skin, eyes and ears)	688	3.12%
Endocrine System/Metabolism	384	1.74%
Multisystemic	4582	20.76%
Ethology / Animal Behaviour /Animal Biology	122	0.55%
Other basic research	1322	5.99%
Total	**22067**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	230	8.33%
Human Infectious Disorders	1394	50.49%
Human Cardiovascular Disorders	510	18.47%
Human Nervous and Mental Disorders	214	7.75%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	28	1.01%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	60	2.17%
Other Human Disorders		
Animal Diseases and Disorders	30	1.09%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	295	10.68%
Total	**2761**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1585	72.64%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	556	25.48%
Routine production	41	1.88%
Total	**2182**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	262	16.53%
Pyrogenicity testing		
Batch potency testing	128	8.08%
Other quality controls	1195	75.39%
Total	**1585**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	556	100%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total	**556**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	556	100%
Total	**556**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	41	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**41**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1799	82.45%
Legislation on medicinal products for veterinary use and their residues	383	17.55%
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	**2182**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2182	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2182**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	28431	99.64%
Yes	103	0.36%
Total	**28534**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3005	10.53%
Mild [up to and including]	8338	29.22%
Moderate	11593	40.63%
Severe	5598	19.62%
Total	**28534**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	28304	99.19%
Yes	230	0.81%
Total	**28534**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	26027	91.21%
Genetically altered without a harmful phenotype	2452	8.59%
Genetically altered with a harmful phenotype	55	0.19%
Total	**28534**	**100.00%**

Cyprus

Cyprus: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a significant increase in the use of animals in 2015 (almost doubled) due to the improvement of the economic situation in Cyprus that resulted in increased funds for research.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1141	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		

Animal Species	Number of animals	Percentage
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**1141**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1141	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**1141**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		

NHP Generation	Number of animals	Percentage
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	685	60.04%
Translational and applied research	456	39.96%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**1141**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	126	18.39%
Cardiovascular Blood and Lymphatic System		
Nervous System	476	69.49%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	83	12.12%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**685**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	215	47.15%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	241	52.85%
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		

Translational and applied research	Number of uses	Percentage
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	456	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	1141	100%
Yes		
Total	**1141**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	110	9.64%
Mild [up to and including]	700	61.35%
Moderate	331	29.01%
Severe		
Total	**1141**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1141	100%
Yes		
Total	**1141**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	607	53.2%
Genetically altered without a harmful phenotype	434	38.04%
Genetically altered with a harmful phenotype	100	8.76%
Total	**1141**	**100.00%**

Cyprus: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a slight expected increase in the number of animal use in 2016 due to the further improvement of the economic situation in Cyprus.

-

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1448	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		

Animal Species	Number of animals	Percentage
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**1448**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1448	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**1448**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		

NHP Generation	Number of animals	Percentage
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	927	64.02%
Translational and applied research	521	35.98%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**1448**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	108	11.65%
Cardiovascular Blood and Lymphatic System		
Nervous System	350	37.76%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	250	26.97%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	180	19.42%
Endocrine System/Metabolism	39	4.21%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**927**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	404	77.54%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	117	22.46%
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		

Translational and applied research	Number of uses	Percentage
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	521	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	1448	100%
Yes		

Re-use	Number of uses	Percentage
Total	**1448**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	1244	85.91%
Moderate	204	14.09%
Severe		
Total	**1448**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1448	100%
Yes		
Total	**1448**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	789	54.49%
Genetically altered without a harmful phenotype	659	45.51%
Genetically altered with a harmful phenotype		
Total	**1448**	**100.00%**

Cyprus: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

-

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In general there were no significant changes in the numbers of animals used since the previous reporting periods.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

-

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

-

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

-

Cyprus: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1209	100%
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		

Animal Species	Number of animals	Percentage
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**1209**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1209	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**1209**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		

NHP Generation	Number of animals	Percentage
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	839	69.4%
Translational and applied research	370	30.6%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**1209**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	129	15.38%
Cardiovascular Blood and Lymphatic System	17	2.03%
Nervous System	368	43.86%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	275	32.78%
Immune System		
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	50	5.96%
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**839**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	370	100%
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		

Translational and applied research	Number of uses	Percentage
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	370	100.00%

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	1209	100%
Yes		

Re-use	Number of uses	Percentage
Total	**1209**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	1197	99.01%
Moderate	12	0.99%
Severe		
Total	**1209**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1209	100%
Yes		
Total	**1209**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	623	51.53%
Genetically altered without a harmful phenotype	586	48.47%
Genetically altered with a harmful phenotype		
Total	**1209**	**100.00%**

Czechia

Czechia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In 2015 statistical data there are no changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2015 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2015 statistical data.

Czechia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	73415	31.94%
Rats	24200	10.53%
Guinea-Pigs	1008	0.44%
Hamsters (Syrian)	48	0.02%
Hamsters (Chinese)		
Mongolian gerbil	18	0.01%
Other Rodents	988	0.43%
Rabbits	4840	2.11%
Cats	341	0.15%

Animal Species	Number of animals	Percentage
Dogs	1135	0.49%
Ferrets	154	0.07%
Other carnivores	10	0%
Horses, donkeys and cross-breeds	113	0.05%
Pigs	2118	0.92%
Goats	318	0.14%
Sheep	1468	0.64%
Cattle	1941	0.84%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	6	0%
Rhesus monkey	51	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	36	0.02%
Domestic fowl	22962	9.99%
Other birds	3003	1.31%
Reptiles	453	0.2%
Rana	100	0.04%
Xenopus	135	0.06%
Other Amphibians	675	0.29%
Zebra fish	2729	1.19%
Other Fish	87604	38.11%
Cephalopods		
Total	**229869**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	197689	87.69%
Animals born in the EU but not at a registered breeder	27419	12.16%
Animals born in rest of Europe		
Animals born in rest of world	334	0.15%
Total	**225442**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		

NHP Generation	Number of animals	Percentage
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	85456	37.18%
Translational and applied research	26835	11.67%
Regulatory use and Routine production	61272	26.66%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	40441	17.59%
Preservation of species	176	0.08%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	15673	6.82%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	16	0.01%
Total	**229869**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	12911	15.11%
Cardiovascular Blood and Lymphatic System	7180	8.4%
Nervous System	13447	15.74%
Respiratory System	314	0.37%
Gastrointestinal System including Liver	1862	2.18%
Musculoskeletal System	509	0.6%
Immune System	11136	13.03%
Urogenital/Reproductive System	8142	9.53%
Sensory Organs (skin, eyes and ears)	549	0.64%
Endocrine System/Metabolism	3889	4.55%
Multisystemic	5835	6.83%
Ethology / Animal Behaviour /Animal Biology	8909	10.43%
Other basic research	10773	12.61%
Total	**85456**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1631	6.08%
Human Infectious Disorders	541	2.02%
Human Cardiovascular Disorders	426	1.59%
Human Nervous and Mental Disorders	803	2.99%
Human Respiratory Disorders	12	0.04%
Human Gastrointestinal Disorders including Liver	45	0.17%
Human Musculoskeletal Disorders	79	0.29%
Human Immune Disorders	219	0.82%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	30	0.11%
Human Endocrine/Metabolism Disorders	1183	4.41%
Other Human Disorders	60	0.22%

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	7189	26.79%
Animal Welfare	7541	28.1%
Diagnosis of diseases	6913	25.76%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	163	0.61%
Total	**26835**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	11354	18.53%
Other efficacy and tolerance testing	219	0.36%
Toxicity and other safety testing including pharmacology	29613	48.33%
Routine production	20086	32.78%
Total	**61272**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1742	15.34%
Pyrogenicity testing	72	0.63%
Batch potency testing	9354	82.39%
Other quality controls	186	1.64%
Total	**11354**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3091	10.44%
Skin irritation/corrosion	12	0.04%
Skin sensitisation	568	1.92%
Eye irritation/corrosion	9	0.03%
Repeated dose toxicity	1532	5.17%
Carcinogenicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Target animal safety		
Genotoxicity	109	0.37%
Reproductive toxicity	1256	4.24%
Developmental toxicity	658	2.22%
Kinetics	554	1.87%
Ecotoxicity	21394	72.25%
Safety testing in food and feed area	72	0.24%
Other toxicity/safety testing	358	1.21%
Total	**29613**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1650	53.38%
Other lethal methods	1435	46.43%
Non lethal methods	6	0.19%
Total	**3091**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	782	51.04%
29 - 90 days	540	35.25%
> 90 days	210	13.71%
Total	**1532**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	19257	90.01%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	2137	9.99%
Total	**21394**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	899	4.48%
Monoclonal antibody by mouse ascites method		
Other product types	19187	95.52%
Total	**20086**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3476	5.67%
Legislation on medicinal products for veterinary use and their residues	29178	47.62%
Medical devices legislation	1320	2.15%
Industrial chemicals legislation	2685	4.38%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	817	1.33%
Feed legislation including legislation for the safety of target animals, workers and environment	12	0.02%
Cosmetics legislation		
Other legislation	23784	38.82%
Total	**61272**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	49869	81.39%
Legislation satisfying national requirements only [within EU]	11403	18.61%
Legislation satisfying Non-EU requirements only		
Total	**61272**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225442	98.07%
Yes	4427	1.93%
Total	**229869**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21573	9.38%
Mild [up to and including]	124277	54.06%
Moderate	60578	26.35%
Severe	23441	10.2%
Total	**229869**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	221507	96.36%
Yes	8362	3.64%
Total	**229869**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	204049	88.77%
Genetically altered without a harmful phenotype	24009	10.44%
Genetically altered with a harmful phenotype	1811	0.79%
Total	**229869**	**100.00%**

Czechia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In 2016 statistical data there are no changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2016 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2016 statistical data.

Czechia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	78249	32.92%
Rats	30323	12.76%
Guinea-Pigs	1202	0.51%
Hamsters (Syrian)	82	0.03%
Hamsters (Chinese)		
Mongolian gerbil	30	0.01%
Other Rodents	1122	0.47%
Rabbits	6834	2.88%
Cats	240	0.1%
Dogs	797	0.34%
Ferrets	42	0.02%

Animal Species	Number of animals	Percentage
Other carnivores	53	0.02%
Horses, donkeys and cross-breeds	155	0.07%
Pigs	2173	0.91%
Goats	48	0.02%
Sheep	1032	0.43%
Cattle	2978	1.25%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	9	0%
Rhesus monkey	26	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	37	0.02%
Domestic fowl	27261	11.47%
Other birds	3124	1.31%
Reptiles	915	0.39%
Rana		
Xenopus	58	0.02%
Other Amphibians	819	0.34%
Zebra fish	4495	1.89%
Other Fish	75558	31.79%
Cephalopods		
Total	**237662**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	212176	90.81%
Animals born in the EU but not at a registered breeder	21429	9.17%
Animals born in rest of Europe		
Animals born in rest of world	51	0.02%
Total	**233656**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		

NHP Generation	Number of animals	Percentage
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	87751	36.92%
Translational and applied research	25941	10.92%
Regulatory use and Routine production	74739	31.45%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	32752	13.78%
Preservation of species	228	0.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	16143	6.79%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	108	0.05%
Total	**237662**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	11267	12.84%
Cardiovascular Blood and Lymphatic System	12055	13.74%
Nervous System	12066	13.75%
Respiratory System	1511	1.72%
Gastrointestinal System including Liver	2348	2.68%
Musculoskeletal System	46	0.05%
Immune System	7811	8.9%
Urogenital/Reproductive System	9041	10.3%
Sensory Organs (skin, eyes and ears)	750	0.85%
Endocrine System/Metabolism	4128	4.7%
Multisystemic	4223	4.81%
Ethology / Animal Behaviour /Animal Biology	7278	8.29%
Other basic research	15227	17.35%
Total	**87751**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3288	12.67%
Human Infectious Disorders	905	3.49%
Human Cardiovascular Disorders	969	3.74%
Human Nervous and Mental Disorders	674	2.6%
Human Respiratory Disorders	12	0.05%
Human Gastrointestinal Disorders including Liver	137	0.53%
Human Musculoskeletal Disorders	93	0.36%
Human Immune Disorders	368	1.42%
Human Urogenital/Reproductive Disorders	551	2.12%
Human Sensory Organ Disorders (skin, eyes and ears)	39	0.15%
Human Endocrine/Metabolism Disorders	1191	4.59%
Other Human Disorders	107	0.41%
Animal Diseases and Disorders	5469	21.08%
Animal Welfare	3611	13.92%

Translational and applied research	Number of uses	Percentage
Diagnosis of diseases	8227	31.71%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	300	1.16%
Total	**25941**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	17569	23.51%
Other efficacy and tolerance testing	316	0.42%
Toxicity and other safety testing including pharmacology	36408	48.71%
Routine production	20446	27.36%
Total	**74739**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1574	8.96%
Pyrogenicity testing	51	0.29%
Batch potency testing	15636	89%
Other quality controls	308	1.75%
Total	**17569**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	14946	41.05%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation	570	1.57%
Eye irritation/corrosion	3	0.01%
Repeated dose toxicity	958	2.63%
Reproductive toxicity	5497	15.1%
Developmental toxicity	127	0.35%
Kinetics	511	1.4%
Ecotoxicity	13552	37.22%
Safety testing in food and feed area	40	0.11%
Target animal safety	12	0.03%
Other toxicity/safety testing	192	0.53%
Total	**36408**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	12250	81.96%
Other lethal methods	2668	17.85%
Non lethal methods	28	0.19%
Total	**14946**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	538	56.16%
29 - 90 days	420	43.84%
> 90 days		
Total	**958**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	12132	89.52%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	1420	10.48%
Total	**13552**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	838	4.1%
Monoclonal antibody by mouse ascites method		
Other product types	19608	95.9%
Total	**20446**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3069	4.11%
Legislation on medicinal products for veterinary use and their residues	35721	47.79%
Medical devices legislation	1110	1.49%
Industrial chemicals legislation	6746	9.03%
Plant protection product legislation		
Biocides legislation	5	0.01%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	28088	37.58%
Total	**74739**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	51716	69.2%
Legislation satisfying national requirements only [within EU]	23023	30.8%
Legislation satisfying Non-EU requirements only		
Total	**74739**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	233656	98.31%
Yes	4006	1.69%
Total	**237662**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	23268	9.79%
Mild [up to and including]	87633	36.87%
Moderate	77641	32.67%
Severe	49120	20.67%
Total	**237662**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	224531	94.47%
Yes	13131	5.53%
Total	**237662**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	205032	86.27%
Genetically altered without a harmful phenotype	30738	12.93%
Genetically altered with a harmful phenotype	1892	0.8%
Total	**237662**	**100.00%**

Czechia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The statistical data has been collected since 1993 in the Czech Republic. In the last three years appears trend increasing number of animal used for preservation of species, in year 2017 is the number of these animals more significant than 2 years ago. In 2017 statistical data there are no other changes in trends observed since the previous reporting periods.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There is no significant increase or decrease in use animals in any of the specific areas.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There are no changes in trends in actual severity.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There are no impacts of principle of 3Rs on 2017 statistical data. We are expecting this impact in subsequent years.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Classification “severe” is not exceeded in 2017 statistical data.

Czechia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	82219	34.02%
Rats	26967	11.16%
Guinea-Pigs	1383	0.57%
Hamsters (Syrian)	15	0.01%
Hamsters (Chinese)		
Mongolian gerbil	46	0.02%
Other Rodents	635	0.26%
Rabbits	2133	0.88%

Animal Species	Number of animals	Percentage
Cats	132	0.05%
Dogs	637	0.26%
Ferrets	1	0%
Other carnivores	1	0%
Horses, donkeys and cross-breeds	105	0.04%
Pigs	2447	1.01%
Goats	97	0.04%
Sheep	918	0.38%
Cattle	2734	1.13%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	21217	8.78%
Other birds	4260	1.76%
Reptiles	558	0.23%
Rana		
Xenopus	50	0.02%
Other Amphibians	531	0.22%
Zebra fish	19765	8.18%
Other Fish	74861	30.97%
Cephalopods		
Total	**241712**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	213502	95.63%
Animals born in the EU but not at a registered breeder	9222	4.13%
Animals born in rest of Europe		
Animals born in rest of world	539	0.24%
Total	**223263**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	100107	41.42%
Translational and applied research	27657	11.44%
Regulatory use and Routine production	54133	22.4%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	47646	19.71%
Preservation of species	6437	2.66%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5732	2.37%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**241712**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	8918	8.91%
Cardiovascular Blood and Lymphatic System	22979	22.95%
Nervous System	9106	9.1%
Respiratory System	503	0.5%
Gastrointestinal System including Liver	1727	1.73%
Musculoskeletal System	484	0.48%
Immune System	13127	13.11%
Urogenital/Reproductive System	12105	12.09%
Sensory Organs (skin, eyes and ears)	525	0.52%
Endocrine System/Metabolism	3777	3.77%
Multisystemic	6311	6.3%
Ethology / Animal Behaviour /Animal Biology	7542	7.53%
Other basic research	13003	12.99%
Total	**100107**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3761	13.6%
Human Infectious Disorders	1309	4.73%
Human Cardiovascular Disorders	1308	4.73%
Human Nervous and Mental Disorders	2009	7.26%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	861	3.11%
Human Musculoskeletal Disorders	114	0.41%
Human Immune Disorders	303	1.1%
Human Urogenital/Reproductive Disorders	496	1.79%
Human Sensory Organ Disorders (skin, eyes and ears)	112	0.4%
Human Endocrine/Metabolism Disorders	2066	7.47%

Translational and applied research	Number of uses	Percentage
Other Human Disorders	379	1.37%
Animal Diseases and Disorders	3643	13.17%
Animal Welfare	3914	14.15%
Diagnosis of diseases	7373	26.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	9	0.03%
Total	**27657**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	12209	22.55%
Other efficacy and tolerance testing	326	0.6%
Toxicity and other safety testing including pharmacology	25293	46.72%
Routine production	16305	30.12%
Total	**54133**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	523	4.28%
Pyrogenicity testing	81	0.66%
Batch potency testing	11397	93.35%
Other quality controls	208	1.7%
Total	**12209**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	4646	18.37%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Skin irritation/corrosion		
Skin sensitisation	637	2.52%
Eye irritation/corrosion	18	0.07%
Repeated dose toxicity	1440	5.69%
Reproductive toxicity	3136	12.4%
Developmental toxicity	274	1.08%
Kinetics	144	0.57%
Pharmaco-dynamics (incl safety pharmacology)	24	0.09%
Ecotoxicity	14374	56.83%
Safety testing in food and feed area	438	1.73%
Target animal safety	50	0.2%
Other toxicity/safety testing	112	0.44%
Total	**25293**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	994	21.39%
Other lethal methods	3652	78.61%
Non lethal methods		
Total	**4646**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	482	33.47%
29 - 90 days	552	38.33%
> 90 days	406	28.19%
Total	**1440**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	12714	88.45%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	1660	11.55%
Total	**14374**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	777	4.77%
Monoclonal antibody by mouse ascites method	230	1.41%
Other product types	15298	93.82%
Total	**16305**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2682	4.95%
Legislation on medicinal products for veterinary use and their residues	27478	50.76%
Medical devices legislation	1411	2.61%
Industrial chemicals legislation	4345	8.03%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	170	0.31%
Feed legislation including legislation for the safety of target animals, workers and environment	525	0.97%
Cosmetics legislation		
Other legislation	17522	32.37%
Total	**54133**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	44484	82.18%
Legislation satisfying national requirements only [within EU]	9649	17.82%
Legislation satisfying Non-EU requirements only		
Total	**54133**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	223263	92.37%
Yes	18449	7.63%
Total	**241712**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	19114	7.91%
Mild [up to and including]	110130	45.56%
Moderate	96317	39.85%
Severe	16151	6.68%
Total	**241712**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	216026	89.37%
Yes	25686	10.63%
Total	**241712**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	199255	82.43%
Genetically altered without a harmful phenotype	39574	16.37%
Genetically altered with a harmful phenotype	2883	1.19%
Total	**241712**	**100.00%**

Denmark

Denmark: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period

Although the number of animals reported in Denmark has been declining for many years, and the total number for 2014 , reported only about 200.000 animals, the number reported for 2015 has increased to about 242.000 animals. This number is almost identical to the number of animals reported for 2013. However, the number for 2014 cannot be compared to previous years, as the reporting format has been changed. These data for 2015 suggest that the number of animals used for research has stabilized around 240.000 animals.

The number of pigs has increased significantly in 2015. The increase is primarily caused by an increase in research using pigs as animal models for human diseases. Also the number of cats has increased significantly in 2015. This is caused by clinical studies in treatment of type-2 diabetes in cats. The number of fish has also increased significantly in 2015. This is primarily caused by an increase in research in aqua cultures. Furthermore in a small country with a small scientific community, the change of focus in one or a few research groups can have a significant impact on the statistics for the whole country.

2. Information on significant increase or decrease in used animals in any of the specific areas and analysis of the reasons thereof

No major significant changes are visible in the statistics from 2015

3. Information on any changes in trends in actual severities and analysis of the reasons thereof

In general only few experiments with severe strain are licensed. This is reflected in that the actual reported severity is 0.89%. This is a decrease compared to 1.5% reported for 2014.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Denmark has established a 3R-center operating from 2014. The centre is funding 3R-research, collection and dissemination information on the 3R´s and establishing initiatives to analyze and implement 3R-strategies. Read more here: http://en.3rcenter.dk/

Furthermore the Danish National Committee strongly supports and collaborates with the animal welfare bodies, i.e. yearly meeting for all bodies, hands on exchange of best practice between institutions and companies and best practice guideline. Visit the website: Danish National Committee

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category

As Denmark has a relatively large production of trout, the species is commonly used in research. Hence it would be a good idea with a specific category for trout. Furthermore Denmark also has a large mink

industry, and this species too is often used in research. A specific category for mink will also be appreciated.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The classification "severe" has not been exceeded in 2015 in Denmark.

Denmark: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	155141	63.64%
Rats	48614	19.94%
Guinea-Pigs	2643	1.08%
Hamsters (Syrian)	172	0.07%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	86	0.04%
Rabbits	1665	0.68%
Cats	59	0.02%
Dogs	157	0.06%
Ferrets		
Other carnivores	886	0.36%
Horses, donkeys and cross-breeds	115	0.05%
Pigs	10576	4.34%
Goats	11	0%
Sheep	47	0.02%
Cattle	534	0.22%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	38	0.02%
Domestic fowl	2407	0.99%
Other birds	438	0.18%
Reptiles	265	0.11%
Rana		
Xenopus	64	0.03%
Other Amphibians	26	0.01%
Zebra fish	2530	1.04%
Other Fish	17318	7.1%
Cephalopods		
Total	**243792**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	205674	85.32%
Animals born in the EU but not at a registered breeder	27687	11.49%
Animals born in rest of Europe	1311	0.54%
Animals born in rest of world	6397	2.65%
Total	**241069**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	88453	36.28%
Translational and applied research	123439	50.63%
Regulatory use and Routine production	22956	9.42%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2660	1.09%
Preservation of species	258	0.11%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6023	2.47%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	3	0%
Total	**243792**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	5382	6.08%
Cardiovascular Blood and Lymphatic System	4860	5.49%
Nervous System	15725	17.78%
Respiratory System	1262	1.43%
Gastrointestinal System including Liver	2539	2.87%
Musculoskeletal System	2682	3.03%
Immune System	29246	33.06%
Urogenital/Reproductive System	2623	2.97%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	1503	1.7%
Endocrine System/Metabolism	12561	14.2%
Multisystemic	883	1%
Ethology / Animal Behaviour /Animal Biology	4924	5.57%
Other basic research	4263	4.82%
Total	**88453**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	9115	7.38%
Human Infectious Disorders	4683	3.79%
Human Cardiovascular Disorders	1404	1.14%
Human Nervous and Mental Disorders	35568	28.81%
Human Respiratory Disorders	75	0.06%
Human Gastrointestinal Disorders including Liver	258	0.21%
Human Musculoskeletal Disorders	400	0.32%
Human Immune Disorders	10037	8.13%
Human Urogenital/Reproductive Disorders	66	0.05%
Human Sensory Organ Disorders (skin, eyes and ears)	852	0.69%
Human Endocrine/Metabolism Disorders	39839	32.27%
Other Human Disorders	9137	7.4%
Animal Diseases and Disorders	7934	6.43%
Animal Welfare	3248	2.63%
Diagnosis of diseases	682	0.55%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	141	0.11%
Total	**123439**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	14819	64.55%
Other efficacy and tolerance testing	95	0.41%
Toxicity and other safety testing including pharmacology	8021	34.94%
Routine production	21	0.09%
Total	**22956**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3687	24.88%
Pyrogenicity testing		
Batch potency testing	11105	74.94%
Other quality controls	27	0.18%
Total	**14819**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	786	9.8%
Skin irritation/corrosion	12	0.15%
Skin sensitisation	138	1.72%
Eye irritation/corrosion	6	0.07%
Repeated dose toxicity	1755	21.88%
Carcinogenicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Developmental toxicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Kinetics	2095	26.12%
Pharmaco-dynamics (incl safety pharmacology)	9	0.11%
Ecotoxicity	3080	38.4%
Target animal safety	120	1.5%
Other toxicity/safety testing	20	0.25%
Total	**8021**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	80	10.18%
Other lethal methods		
Non lethal methods	706	89.82%
Total	**786**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1136	64.73%
29 - 90 days	488	27.81%
> 90 days	131	7.46%
Total	**1755**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	3080	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**3080**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	21	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**21**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19630	85.51%
Legislation on medicinal products for veterinary use and their residues	142	0.62%
Medical devices legislation	24	0.1%
Industrial chemicals legislation	1360	5.92%
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	1800	7.84%
Total	**22956**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	21134	92.06%
Legislation satisfying national requirements only [within EU]	1822	7.94%
Legislation satisfying Non-EU requirements only		
Total	**22956**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	241069	98.88%
Yes	2723	1.12%
Total	**243792**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	21199	8.7%
Mild [up to and including]	136701	56.07%
Moderate	83727	34.34%
Severe	2165	0.89%
Total	**243792**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	238948	98.01%
Yes	4844	1.99%
Total	**243792**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	204237	83.78%
Genetically altered without a harmful phenotype	26191	10.74%
Genetically altered with a harmful phenotype	13364	5.48%
Total	**243792**	**100.00%**

Denmark: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period

The overall number at animals used for scientific purposes in Denmark in 2016 is 253.546. In 2015 the same number was 244.411animals. This strengthens a trend, that the number of animals used in Denmark has been relatively stable over the last years.

As usually, mice, rats and fish covers more than 90 % of the animals, but the number of fish has increased a lot, going from 19.848 to 51.659. See 2. for further specification. At the same time, the number of mice and rats has decreased by 10 %.

The percentage of animals used for basic research has increased from 36 % to 41 %. This is due to the fact, that increased number of fish primarily has been used in basic research.

Animals used for regulatory purposes and for routine production have decreased from 9 % to less than 6 %.

Finally the number of animals experiencing severe suffering has doubled in 2016, still being on a relative low level of 1.78 %.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof

The clearest trend in 2016 was the large increase in the use of fish for research. But almost the whole increase was due to introduction of a new species and a new field of research in the statistics. There is a very strong research community in Denmark concerning breeding eel for human consumption.

Until now it has not been possible to breed eel, which could survive beyond the larvae stadium. However due to scientific breakthroughs, it has recently changed, and the bread eel larvae now develop into fish covered by the directive. This covers a number of 23.935 animals, accounting for almost the whole increase in the use of fish. Procedures also covered by the directive are then performed on the animals, making them part of the statistic.

As this is a very important and economical interesting area, the numbers of eel in research are suspected to rise in the coming years. As this area is considered to be basic research, the increase in eel will affect the ratio.

In regard to the decrease in the numbers of rats and mice, the overall assessment is, that a stronger competition on research grands and stronger financially focus on the universities have made an impact on the number of research project using animals.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The number of animals experiencing severe severity has doubled in 2016 from 0,89 % to 1,75 %. The main reason is that two large research groups have had specific new focus on models with the highest severity. As Denmark generally has few animals experiencing severe severity, a new focus from just one or two research groups will affect the numbers dramatically. However the level of severe severity in Denmark is still relatively low.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Also in 2016, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on www.3rcenter.dk.

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2016. Further information can be found on: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposium for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

It is difficult to investigate whether these efforts has a directly impact on the use of animals for research. However the decrease in the numbers of traditional animals as mice and rats will be followed to see, if some of this decrease has been influenced by the 3R initiatives.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The use of “other” categories has been used on an acceptable level in 2016.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No cases of animal experiencing the severe clarification exceeded was recorded in 2016 in Denmark.

Denmark: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	169970	58.77%
Rats	47575	16.45%
Guinea-Pigs	3362	1.16%
Hamsters (Syrian)	152	0.05%
Hamsters (Chinese)		
Mongolian gerbil		

Animal Species	Number of animals	Percentage
Other Rodents	4	0%
Rabbits	2370	0.82%
Cats	18	0.01%
Dogs	266	0.09%
Ferrets	2	0%
Other carnivores	627	0.22%
Horses, donkeys and cross-breeds	328	0.11%
Pigs	8066	2.79%
Goats	6	0%
Sheep	37	0.01%
Cattle	2077	0.72%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	55	0.02%
Domestic fowl	1732	0.6%
Other birds	373	0.13%
Reptiles	220	0.08%
Rana		
Xenopus	56	0.02%
Other Amphibians	30	0.01%
Zebra fish	3308	1.14%
Other Fish	48591	16.8%
Cephalopods		
Total	**289225**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	236103	83.01%
Animals born in the EU but not at a registered breeder	40201	14.13%
Animals born in rest of Europe	684	0.24%
Animals born in rest of world	7456	2.62%
Total	**284444**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	104787	36.23%
Translational and applied research	153016	52.91%
Regulatory use and Routine production	21532	7.44%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2792	0.97%
Preservation of species	1491	0.52%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5547	1.92%
Forensic enquiries	60	0.02%
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**289225**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6312	6.02%
Cardiovascular Blood and Lymphatic System	4789	4.57%
Nervous System	17706	16.9%
Respiratory System	1601	1.53%
Gastrointestinal System including Liver	4618	4.41%
Musculoskeletal System	2723	2.6%
Immune System	19079	18.21%
Urogenital/Reproductive System	1538	1.47%
Sensory Organs (skin, eyes and ears)	876	0.84%
Endocrine System/Metabolism	13964	13.33%
Multisystemic	949	0.91%
Ethology / Animal Behaviour /Animal Biology	25748	24.57%
Other basic research	4884	4.66%
Total	**104787**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	27113	17.72%
Human Infectious Disorders	6632	4.33%
Human Cardiovascular Disorders	1786	1.17%
Human Nervous and Mental Disorders	34826	22.76%
Human Respiratory Disorders	137	0.09%
Human Gastrointestinal Disorders including Liver	139	0.09%
Human Musculoskeletal Disorders	401	0.26%
Human Immune Disorders	7015	4.58%
Human Urogenital/Reproductive Disorders	641	0.42%
Human Sensory Organ Disorders (skin, eyes and ears)	455	0.3%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	40930	26.75%
Other Human Disorders	9135	5.97%
Animal Diseases and Disorders	19732	12.9%
Animal Welfare	2524	1.65%
Diagnosis of diseases	884	0.58%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	666	0.44%
Total	**153016**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	8833	41.02%
Other efficacy and tolerance testing	113	0.52%
Toxicity and other safety testing including pharmacology	12586	58.45%
Routine production		
Total	**21532**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3295	37.3%
Pyrogenicity testing		
Batch potency testing	5486	62.11%
Other quality controls	52	0.59%
Total	**8833**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	5366	42.63%
Skin irritation/corrosion	35	0.28%
Skin sensitisation	80	0.64%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	1701	13.52%
Kinetics	267	2.12%
Pharmaco-dynamics (incl safety pharmacology)	609	4.84%
Ecotoxicity	4528	35.98%
Total	**12586**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	5366	100%

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Other lethal methods		
Non lethal methods		
Total	**5366**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	862	50.68%
29 - 90 days	229	13.46%
> 90 days	610	35.86%
Total	**1701**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	3030	66.92%
Reproductive ecotoxicity		
Endocrine activity	1440	31.8%
Bioaccumulation	58	1.28%
Other ecotoxicity		
Total	**4528**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	17000	78.95%
Legislation on medicinal products for veterinary use and their residues	4	0.02%
Medical devices legislation		
Industrial chemicals legislation	2458	11.42%
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	2070	9.61%
Total	**21532**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19398	90.09%
Legislation satisfying national requirements only [within EU]	2134	9.91%
Legislation satisfying Non-EU requirements only		
Total	**21532**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	284444	98.35%
Yes	4781	1.65%
Total	**289225**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	22852	7.9%
Mild [up to and including]	181393	62.72%
Moderate	80451	27.82%
Severe	4529	1.57%
Total	**289225**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	287229	99.31%
Yes	1996	0.69%
Total	**289225**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	247082	85.43%
Genetically altered without a harmful phenotype	28548	9.87%
Genetically altered with a harmful phenotype	13595	4.7%
Total	**289225**	**100.00%**

Denmark: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

The overall number of animals used for scientific purposes in Denmark in 2017 is 236,100. This is a significant decrease since 2016, where the number was 273,224 animals. But the total decrease is covered by the large drop in the number of fish – from 51,899 in 2016 to 17,125 in 2017. Taking this in account, the number of animals used in Denmark has been relatively stable over the last years

As usually, mice, rats and fish covers more than 90 % of the animals. The number of mice and rats has remained stable for several years (202,035 in 2015, 201,973 in 2016 and 201,621 in 2017).

The percentage of animals used for basic research is fallen from 38 % to 35 % reflecting the drop in fish (eel) used for this purpose.

Animals used for regulatory purposes and for routine production continues to be 8 %, confirming the relatively low number of animals used for that purpose in Denmark.

Finally the number of animals experiencing severe suffering has fallen in 2017 to a level of 0.74 %. This is confirming the trend that the percentage of severe suffering is varying around 1 %.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof

The clearest trend in 2017 was the large decrease in the use of fish for research. But as the large increase in 2016 was due to introduction of a new field of research in eel in the statistics, the large decrease is due to a change in research focus concerning the same animals.

Even though the total number of mice and rats is relatively stable, the number of mice has increased from 153,748 to 163,666 and the number of rats has decreased from 45,951 to 37,955. Some establishments traditionally using rats have been restructuring their laboratories in 2017, probably explaining the decrease in numbers. There is no obvious reason for the rice in the use of mice, but in a small country a strengthened focuses from a few research groups can have a large impact on the statistics. A rising use of GA animals could affect the number of mice, but the use of GA animals has not changed significantly from 2016 to 2017.

Finally the use of 3,680 cattle in 2017 is remarkable, as the number in 2016 was as low as 419 animals. However this is due to a few large “on farm” studies on cattle. The number probably will return to a much lower level in 2018.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The number of animals experiencing severe severity has fallen from 1,68 % in 2016 to 0,74 % in 2017. As Denmark generally has few animals experiencing severe severity, a changed focus from just one or two research groups will affect the numbers dramatically. The level of severe severity in Denmark is consistently relatively low.

There has been an increase in the percentage of moderate severity from 29 % to 36 % and a corresponding drop in the percentage of mild severity from 61 % to 53 %. There is no apparent explanation for this change, but the numbers will be followed closely to identify any lasting change.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Also in 2017, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on www.3rcenter.dk.

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2017. Further information can be found on: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposiums for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In two cases the use of “other” is relatively high in Denmark – in other carnivores and other fish. The carnivores represent a strong focus on research in mink for farming and concerning fish, Denmark has a large focus on research on rainbow trout for farming, as well as a continuing focus on eel research.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No cases of animal experiencing the severe clarification exceeded were recorded in 2017 in Denmark.

Denmark: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	164137	68.98%
Rats	38498	16.18%
Guinea-Pigs	2947	1.24%
Hamsters (Syrian)	282	0.12%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	3	0%
Rabbits	2443	1.03%
Cats		
Dogs	214	0.09%

Animal Species	Number of animals	Percentage
Ferrets	4	0%
Other carnivores	1035	0.43%
Horses, donkeys and cross-breeds	119	0.05%
Pigs	5803	2.44%
Goats	1	0%
Sheep	66	0.03%
Cattle	3677	1.55%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	28	0.01%
Domestic fowl	466	0.2%
Other birds	408	0.17%
Reptiles	289	0.12%
Rana	4	0%
Xenopus	285	0.12%
Other Amphibians	47	0.02%
Zebra fish	1587	0.67%
Other Fish	15606	6.56%
Cephalopods		
Total	**237949**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	205163	87.11%
Animals born in the EU but not at a registered breeder	24582	10.44%
Animals born in rest of Europe	552	0.23%
Animals born in rest of world	5215	2.21%
Total	**235512**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		

NHP Generation	Number of animals	Percentage
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	82918	34.85%
Translational and applied research	122146	51.33%
Regulatory use and Routine production	19865	8.35%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2875	1.21%
Preservation of species	5637	2.37%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4463	1.88%
Forensic enquiries	16	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	29	0.01%
Total	**237949**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6727	8.11%
Cardiovascular Blood and Lymphatic System	4270	5.15%
Nervous System	18241	22%
Respiratory System	2444	2.95%
Gastrointestinal System including Liver	2478	2.99%
Musculoskeletal System	3280	3.96%
Immune System	22727	27.41%
Urogenital/Reproductive System	2220	2.68%
Sensory Organs (skin, eyes and ears)	77	0.09%
Endocrine System/Metabolism	12632	15.23%
Multisystemic	485	0.58%
Ethology / Animal Behaviour /Animal Biology	2454	2.96%
Other basic research	4883	5.89%
Total	**82918**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	18429	15.09%
Human Infectious Disorders	7665	6.28%
Human Cardiovascular Disorders	2016	1.65%
Human Nervous and Mental Disorders	31509	25.8%
Human Respiratory Disorders	176	0.14%
Human Gastrointestinal Disorders including Liver	762	0.62%
Human Musculoskeletal Disorders	378	0.31%
Human Immune Disorders	4959	4.06%
Human Urogenital/Reproductive Disorders	647	0.53%
Human Sensory Organ Disorders (skin, eyes and ears)	336	0.28%
Human Endocrine/Metabolism Disorders	37015	30.3%
Other Human Disorders	9168	7.51%
Animal Diseases and Disorders	5708	4.67%

Translational and applied research	Number of uses	Percentage
Animal Welfare	1568	1.28%
Diagnosis of diseases	1023	0.84%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	787	0.64%
Total	**122146**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	8139	40.97%
Other efficacy and tolerance testing	725	3.65%
Toxicity and other safety testing including pharmacology	10257	51.63%
Routine production	744	3.75%
Total	**19865**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2504	30.77%
Pyrogenicity testing		
Batch potency testing	5601	68.82%
Other quality controls	34	0.42%
Total	**8139**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3968	38.69%
Skin irritation/corrosion	28	0.27%
Skin sensitisation	177	1.73%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	2205	21.5%
Reproductive toxicity	935	9.12%
Kinetics	818	7.98%
Pharmaco-dynamics (incl safety pharmacology)	26	0.25%
Ecotoxicity	2100	20.47%
Total	**10257**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	3968	100%
Other lethal methods		
Non lethal methods		
Total	**3968**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1382	62.68%
29 - 90 days	586	26.58%
> 90 days	237	10.75%
Total	**2205**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	120	5.71%
Chronic toxicity	1800	85.71%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	180	8.57%
Other ecotoxicity		
Total	**2100**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	288	38.71%
Monoclonal antibody by mouse ascites method		
Other product types	456	61.29%
Total	**744**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16634	83.74%
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation	2987	15.04%
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	244	1.23%
Total	**19865**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19765	99.5%
Legislation satisfying national requirements only [within EU]	100	0.5%
Legislation satisfying Non-EU requirements only		
Total	**19865**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235512	98.98%
Yes	2437	1.02%
Total	**237949**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	22871	9.61%
Mild [up to and including]	127013	53.38%
Moderate	86303	36.27%
Severe	1762	0.74%
Total	**237949**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	234261	98.45%
Yes	3688	1.55%
Total	**237949**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	198043	83.23%
Genetically altered without a harmful phenotype	27907	11.73%
Genetically altered with a harmful phenotype	11999	5.04%
Total	**237949**	**100.00%**

Estonia

Estonia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

No significant trends are observed in 2015 compared to 2014. The number of companies dealing with experimental animals is the same. No new authorisations were given to small companies which do not have separate AWB at the place. Experiments done in such small companies are with small number of animals. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2014 Estonia reported that 50.55% of the animals used were used for basic research purpose. In 2015 the percentage for basic research was 83.53. In 2014 47.70% of animals were used for translational and applied research, in 2015 this percentage was 14.28. In 2014 8.28% of animals were used for legislation satisfying EU requirements, in 2015 this percentage was 38.53. In 2014 24.05% of animals were used for human cancer research, in 2015 this percentage was 85.38. These were the biggest changes in the number of animals used in certain categories. Main reason for such changes is finance. Human cancer, legislation satisfying EU requirements and translational and applied research projects got grants in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2014 13.16% of animals were classified as non-recovery, in 2015 this percentage was 7.01. In 2014 1.87% of animals were classified as severe, in 2015 this percentage was 8.02. As Estonia only gave 26 licences in 2015 these changes are not significant. The usage of animals mostly depends on finance (what grants are received). All projects are evaluated by PAC members.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

All fish classified as other fish were roaches. All birds classified as other birds were common gulls.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2965	76.99%
Rats	123	3.19%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	6	0.16%
Goats		
Sheep		
Cattle	283	7.35%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	294	7.63%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	180	4.67%
Cephalopods		
Total	**3851**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2920	78.2%
Animals born in the EU but not at a registered breeder	736	19.71%
Animals born in rest of Europe	78	2.09%
Animals born in rest of world		
Total	**3734**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3190	82.84%
Translational and applied research	570	14.8%
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	83	2.16%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	8	0.21%
Total	**3851**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1338	41.94%
Cardiovascular Blood and Lymphatic System	12	0.38%
Nervous System	274	8.59%
Respiratory System		
Gastrointestinal System including Liver	78	2.45%
Musculoskeletal System		
Immune System	435	13.64%
Urogenital/Reproductive System	60	1.88%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	213	6.68%
Multisystemic	50	1.57%
Ethology / Animal Behaviour /Animal Biology	215	6.74%
Other basic research	515	16.14%
Total	**3190**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	483	84.74%
Human Infectious Disorders		
Human Cardiovascular Disorders	87	15.26%
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	**570**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3734	96.96%
Yes	117	3.04%
Total	**3851**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	284	7.37%
Mild [up to and including]	1552	40.3%
Moderate	1681	43.65%
Severe	334	8.67%
Total	**3851**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3851	100%
Yes		
Total	**3851**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	3397	88.21%
Genetically altered without a harmful phenotype	454	11.79%
Genetically altered with a harmful phenotype		
Total	**3851**	**100.00%**

Estonia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

No significant trends are observed in 2016 compared to 2015. One new authorisation was given to a company dealing with experimental animals, however they did not apply for a licence in 2016. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 2376 mice, 51 rats, 6 pigs, 566 cattle, 294 other birds, 180 other fish were used for basic research. In 2016 3079 mice, 90 rats, 252 other birds and 32 other fish were used for basic research. In 2015 550 mice and 45 rats were used for translational and applied research, in 2016 31 mice and no rats were used for that purpose. In 2015 56 mice and 27 rats were used for higher education purposes, however no animals were used for that purpose in 2016. In 2015 16 mice were used for the purpose of maintaining colonies, in 2016 the number of mice used for that purpose was 242. It can be said that the main difference between the years was that the number of animal used for maintaining colonies significantly increased and compared to 2015, in 2016 no animals were used for higher education purpose. Also, no cattle or other animal species were used in 2016 compared to 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 44.04% of animals used were classified as mild, in 2016 this percentage was 37.44. In 2015, 40.94% of animals used were classified as moderate, in 2016 this percentage was 48.85. In 2015, 8.02% of animals were severely used, in 2016 this percentage was 10.82. In 2015, 7.01% of animals were classified as non- recovery. In 2016 this percentage was 2.90. There are no major changes in actual severities when comparing the two years.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

All birds classified as other birds were great tits (*Parus major*). All fish classified as other fish were round gobies (*Neogobius melanostomus*).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3193	89.51%
Rats	90	2.52%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	252	7.06%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	32	0.9%
Cephalopods		
Total	**3567**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	3176	91.79%
Animals born in the EU but not at a registered breeder	284	8.21%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**3460**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3294	92.35%
Translational and applied research	31	0.87%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	242	6.78%
Total	**3567**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1638	49.73%
Cardiovascular Blood and Lymphatic System	12	0.36%
Nervous System	546	16.58%
Respiratory System		
Gastrointestinal System including Liver	140	4.25%
Musculoskeletal System	75	2.28%
Immune System	20	0.61%
Urogenital/Reproductive System	30	0.91%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	549	16.67%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology	284	8.62%
Other basic research		
Total	**3294**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	31	100%
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	**31**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3460	97%
Yes	107	3%
Total	**3567**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	108	3.03%
Mild [up to and including]	1395	39.11%
Moderate	1724	48.33%
Severe	340	9.53%
Total	**3567**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3351	93.94%
Yes	216	6.06%
Total	**3567**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2668	74.8%
Genetically altered without a harmful phenotype	899	25.2%
Genetically altered with a harmful phenotype		
Total	**3567**	**100.00%**

Estonia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Compared to 2016 some changes in trends were observed. Number of animals used dropped another 12% (decrease in 2015 vs 2016 was 10%). This year there we none in re-use (in 2016 3% from all uses). Creation of new GL dropped again, from 6,06% to 2,8% (none in 2015). Like in 2015 and 2016 no harmful GA lines were used in 2017. The GA animals used are thoroughly researched and known to have no harmful qualities. About 2/3 of the animals used are not genetically altered. This number has dropped from last year where about ¾ were not altered since more projects use GA animals. Insignificant changes in severities - non-recovery and mild have mildly increased, moderate and severe decreased. Changes in species – less mice, more rats were used; quantity of birds decreased as well; no fish were used but in 2017 again 16 cattle and 4 pigs were used (no projects in 2016). More animals came from an EU registered breeder (94,28% vs 91,79%).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Number of uses in translational and applied research rose from 0,87% to 6,68%. Human respiratory disorders were investigated with 210 uses. There were no projects of higher education or training for the acquisition, maintenance or improvement of vocational skills in 2016 but now in 2017 it took 1,21% of all uses. There were no competence courses in laboratory animal science in Estonia that year. Maintenance of colonies rose from 6,78% to 12,52% since laboratories are using more GA lines. No regulatory use in 2016 but 112 in 2017 – legislation on medicinal products for human use (from that 38 uses for carcinogenicity and 74 for genotoxicity). Oncology still is the most important research area, where 41% of the work is done. More uses than last year had cardiovascular, sensory, multisystemic, immune and nervous system.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016 39% of animals used were classified as mild, in 2017 this percentage was 44. In 2016, 48% of animals used were classified as moderate, in 2017 this percentage was 43. In 2016, 9,5% of animals were severely used, in 2017 this percentage was 8,7. In 2016, 3% of animals were classified as non-recovery. In 2017 this percentage was 4. There are no major changes in actual severities when comparing the two years. The proportion of moderate is higher than the average EU and might come from the facts that the committee is strict and that more harsh projects are done.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

From the birds that were classified as other birds 115 were common gulls and 65 were great tits. Proportion of birds 5,72% of all animals.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

PAC has not given licences exceeding severe classification.

Estonia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2578	81.95%
Rats	368	11.7%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	4	0.13%
Goats		
Sheep		
Cattle	16	0.51%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	180	5.72%
Reptiles		
Rana		
Xenopus		
Other Amphibians		

Animal Species	Number of animals	Percentage
Zebra fish		
Other Fish		
Cephalopods		
Total	**3146**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2966	94.28%
Animals born in the EU but not at a registered breeder	180	5.72%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**3146**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2392	76.03%
Translational and applied research	210	6.68%
Regulatory use and Routine production	112	3.56%
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	38	1.21%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	394	12.52%
Total	**3146**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	985	41.18%
Cardiovascular Blood and Lymphatic System	93	3.89%
Nervous System	495	20.69%

Basic Research	Number of uses	Percentage
Respiratory System		
Gastrointestinal System including Liver	32	1.34%
Musculoskeletal System	88	3.68%
Immune System	99	4.14%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)	32	1.34%
Endocrine System/Metabolism	219	9.16%
Multisystemic	153	6.4%
Ethology / Animal Behaviour /Animal Biology	180	7.53%
Other basic research	16	0.67%
Total	**2392**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders	210	100%
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	**210**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	112	100%
Total	**112**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	38	33.93%
Carcinogenicity	74	66.07%
Total	**112**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	38	100%
29 - 90 days		
> 90 days		
Total	**38**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		

Routine production	Number of uses	Percentage
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	112	100%
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	**112**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	112	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**112**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	3146	100%
Yes		
Total	**3146**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	132	4.2%
Mild [up to and including]	1385	44.02%
Moderate	1354	43.04%
Severe	275	8.74%
Total	**3146**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3058	97.2%
Yes	88	2.8%
Total	**3146**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1956	62.17%
Genetically altered without a harmful phenotype	1190	37.83%
Genetically altered with a harmful phenotype		
Total	**3146**	**100.00%**

Finland

Finland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, a total of 96 817 procedures in animals were done in Finland, which was 33 % less than 2014 (145 542 procedures in 2014). The greatest reductions were in the procedures with fish (other than zebra fish 38 483). The change was due to the ending of one project with large fish use. The use of mice in procedures decreased also (10 941). This may however be explained with the more precise reporting. The reductions in use of both species were mainly in basic research. The use of rats increased by 1679 rats in translational and applied research.

28 % of animals used were genetically altered (mice, rats and zebra fish). 7 % of them had a harmful phenotype.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 62 223 procedures - main areas being nervous system, immune system, multisystemic and ethology/animal behavior/animal biology. For the translational and applied research (25 634 procedures) the main category of purposes were human nervous and mental disorders (15 878 procedures).

Dogs reported as used in procedures (2619) included 2326 pet dogs which gave a blood sample for a study of disease genes and 196 pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 97 procedures including 71 re-use. Cats reported as used in procedures (100) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Actual severities of procedures: 60 % of the procedures were classified as non-recovery or mild, 34 % moderate and 6 % severe. By species, the severe procedures involved 2934 mice (5199 mice in 2014) and 2679 rats (1960 rats in 2014). Most of the severe procedures (4008) were done in category of human nervous and mental disorders.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	50047	51.69%
Rats	15976	16.5%
Guinea-Pigs	50	0.05%
Hamsters (Syrian)	197	0.2%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	213	0.22%
Cats	100	0.1%
Dogs	2619	2.71%
Ferrets		
Other carnivores	270	0.28%
Horses, donkeys and cross-breeds	48	0.05%
Pigs	479	0.49%
Goats		
Sheep	1128	1.17%
Cattle	87	0.09%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	2880	2.97%
Domestic fowl	3646	3.77%
Other birds	717	0.74%
Reptiles		
Rana	10	0.01%
Xenopus		
Other Amphibians		
Zebra fish	10821	11.18%
Other Fish	7529	7.78%
Cephalopods		
Total	**96817**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	76799	79.95%
Animals born in the EU but not at a registered breeder	18207	18.95%
Animals born in rest of Europe	7	0.01%
Animals born in rest of world	1042	1.08%
Total	**96055**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	62223	64.27%
Translational and applied research	25634	26.48%
Regulatory use and Routine production	5364	5.54%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1455	1.5%
Preservation of species	41	0.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1170	1.21%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	930	0.96%
Total	**96817**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	7529	12.1%
Cardiovascular Blood and Lymphatic System	5253	8.44%
Nervous System	14531	23.35%
Respiratory System		
Gastrointestinal System including Liver	558	0.9%
Musculoskeletal System	701	1.13%
Immune System	10115	16.26%
Urogenital/Reproductive System	500	0.8%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	1223	1.97%
Endocrine System/Metabolism	4000	6.43%
Multisystemic	8112	13.04%
Ethology / Animal Behaviour /Animal Biology	9425	15.15%
Other basic research	276	0.44%
Total	**62223**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2375	9.27%
Human Infectious Disorders		
Human Cardiovascular Disorders	604	2.36%
Human Nervous and Mental Disorders	15878	61.94%
Human Respiratory Disorders	62	0.24%
Human Gastrointestinal Disorders including Liver	24	0.09%
Human Musculoskeletal Disorders	16	0.06%
Human Immune Disorders	24	0.09%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1237	4.83%
Human Endocrine/Metabolism Disorders	85	0.33%
Other Human Disorders	23	0.09%
Animal Diseases and Disorders	4593	17.92%
Animal Welfare	444	1.73%
Diagnosis of diseases	127	0.5%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	142	0.55%
Total	**25634**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1576	29.38%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	2538	47.32%
Routine production	1250	23.3%
Total	**5364**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	1576	100%
Total	**1576**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	50	1.97%
Skin irritation/corrosion	10	0.39%
Skin sensitisation	40	1.58%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Repeated dose toxicity	94	3.7%
Kinetics	590	23.25%
Pharmaco-dynamics (incl safety pharmacology)	1754	69.11%
Total	**2538**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	50	100%
Total	**50**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	94	100%
29 - 90 days		
> 90 days		
Total	**94**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	1250	100%
Total	**1250**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3708	69.13%
Legislation on medicinal products for veterinary use and their residues	1656	30.87%
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	**5364**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	5364	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**5364**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	96055	99.21%
Yes	762	0.79%
Total	**96817**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	4977	5.14%
Mild [up to and including]	53408	55.16%
Moderate	32819	33.9%
Severe	5613	5.8%
Total	**96817**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	87608	90.49%
Yes	9209	9.51%
Total	**96817**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	69334	71.61%
Genetically altered without a harmful phenotype	22004	22.73%
Genetically altered with a harmful phenotype	5479	5.66%
Total	**96817**	**100.00%**

Finland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, a total of 105 615 procedures in animals were done in Finland, which was 9 % more than in 2015 (96 817 procedures). The greatest increases were in the procedures with mice (7 792 animals more), other rodents (1364 more) and domestic fowls (4 765 more).

45 % of mice used were genetically altered and 13 % (7328 mice) had a harmful phenotype. With rats, 3 % were genetically altered, one rat with harmful phenotype. With zebrafish, the numbers were 58 % and 16 % (1206 zebra fish), respectively.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 55 744 procedures, main areas being Nervous system (14 320 procedures), Immune system, Multisystemic and Ethology/Animal behavior/Animal biology (8 795, 10 539 and 7 376, respectively). For the translational and applied research (40 591 procedures) the main categories of purposes were Human nervous and mental disorders (20 831 procedures) and Animal diseases and disorders (9 869 procedures). In regulatory use and routine production, 2 645 domestic fowls were used for quality control, 1 457 animals (sheep, pigs, domestic fowls and horses) for routine products and 2 916 animals (mice, rats, dogs, pigs) in toxicity and other safety testing.

The increased use of mice in procedures (16 %) took place in the translational and applied research in studies for Human nervous and mental disorders. Other rodents (bank voles: 1314 animals) were used in the basic research (Ethology/Animal behavior/Animal biology). The procedures in domestic fowls increased in the translational and applied research (Animal diseases and disorders) and in the regulatory use and routine production (Quality control).

Procedures reported as done in dogs (3961) included 3582 procedures in pet dogs which gave a blood sample for a study of disease genes. 244 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 135 procedures including 116 re-use. Cats reported as used in procedures (259) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

61,5 % of the procedures were classified as non-recovery or mild, 30 % moderate and 8,5 % severe. By species, the severe procedures involved 6 862 mice (2934 in 2015) and 2161 rats (2 679 in 2015). The severe procedures in mice and rats were done mainly in the purpose of Human nervous and mental disorders both in basic and translational research. The significant increase or severe procedures with mice was due to single projects with high animal numbers.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	57839	54.76%
Rats	15297	14.48%
Guinea-Pigs	10	0.01%
Hamsters (Syrian)	273	0.26%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	1364	1.29%
Rabbits	237	0.22%
Cats	259	0.25%
Dogs	3961	3.75%
Ferrets		
Other carnivores	18	0.02%
Horses, donkeys and cross-breeds	76	0.07%
Pigs	611	0.58%
Goats		
Sheep	1350	1.28%
Cattle	541	0.51%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	103	0.1%
Domestic fowl	8411	7.96%

Animal Species	Number of animals	Percentage
Other birds	501	0.47%
Reptiles		
Rana	2	0%
Xenopus		
Other Amphibians		
Zebra fish	7483	7.09%
Other Fish	7279	6.89%
Cephalopods		
Total	**105615**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	84134	80.23%
Animals born in the EU but not at a registered breeder	15053	14.35%
Animals born in rest of Europe	981	0.94%
Animals born in rest of world	4702	4.48%
Total	**104870**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	55744	52.78%
Translational and applied research	40591	38.43%
Regulatory use and Routine production	7026	6.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	35	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1753	1.66%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	466	0.44%
Total	**105615**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4212	7.56%
Cardiovascular Blood and Lymphatic System	5187	9.31%
Nervous System	14320	25.69%
Respiratory System	258	0.46%
Gastrointestinal System including Liver	501	0.9%
Musculoskeletal System	562	1.01%
Immune System	8795	15.78%
Urogenital/Reproductive System	524	0.94%
Sensory Organs (skin, eyes and ears)	310	0.56%
Endocrine System/Metabolism	2614	4.69%
Multisystemic	10539	18.91%
Ethology / Animal Behaviour /Animal Biology	7376	13.23%
Other basic research	546	0.98%
Total	**55744**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3325	8.19%
Human Infectious Disorders	995	2.45%
Human Cardiovascular Disorders	676	1.67%
Human Nervous and Mental Disorders	20831	51.32%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	74	0.18%
Human Musculoskeletal Disorders	1204	2.97%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	2169	5.34%
Human Endocrine/Metabolism Disorders	386	0.95%
Other Human Disorders	586	1.44%
Animal Diseases and Disorders	9869	24.31%
Animal Welfare	199	0.49%
Diagnosis of diseases	89	0.22%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	188	0.46%
Total	**40591**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2645	37.65%
Other efficacy and tolerance testing	8	0.11%
Toxicity and other safety testing including pharmacology	2916	41.5%
Routine production	1457	20.74%
Total	**7026**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	2645	100%

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total	**2645**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	49	1.68%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	196	6.72%
Kinetics	850	29.15%
Pharmaco-dynamics (incl safety pharmacology)	1821	62.45%
Total	**2916**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	9	18.37%
Other lethal methods		
Non lethal methods	40	81.63%
Total	**49**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	100	51.02%
29 - 90 days		
> 90 days	96	48.98%
Total	**196**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	317	21.76%
Monoclonal antibody by mouse ascites method		
Other product types	1140	78.24%
Total	**1457**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4332	61.66%
Legislation on medicinal products for veterinary use and their residues	2694	38.34%
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	**7026**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6709	95.49%
Legislation satisfying national requirements only [within EU]	317	4.51%
Legislation satisfying Non-EU requirements only		
Total	**7026**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	104870	99.29%
Yes	745	0.71%
Total	**105615**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9198	8.71%
Mild [up to and including]	55602	52.65%
Moderate	31797	30.11%
Severe	9018	8.54%
Total	**105615**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	101359	95.97%
Yes	4256	4.03%
Total	**105615**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	74960	70.97%
Genetically altered without a harmful phenotype	22120	20.94%
Genetically altered with a harmful phenotype	8535	8.08%
Total	**105615**	**100.00%**

Finland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, a total of 102 575 procedures in animals were done in Finland, which was 3 % less than in 2016 (105 615 procedures). The greatest decreases were in the procedures with mice (4 838 animals less) mainly in basic research and rats (1 825 less) in translational and applied research. The number of procedures with other fish increased (4 450 more).

48 % of mice used were genetically altered and 17 % (8817 mice) had a harmful phenotype. With rats, 4 % were genetically altered, all without a harmful phenotype. With zebrafish, 51 % of the used fish were genetically altered, all without a harmful phenotype.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of procedures done in basic research were 59 278 procedures, main areas being Nervous system (11 905 procedures, decreased) and Immune system (11 024 procedures, increased). Other areas of basic research were Multisystemic (7 587, decreased), Ethology/Animal Behavior/Animal Biology (7 546, no change), Oncology (6 791, increased) and Cardiovascular Blood and Lymphatic Systems (5 145, no change).

For the translational and applied research (33 521 procedures) the main categories of purposes were Human nervous and mental disorders (19 703 procedures, decreased), Human Cancer (5 016, increased) and Animal diseases and disorders (4 384 procedures, decreased).

In Regulatory use and Routine production, 3 395 domestic fowls were used for Quality control and 1 476 animals (sheep, pigs, domestic fowls and horses) for Routine products. For Toxicity and other safety testing, 2 868 animals (mice, rats, dogs, pigs, rabbits) were used mainly for Kinetics and Pharmaco-dynamics.

Procedures reported as done in dogs (3 061) included 2 840 procedures in pet dogs which gave a blood sample for a study of disease genes. 195 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 26 procedures including 26 re-use. Cats reported as used in procedures (311) were all pet cats with blood sampling for a study of disease genes.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Actual severities of procedures: 8,9 % of the procedures were classified as non-recovery, 48,5 % mild, 34,1 % moderate and 8,5 % severe. By species, the severe procedures involved 7 125 mice (6 862 in 2016) and 1 568 rats (2 161 in 2016). There were changes in the numbers of procedures with mild or moderate severity without clear reasons for them. As in previous years, the severe procedures were done mainly in the purpose of Human nervous and mental disorders in translational research (6 722 procedures).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

-

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	53001	51.67%
Rats	13472	13.13%
Guinea-Pigs	9	0.01%
Hamsters (Syrian)	149	0.15%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	690	0.67%
Rabbits	227	0.22%
Cats	311	0.3%
Dogs	3061	2.98%
Ferrets		
Other carnivores	107	0.1%
Horses, donkeys and cross-breeds	77	0.08%
Pigs	632	0.62%
Goats		
Sheep	1319	1.29%
Cattle	216	0.21%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1533	1.49%
Domestic fowl	8485	8.27%

Animal Species	Number of animals	Percentage
Other birds	404	0.39%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	7153	6.97%
Other Fish	11729	11.43%
Cephalopods		
Total	**102575**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	76287	74.48%
Animals born in the EU but not at a registered breeder	23562	23%
Animals born in rest of Europe	5	0%
Animals born in rest of world	2572	2.51%
Total	**102426**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	59278	57.79%
Translational and applied research	33521	32.68%
Regulatory use and Routine production	7895	7.7%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	60	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1606	1.57%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	215	0.21%
Total	**102575**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	6791	11.46%
Cardiovascular Blood and Lymphatic System	5145	8.68%
Nervous System	11905	20.08%
Respiratory System	80	0.13%
Gastrointestinal System including Liver	545	0.92%
Musculoskeletal System	337	0.57%
Immune System	11024	18.6%
Urogenital/Reproductive System	181	0.31%
Sensory Organs (skin, eyes and ears)	268	0.45%
Endocrine System/Metabolism	1387	2.34%
Multisystemic	7587	12.8%
Ethology / Animal Behaviour /Animal Biology	7546	12.73%
Other basic research	6482	10.93%
Total	**59278**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	5016	14.96%
Human Infectious Disorders	860	2.57%
Human Cardiovascular Disorders	662	1.97%
Human Nervous and Mental Disorders	19703	58.78%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	117	0.35%
Human Musculoskeletal Disorders	605	1.8%
Human Immune Disorders	71	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	477	1.42%
Human Endocrine/Metabolism Disorders	442	1.32%
Other Human Disorders	759	2.26%
Animal Diseases and Disorders	4384	13.08%
Animal Welfare	226	0.67%
Diagnosis of diseases	123	0.37%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	68	0.2%
Total	**33521**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	3395	43%
Other efficacy and tolerance testing	156	1.98%
Toxicity and other safety testing including pharmacology	2868	36.33%
Routine production	1476	18.7%
Total	**7895**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	3395	100%

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total	**3395**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	134	4.67%
Kinetics	1171	40.83%
Pharmaco-dynamics (incl safety pharmacology)	1556	54.25%
Other toxicity/safety testing	7	0.24%
Total	**2868**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	134	100%
29 - 90 days		
> 90 days		
Total	**134**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	296	20.05%
Monoclonal antibody by mouse ascites method		
Other product types	1180	79.95%
Total	**1476**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4468	56.59%
Legislation on medicinal products for veterinary use and their residues	3395	43%
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	32	0.41%
Cosmetics legislation		
Other legislation		
Total	**7895**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7599	96.25%
Legislation satisfying national requirements only [within EU]	296	3.75%
Legislation satisfying Non-EU requirements only		
Total	**7895**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	102426	99.85%
Yes	149	0.15%
Total	**102575**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9082	8.85%
Mild [up to and including]	49770	48.52%
Moderate	34984	34.11%
Severe	8739	8.52%
Total	**102575**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	97716	95.26%
Yes	4859	4.74%
Total	**102575**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	73080	71.25%
Genetically altered without a harmful phenotype	20678	20.16%
Genetically altered with a harmful phenotype	8817	8.6%
Total	**102575**	**100.00%**

France

France: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period (2014).

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2015 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2014 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

- only animals for which the experimental procedures ended in 2015 are recorded;
- captive-bred animals present in user establishments are excluded;
- animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
- animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection

Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Grouping species of the same taxon in the 'other' category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.6% of animals used (11,665 animals), 'other fish' account for 29.6% (524,024 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as 'other' (44,248 animals), while 'domestic fowl' account for 48,528.

Finally, with respect to the distribution of animals involved in procedures laid down in the rules, almost half are entered in the 'other' category, which suggests that the proposed headings are not the most appropriate, or have been misunderstood by users. Particular attention will be given to how this section is completed in the next survey.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the 'severe' classification being exceeded have been identified.

France: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1007245	52.97%
Rats	157183	8.27%
Guinea-Pigs	44414	2.34%
Hamsters (Syrian)	10986	0.58%
Hamsters (Chinese)		
Mongolian gerbil	1417	0.07%
Other Rodents	755	0.04%
Rabbits	108110	5.69%
Cats	336	0.02%

Animal Species	Number of animals	Percentage
Dogs	3143	0.17%
Ferrets	155	0.01%
Other carnivores	30	0%
Horses, donkeys and cross-breeds	629	0.03%
Pigs	12203	0.64%
Goats	436	0.02%
Sheep	3446	0.18%
Cattle	2203	0.12%
Prosimians	157	0.01%
Marmoset and tamarins	97	0.01%
Cynomolgus monkey	2756	0.14%
Rhesus monkey	64	0%
Vervets (Chlorocebus spp.)	56	0%
Baboons	18	0%
Squirrel monkey	13	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1772	0.09%
Domestic fowl	66734	3.51%
Other birds	46433	2.44%
Reptiles	1051	0.06%
Rana	306	0.02%
Xenopus	1644	0.09%
Other Amphibians	3167	0.17%
Zebra fish	11399	0.6%
Other Fish	413183	21.73%
Cephalopods	1	0%
Total	**1901542**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1550643	82.26%
Animals born in the EU but not at a registered breeder	258592	13.72%
Animals born in rest of Europe	66947	3.55%
Animals born in rest of world	8893	0.47%
Total	**1885075**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	128	6.92%
Animals born in rest of Europe	14	0.76%
Animals born in Asia	42	2.27%
Animals born in America	55	2.97%
Animals born in Africa	1521	82.17%
Animals born elsewhere	91	4.92%
Total	**1851**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0	1	0.05%
F1	1202	64.94%
F2 or greater	433	23.39%
Self-sustaining colony	215	11.62%
Total	**1851**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	792453	41.67%
Translational and applied research	432557	22.75%
Regulatory use and Routine production	572144	30.09%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1122	0.06%
Preservation of species	3380	0.18%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	28062	1.48%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	71824	3.78%
Total	**1901542**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	63910	8.06%
Cardiovascular Blood and Lymphatic System	40007	5.05%
Nervous System	92332	11.65%
Respiratory System	11520	1.45%
Gastrointestinal System including Liver	63028	7.95%
Musculoskeletal System	9931	1.25%
Immune System	68167	8.6%
Urogenital/Reproductive System	26770	3.38%
Sensory Organs (skin, eyes and ears)	12399	1.56%
Endocrine System/Metabolism	26196	3.31%
Multisystemic	29703	3.75%
Ethology / Animal Behaviour /Animal Biology	345624	43.61%
Other basic research	2866	0.36%
Total	**792453**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	126277	29.19%
Human Infectious Disorders	65335	15.1%
Human Cardiovascular Disorders	9735	2.25%
Human Nervous and Mental Disorders	61259	14.16%
Human Respiratory Disorders	3043	0.7%
Human Gastrointestinal Disorders including Liver	7405	1.71%
Human Musculoskeletal Disorders	12075	2.79%
Human Immune Disorders	11943	2.76%
Human Urogenital/Reproductive Disorders	2756	0.64%
Human Sensory Organ Disorders (skin, eyes and ears)	9717	2.25%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	22966	5.31%
Other Human Disorders	1387	0.32%
Animal Diseases and Disorders	45194	10.45%
Animal Welfare	2656	0.61%
Diagnosis of diseases	31652	7.32%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	19157	4.43%
Total	**432557**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	276166	48.27%
Other efficacy and tolerance testing	39738	6.95%
Toxicity and other safety testing including pharmacology	102867	17.98%
Routine production	153373	26.81%
Total	**572144**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	62846	22.76%
Pyrogenicity testing	5981	2.17%
Batch potency testing	207339	75.08%
Other quality controls		
Total	**276166**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	7869	7.65%
Skin irritation/corrosion	1750	1.7%
Skin sensitisation	11491	11.17%
Eye irritation/corrosion	548	0.53%
Repeated dose toxicity	22904	22.27%
Carcinogenicity	1054	1.02%
Genotoxicity	854	0.83%
Reproductive toxicity	13109	12.74%
Developmental toxicity	8293	8.06%
Neurotoxicity	202	0.2%
Kinetics	8841	8.59%
Pharmaco-dynamics (incl safety pharmacology)	9119	8.86%
Phototoxicity	420	0.41%
Ecotoxicity	13360	12.99%
Safety testing in food and feed area	733	0.71%
Target animal safety	273	0.27%
Other toxicity/safety testing	2047	1.99%
Total	**102867**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	2713	34.48%
Other lethal methods	1373	17.45%
Non lethal methods	3783	48.07%
Total	**7869**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13008	56.79%
29 - 90 days	4542	19.83%
> 90 days	5354	23.38%
Total	**22904**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	9383	70.23%
Chronic toxicity	3977	29.77%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**13360**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	91483	59.65%
Monoclonal antibody by mouse ascites method	24200	15.78%
Other product types	37690	24.57%
Total	**153373**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	368792	64.46%
Legislation on medicinal products for veterinary use and their residues	115003	20.1%
Medical devices legislation	40847	7.14%
Industrial chemicals legislation	7479	1.31%
Plant protection product legislation	7026	1.23%
Biocides legislation	394	0.07%
Food legislation including food contact material	1033	0.18%
Feed legislation including legislation for the safety of target animals, workers and environment	27971	4.89%
Cosmetics legislation		
Other legislation	3599	0.63%
Total	**572144**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	565901	98.91%
Legislation satisfying national requirements only [within EU]	1871	0.33%
Legislation satisfying Non-EU requirements only	4372	0.76%
Total	**572144**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1886926	99.23%
Yes	14616	0.77%
Total	**1901542**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	81482	4.29%
Mild [up to and including]	845322	44.45%
Moderate	782033	41.13%
Severe	192705	10.13%
Total	**1901542**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1873951	98.55%
Yes	27591	1.45%
Total	**1901542**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1487378	78.22%
Genetically altered without a harmful phenotype	324456	17.06%
Genetically altered with a harmful phenotype	89708	4.72%
Total	**1901542**	**100.00%**

France: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period (2015).

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2016 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2015 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

- only animals for which the experimental procedures ended in 2016 are recorded;
- captive-bred animals present in user establishments are excluded;
- animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
- animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals

for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Grouping species of the same taxon in the 'other' category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.5 % of animals used (11,399 animals), 'other fish' account for 21.7 % (413,183 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as 'other' (46,433 animals), while 'domestic fowl' account for 66,734.

Finally, with respect to the distribution of animals involved in procedures imposed by the rules, particular attention was given to completing this section, which had been misunderstood by users in the previous survey. Only 1% of animals were entered in the 'other' category in this survey.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the 'severe' classification being exceeded have been identified.

France: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1144745	59.67%
Rats	172209	8.98%
Guinea-Pigs	44705	2.33%
Hamsters (Syrian)	10481	0.55%
Hamsters (Chinese)	287	0.01%
Mongolian gerbil	817	0.04%
Other Rodents	651	0.03%
Rabbits	117531	6.13%
Cats	1067	0.06%
Dogs	4204	0.22%
Ferrets	160	0.01%
Other carnivores	23	0%
Horses, donkeys and cross-breeds	540	0.03%

Animal Species	Number of animals	Percentage
Pigs	11707	0.61%
Goats	1025	0.05%
Sheep	5763	0.3%
Cattle	2492	0.13%
Prosimians	1	0%
Marmoset and tamarins	41	0%
Cynomolgus monkey	3170	0.17%
Rhesus monkey	173	0.01%
Vervets (Chlorocebus spp.)	23	0%
Baboons	92	0%
Squirrel monkey	8	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	20	0%
Domestic fowl	56759	2.96%
Other birds	14633	0.76%
Reptiles	4958	0.26%
Rana	36	0%
Xenopus	10078	0.53%
Other Amphibians	2081	0.11%
Zebra fish	13893	0.72%
Other Fish	293589	15.3%
Cephalopods	440	0.02%
Total	**1918402**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1611211	85.67%
Animals born in the EU but not at a registered breeder	185781	9.88%
Animals born in rest of Europe	59305	3.15%
Animals born in rest of world	24313	1.29%
Total	**1880610**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	126	5.44%
Animals born in rest of Europe		
Animals born in Asia	182	7.85%
Animals born in America	12	0.52%
Animals born in Africa	1979	85.38%
Animals born elsewhere	19	0.82%
Total	**2318**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0	5	0.22%
F1	1030	44.43%
F2 or greater	1272	54.87%
Self-sustaining colony	11	0.47%
Total	**2318**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	809504	42.2%
Translational and applied research	482233	25.14%
Regulatory use and Routine production	517479	26.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	635	0.03%
Preservation of species	16750	0.87%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	34195	1.78%
Forensic enquiries	28	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	57578	3%
Total	**1918402**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	81024	10.01%
Cardiovascular Blood and Lymphatic System	30831	3.81%
Nervous System	133609	16.51%
Respiratory System	7721	0.95%
Gastrointestinal System including Liver	33673	4.16%
Musculoskeletal System	14431	1.78%
Immune System	81497	10.07%
Urogenital/Reproductive System	14140	1.75%
Sensory Organs (skin, eyes and ears)	12221	1.51%
Endocrine System/Metabolism	63208	7.81%
Multisystemic	36302	4.48%
Ethology / Animal Behaviour /Animal Biology	226122	27.93%
Other basic research	74725	9.23%
Total	**809504**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	95944	19.9%
Human Infectious Disorders	39380	8.17%
Human Cardiovascular Disorders	10632	2.2%
Human Nervous and Mental Disorders	51007	10.58%
Human Respiratory Disorders	1530	0.32%
Human Gastrointestinal Disorders including Liver	11753	2.44%
Human Musculoskeletal Disorders	12804	2.66%
Human Immune Disorders	19730	4.09%
Human Urogenital/Reproductive Disorders	727	0.15%
Human Sensory Organ Disorders (skin, eyes and ears)	10749	2.23%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	17398	3.61%
Other Human Disorders	5443	1.13%
Animal Diseases and Disorders	70126	14.54%
Animal Welfare	749	0.16%
Diagnosis of diseases	115230	23.9%
Plant diseases	56	0.01%
Non-regulatory toxicology and ecotoxicology	18975	3.93%
Total	**482233**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	236097	45.62%
Other efficacy and tolerance testing	27122	5.24%
Toxicity and other safety testing including pharmacology	104065	20.11%
Routine production	150195	29.02%
Total	**517479**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	25789	10.92%
Pyrogenicity testing	7689	3.26%
Batch potency testing	164164	69.53%
Other quality controls	38455	16.29%
Total	**236097**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	4796	4.61%
Skin irritation/corrosion	823	0.79%
Skin sensitisation	13287	12.77%
Eye irritation/corrosion	283	0.27%
Repeated dose toxicity	24301	23.35%
Carcinogenicity	412	0.4%
Genotoxicity	736	0.71%
Reproductive toxicity	16635	15.99%
Developmental toxicity	6451	6.2%
Neurotoxicity	18	0.02%
Kinetics	12205	11.73%
Pharmaco-dynamics (incl safety pharmacology)	10704	10.29%
Phototoxicity	403	0.39%
Ecotoxicity	11352	10.91%
Safety testing in food and feed area	294	0.28%
Target animal safety	58	0.06%
Other toxicity/safety testing	1307	1.26%
Total	**104065**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	706	14.72%
Other lethal methods	1256	26.19%
Non lethal methods	2834	59.09%
Total	**4796**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13624	56.06%
29 - 90 days	5861	24.12%
> 90 days	4816	19.82%
Total	**24301**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10156	89.46%
Chronic toxicity	1078	9.5%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	42	0.37%
Other ecotoxicity	76	0.67%
Total	**11352**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	73841	49.16%
Monoclonal antibody by mouse ascites method	46128	30.71%
Other product types	30226	20.12%
Total	**150195**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	340076	65.72%
Legislation on medicinal products for veterinary use and their residues	79098	15.29%
Medical devices legislation	66507	12.85%
Industrial chemicals legislation	12412	2.4%
Plant protection product legislation	3970	0.77%
Biocides legislation	439	0.08%
Food legislation including food contact material	715	0.14%
Feed legislation including legislation for the safety of target animals, workers and environment	13556	2.62%
Cosmetics legislation		
Other legislation	706	0.14%
Total	**517479**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	497155	96.07%
Legislation satisfying national requirements only [within EU]	1318	0.25%
Legislation satisfying Non-EU requirements only	19006	3.67%
Total	**517479**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1882928	98.15%
Yes	35474	1.85%
Total	**1918402**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	105941	5.52%
Mild [up to and including]	766947	39.98%
Moderate	726836	37.89%
Severe	318678	16.61%
Total	**1918402**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1874323	97.7%
Yes	44079	2.3%
Total	**1918402**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1501546	78.27%
Genetically altered without a harmful phenotype	372200	19.4%
Genetically altered with a harmful phenotype	44656	2.33%
Total	**1918402**	**100.00%**

France: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period (2016).

The 2017 survey comprises the responses of 552 establishments authorised to use animals for scientific purposes, representing an increase of 8.2% compared to 2016, which reflects an improved response rate to the survey.

The number of animals is decreasing (1,914,174 in 2017 compared to 1,918,481 in 2016, amounting to a decrease of 4,307 animals or 0.22%). This decrease is all the more significant since the number of respondents to the 2017 survey is considerably higher than it was in 2016. This trend will be reviewed once the 2018 figures are available at the end of 2019.

The decrease observed is significant and supported by the fact the survey response rate has increased by around 8%.

Apart from the number of animals, the type of species used in experimental procedures, the degree of severity and the proportion of genetically modified animals remain extremely close to the previous year's figures.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The statistics are not yet fully comparable from one year to the next, because France is still in a transitional period in order to implement the Directive. Subject to that reservation, we can nevertheless detect the following trends:

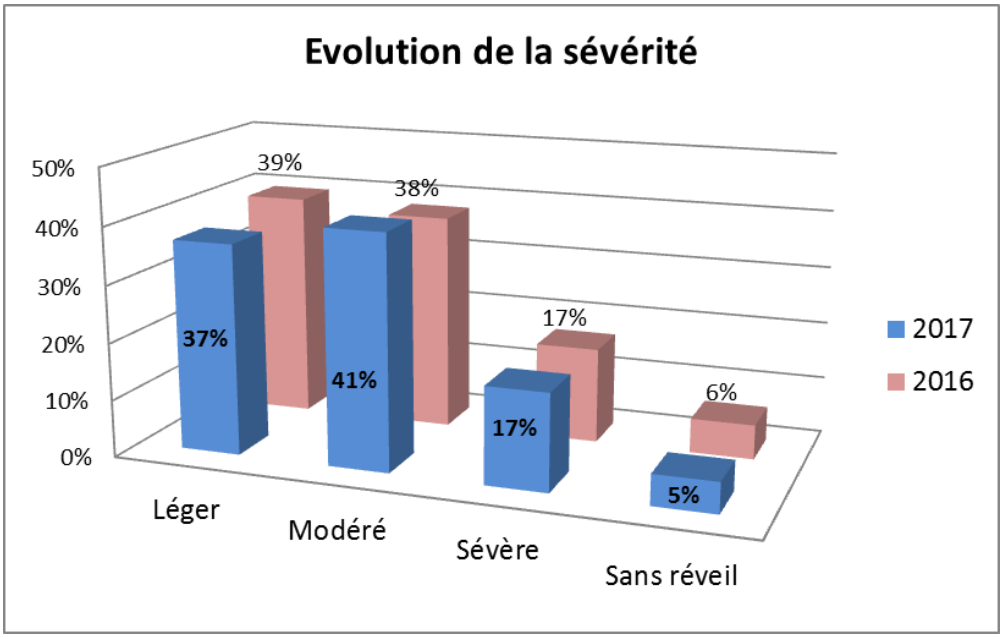
- stable use of non-human primates and a decrease in the number of domestic carnivores (dogs and cats) compared to 2016, which can be linked with concerted efforts made for several years to reduce the use of these sensitive species;

- an increase in the proportion of F2 generation non-human primates, reflecting a gradual shift towards achieving the 100% target set for 2022;

- stable use of genetically modified animals and a large reduction in the proportion of harmful genotypes (2.8% of animals in 2017).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severity is very stable from one year to the next. There has been a slight increase in the number of animals used in moderate procedures compared to mild procedures (see graph below). However, this change does not appear to be significant: it could be the result of establishments applying the severity assessment criteria better, thanks to the educational work carried out by the ethics committees and the Ministry responsible for research.



Key to graph:

Changes in severity			
Mild	Moderate	Severe	Non-recovery

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

France continues to promote the principles of replacement, refinement and reduction very actively, in particular through an ambitious training programme for staff in charge of both caring for animals and designing and carrying out scientific projects. The work of the National Commission for Animal Testing (CNEA) and the National Ethical Reflection Committee on Animal Testing (CNREEA), each of which meets several times a year, is also crucial.

The national platform for the development of alternative methods (FRANCOPA), which is a member of the European ECOPA network and brings together all stakeholders, also works to promote the three Rs.

The French authorities can also draw on the expertise of almost 130 ethical committees spread throughout France, which, on a local level, all help researchers think more about ethical issues, raise awareness of these three principles and encourage the sharing of best practice.

We believe that the decrease in the average number of animals used per establishment, referred to above (question 1), is partly the result of these efforts.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As in previous years, the 'other fish' category remains very large, corresponding to 13.8% of the animals used (267,800 animals). This category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

The 'other birds' category still covers 1.4% of animals (27,200 animals), compared to 43,100 'domestic fowl'.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.'

No authorisations were granted in 2017 for requests exceeding the 'severe' classification.

France: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1134517	59.27%
Rats	183714	9.6%
Guinea-Pigs	45034	2.35%
Hamsters (Syrian)	6529	0.34%
Hamsters (Chinese)	167	0.01%
Mongolian gerbil	429	0.02%
Other Rodents	957	0.05%
Rabbits	127204	6.65%
Cats	867	0.05%
Dogs	4106	0.21%
Ferrets	148	0.01%
Other carnivores	27	0%
Horses, donkeys and cross-breeds	305	0.02%
Pigs	10346	0.54%
Goats	838	0.04%
Sheep	5396	0.28%
Cattle	1777	0.09%
Prosimians	86	0%
Marmoset and tamarins	224	0.01%
Cynomolgus monkey	3279	0.17%
Rhesus monkey	71	0%
Vervets (Chlorocebus spp.)	38	0%
Baboons	32	0%
Squirrel monkey	7	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	9	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	18525	0.97%

Animal Species	Number of animals	Percentage
Domestic fowl	43144	2.25%
Other birds	27225	1.42%
Reptiles	3462	0.18%
Rana	118	0.01%
Xenopus	4897	0.26%
Other Amphibians	742	0.04%
Zebra fish	21879	1.14%
Other Fish	268074	14%
Cephalopods	1	0%
Total	**1914174**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1564017	83.58%
Animals born in the EU but not at a registered breeder	204920	10.95%
Animals born in rest of Europe	48681	2.6%
Animals born in rest of world	53666	2.87%
Total	**1871284**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	236	10.24%
Animals born in rest of Europe	5	0.22%
Animals born in Asia	130	5.64%
Animals born in America	35	1.52%
Animals born in Africa	1729	75.04%
Animals born elsewhere	169	7.34%
Total	**2304**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	885	38.41%
F2 or greater	1285	55.77%
Self-sustaining colony	134	5.82%
Total	**2304**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	731041	38.19%
Translational and applied research	479372	25.04%
Regulatory use and Routine production	574030	29.99%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4918	0.26%
Preservation of species	18786	0.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	35512	1.86%
Forensic enquiries	8	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	70507	3.68%
Total	**1914174**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	94213	12.89%
Cardiovascular Blood and Lymphatic System	32577	4.46%
Nervous System	141408	19.34%
Respiratory System	12314	1.68%
Gastrointestinal System including Liver	28076	3.84%
Musculoskeletal System	17501	2.39%
Immune System	92193	12.61%
Urogenital/Reproductive System	19906	2.72%
Sensory Organs (skin, eyes and ears)	5435	0.74%
Endocrine System/Metabolism	40708	5.57%
Multisystemic	20896	2.86%
Ethology / Animal Behaviour /Animal Biology	164456	22.5%
Other basic research	61358	8.39%
Total	**731041**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	120343	25.1%
Human Infectious Disorders	52555	10.96%
Human Cardiovascular Disorders	15203	3.17%
Human Nervous and Mental Disorders	46348	9.67%
Human Respiratory Disorders	6669	1.39%
Human Gastrointestinal Disorders including Liver	12373	2.58%
Human Musculoskeletal Disorders	14481	3.02%
Human Immune Disorders	19048	3.97%
Human Urogenital/Reproductive Disorders	2240	0.47%
Human Sensory Organ Disorders (skin, eyes and ears)	7760	1.62%
Human Endocrine/Metabolism Disorders	12502	2.61%
Other Human Disorders	9742	2.03%
Animal Diseases and Disorders	37943	7.92%
Animal Welfare	216	0.05%
Diagnosis of diseases	97413	20.32%
Plant diseases	89	0.02%
Non-regulatory toxicology and ecotoxicology	24447	5.1%
Total	**479372**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	201610	35.12%
Other efficacy and tolerance testing	83928	14.62%
Toxicity and other safety testing including pharmacology	113238	19.73%
Routine production	175254	30.53%
Total	**574030**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	20294	10.07%
Pyrogenicity testing	6191	3.07%
Batch potency testing	138017	68.46%
Other quality controls	37108	18.41%
Total	**201610**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3294	2.91%
Skin irritation/corrosion	1754	1.55%
Skin sensitisation	14019	12.38%
Eye irritation/corrosion	253	0.22%
Repeated dose toxicity	24250	21.42%
Carcinogenicity	2295	2.03%
Genotoxicity	486	0.43%
Reproductive toxicity	14165	12.51%
Developmental toxicity	7483	6.61%
Neurotoxicity		
Kinetics	18338	16.19%
Pharmaco-dynamics (incl safety pharmacology)	9821	8.67%
Phototoxicity	521	0.46%
Ecotoxicity	13533	11.95%
Safety testing in food and feed area	1570	1.39%
Target animal safety	171	0.15%
Other toxicity/safety testing	1285	1.13%
Total	**113238**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	702	21.31%
Other lethal methods	561	17.03%
Non lethal methods	2031	61.66%
Total	**3294**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	12892	53.16%
29 - 90 days	6543	26.98%
> 90 days	4815	19.86%
Total	**24250**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10955	80.95%
Chronic toxicity	1107	8.18%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	846	6.25%
Other ecotoxicity	625	4.62%
Total	**13533**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	74243	42.36%
Monoclonal antibody by mouse ascites method	44198	25.22%
Other product types	56813	32.42%
Total	**175254**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	334865	58.34%
Legislation on medicinal products for veterinary use and their residues	82088	14.3%
Medical devices legislation	64309	11.2%
Industrial chemicals legislation	12737	2.22%
Plant protection product legislation	4541	0.79%
Biocides legislation	757	0.13%
Food legislation including food contact material	698	0.12%
Feed legislation including legislation for the safety of target animals, workers and environment	73260	12.76%
Cosmetics legislation		
Other legislation	775	0.14%
Total	**574030**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	552522	96.25%
Legislation satisfying national requirements only [within EU]	2643	0.46%
Legislation satisfying Non-EU requirements only	18865	3.29%
Total	**574030**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1873588	97.88%
Yes	40586	2.12%
Total	**1914174**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	103094	5.39%
Mild [up to and including]	703783	36.77%
Moderate	780853	40.79%
Severe	326444	17.05%
Total	**1914174**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1868750	97.63%
Yes	45424	2.37%
Total	**1914174**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1485568	77.61%
Genetically altered without a harmful phenotype	375530	19.62%
Genetically altered with a harmful phenotype	53076	2.77%
Total	**1914174**	**100.00%**

Germany

Germany: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 82% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 68% of the animals used. Approximately 8% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 755,000 animals were used to this end in 2015, which means that overall approximately 34,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,115,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 40% (in 2014 this was approximately 34%). In particular mice (91%) and fish (7%) were used.

Primates

The number of primates used also rose slightly. In 2015 a total of 3,141 primates were used, 293 more than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 4,491 and 1,112 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. There are no relevant differences compared to the previous year.

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 48% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal

diseases. Approximately 31% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 6% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2014 there was an increase in the areas of basic research (approximately 5%) and the manufacture and quality control of medical products or toxicological safety tests (approximately 6%), while in the area of other purposes there was a decrease of approximately 10%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 14%) and the immune system (approximately 27%) was particularly important in 2015. As such, research into the immune system showed an increase of approximately 10% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. Here, too, there was an increase of approximately 10% as compared to 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 63%). Here a slight increase as compared to the previous year (approximately 60%) can be seen. The share of animal experiments classified as 'medium' or 'severe' was approximately 24% and 5% respectively. A slight decrease can be seen as compared to the previous year (21% and 6% respectively). The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 8%. Here as well, a decrease can be seen as compared to 2014 (13%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. This prize consists of a monetary award of €15,000. In addition, the German government's involvement in reducing the number of animals used in experiments is part of the BMEL's initiative 'Minding animals – new ways to improve animal welfare'. In the context of this initiative, the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch, ZEBET) within the German Federal Institute for Risk

Assessment (Bundesinstitut für Risikobewertung) was expanded into the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R).

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Category 'other animal species'

In this category, particularly in the areas 'other rodent species' and 'other fish species', there are a greater number of additional animal species.

Under rodents, the common vole was used in particular. This primarily concerns animals caught in the wild which were re-released after the experiment was finished. These animals were mainly used in the context of research into common vole populations and their development on agricultural land. As a rule the severity classification for the animals involved was 'low'.

For fish, primarily local wild fish (e.g. common bream, brown trout, common roach, stickleback) were used in the context of basic ethological research. Here, too, this primarily concerns animals caught in the wild which were re-released after the experiment was finished. And here too the severity classification was 'low' as a rule.

Category 'other uses'

The emphasis in this category is in the areas 'basic research' and 'regulatory purposes'.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- studies of evolutionary changes in humans and animals;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research into the structure and function of G-protein-coupled receptors;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was 'low'.

In addition, in the area of **regulatory experiments** the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
- propagation of pathogens for developing in vitro diagnostics;

- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was 'low'.

Category 'other legal provisions'

In the context of this category, predominantly experiments were carried out to test substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz). The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2015 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1400822	68.49%
Rats	263318	12.87%
Guinea-Pigs	18237	0.89%
Hamsters (Syrian)	1390	0.07%
Hamsters (Chinese)	30	0%
Mongolian gerbil	4568	0.22%
Other Rodents	12793	0.63%
Rabbits	110988	5.43%
Cats	1112	0.05%
Dogs	4491	0.22%
Ferrets	230	0.01%
Other carnivores	686	0.03%
Horses, donkeys and cross-breeds	1507	0.07%
Pigs	12305	0.6%
Goats	904	0.04%
Sheep	2290	0.11%
Cattle	4029	0.2%
Prosimians	102	0%
Marmoset and tamarins	292	0.01%
Cynomolgus monkey	2678	0.13%
Rhesus monkey	39	0%
Vervets (Chlorocebus spp.)		
Baboons	6	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	1	0%
Other species of New World Monkeys (Ceboidea)		

Animal Species	Number of animals	Percentage
Apes		
Other Mammals	1383	0.07%
Domestic fowl	25658	1.25%
Other birds	13663	0.67%
Reptiles	501	0.02%
Rana	132	0.01%
Xenopus	4038	0.2%
Other Amphibians	2190	0.11%
Zebra fish	88147	4.31%
Other Fish	66731	3.26%
Cephalopods		
Total	**2045261**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1888405	94.58%
Animals born in the EU but not at a registered breeder	82266	4.12%
Animals born in rest of Europe	11491	0.58%
Animals born in rest of world	14466	0.72%
Total	**1996628**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	414	17.31%
Animals born in rest of Europe		
Animals born in Asia	1237	51.71%
Animals born in America	9	0.38%
Animals born in Africa	732	30.6%
Animals born elsewhere		
Total	**2392**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	505	21.11%
F2 or greater	1204	50.33%
Self-sustaining colony	683	28.55%
Total	**2392**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	975689	47.7%
Translational and applied research	312138	15.26%
Regulatory use and Routine production	629182	30.76%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5991	0.29%
Preservation of species	29297	1.43%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	49389	2.41%
Forensic enquiries	15	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	43560	2.13%
Total	**2045261**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	81162	8.32%
Cardiovascular Blood and Lymphatic System	81552	8.36%
Nervous System	140795	14.43%
Respiratory System	33612	3.44%
Gastrointestinal System including Liver	26877	2.75%
Musculoskeletal System	18068	1.85%
Immune System	263000	26.96%
Urogenital/Reproductive System	20090	2.06%
Sensory Organs (skin, eyes and ears)	27615	2.83%
Endocrine System/Metabolism	43757	4.48%
Multisystemic	49023	5.02%
Ethology / Animal Behaviour /Animal Biology	31730	3.25%
Other basic research	158408	16.24%
Total	**975689**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	115200	36.91%
Human Infectious Disorders	21784	6.98%
Human Cardiovascular Disorders	16246	5.2%
Human Nervous and Mental Disorders	47429	15.19%
Human Respiratory Disorders	15252	4.89%
Human Gastrointestinal Disorders including Liver	8736	2.8%
Human Musculoskeletal Disorders	3253	1.04%
Human Immune Disorders	14081	4.51%
Human Urogenital/Reproductive Disorders	5321	1.7%
Human Sensory Organ Disorders (skin, eyes and ears)	3123	1%
Human Endocrine/Metabolism Disorders	20409	6.54%
Other Human Disorders	2224	0.71%
Animal Diseases and Disorders	20203	6.47%
Animal Welfare	4743	1.52%
Diagnosis of diseases	4539	1.45%
Plant diseases	21	0.01%
Non-regulatory toxicology and ecotoxicology	9574	3.07%
Total	**312138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	235332	37.4%
Other efficacy and tolerance testing	45385	7.21%
Toxicity and other safety testing including pharmacology	256282	40.73%
Routine production	92183	14.65%
Total	**629182**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	43768	18.6%
Pyrogenicity testing	6992	2.97%
Batch potency testing	184434	78.37%
Other quality controls	138	0.06%
Total	**235332**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	8608	3.36%
Skin irritation/corrosion	894	0.35%
Skin sensitisation	11170	4.36%
Eye irritation/corrosion	225	0.09%
Repeated dose toxicity	22769	8.88%
Carcinogenicity	5053	1.97%
Genotoxicity	4167	1.63%
Reproductive toxicity	22388	8.74%
Developmental toxicity	15019	5.86%
Neurotoxicity	90	0.04%
Kinetics	37692	14.71%
Pharmaco-dynamics (incl safety pharmacology)	88650	34.59%
Phototoxicity	12	0%
Ecotoxicity	31374	12.24%
Safety testing in food and feed area		
Target animal safety	1601	0.62%
Other toxicity/safety testing	6570	2.56%
Total	**256282**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	3559	41.35%
Other lethal methods	117	1.36%
Non lethal methods	4932	57.3%
Total	**8608**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	17256	75.79%
29 - 90 days	3132	13.76%
> 90 days	2381	10.46%
Total	**22769**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	8021	25.57%
Chronic toxicity	6288	20.04%
Reproductive ecotoxicity	1643	5.24%
Endocrine activity	8258	26.32%
Bioaccumulation	1858	5.92%
Other ecotoxicity	5306	16.91%
Total	**31374**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	86209	93.52%
Monoclonal antibody by mouse ascites method	894	0.97%
Other product types	5080	5.51%
Total	**92183**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	441537	70.18%
Legislation on medicinal products for veterinary use and their residues	38179	6.07%
Medical devices legislation	61866	9.83%
Industrial chemicals legislation	50563	8.04%
Plant protection product legislation	31544	5.01%
Biocides legislation	1200	0.19%
Food legislation including food contact material	38	0.01%
Feed legislation including legislation for the safety of target animals, workers and environment	1638	0.26%
Cosmetics legislation		
Other legislation	2617	0.42%
Total	**629182**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	593854	94.39%
Legislation satisfying national requirements only [within EU]	19377	3.08%
Legislation satisfying Non-EU requirements only	15951	2.54%
Total	**629182**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	1999020	97.74%
Yes	46241	2.26%
Total	**2045261**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	159720	7.81%
Mild [up to and including]	1282093	62.69%
Moderate	489855	23.95%
Severe	113593	5.55%
Total	**2045261**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1889941	92.41%
Yes	155320	7.59%
Total	**2045261**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1304619	63.79%
Genetically altered without a harmful phenotype	626034	30.61%
Genetically altered with a harmful phenotype	114608	5.6%
Total	**2045261**	**100.00%**

Germany: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 79% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 726,000 animals were used to this end in 2016, which means that overall approximately 29,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,200,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 42% (in 2015 this was approximately 40%). In particular mice (86%) and fish (12%) were used.

Primates

The number of primates used also showed a definite decrease. In 2015 a total of 2,462 primates were used, 679 fewer than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 3,977 and 766 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. As compared to the previous year, there was a decrease in the number of dogs (4,491 in 2015) and cats (1,112 in 2015).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 53% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 14% were used for researching human and animal diseases. Approximately 26% of the animals were used in the manufacture and quality control of

medical products or for toxicological safety tests. Approximately 7% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2015 there was an increase in the area of basic research (approximately 5%), while in the area of the manufacture and quality control of medical products or toxicological safety tests there was a decrease of approximately 6%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 15%) and the immune system (approximately 20%) was particularly important in 2016. As such, research into the immune system showed a decrease of approximately 7% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. No change can be seen here as compared to 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 63%). The share of animal experiments classified as 'medium' or 'severe' was approximately 23% and 7% respectively. Compared to the previous year, the number of experiments classified as 'severe' showed a slight increase of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 7% and thereby at the level of the previous year (approximately 8%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. In 2016 the amount of the prize was increased from €15,000 to €25,000. In addition, the German government's involvement in reducing the number of animals used in experiments is part of the BMEL's initiative 'Minding animals - new ways to improve animal welfare'.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

<u>Category 'other animal species'</u>

In this category, particularly in the areas ‘other fish species’ and ‘other bird species’, there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, common nase) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was ‘low’.

Among birds, primarily turkeys and local wild bird species (e.g. tit, pheasant, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was ‘low’.

Category ‘other uses’

The emphasis in this category is in the areas ‘basic research’ and ‘regulatory purposes’.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was ‘low’.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
- propagation of pathogens for developing in vitro diagnostics;
- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was ‘low’.

Category ‘other legal provisions’

In the context of this category the following other legal provisions are particularly referred to:

- test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
- test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);

- test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
- test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2016 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1400971	65.83%
Rats	244274	11.48%
Guinea-Pigs	14184	0.67%
Hamsters (Syrian)	1101	0.05%
Hamsters (Chinese)	2	0%
Mongolian gerbil	4769	0.22%
Other Rodents	6639	0.31%
Rabbits	98331	4.62%
Cats	766	0.04%
Dogs	3964	0.19%
Ferrets	130	0.01%
Other carnivores	474	0.02%
Horses, donkeys and cross-breeds	1270	0.06%
Pigs	16727	0.79%
Goats	223	0.01%
Sheep	3750	0.18%
Cattle	5432	0.26%
Prosimians	117	0.01%
Marmoset and tamarins	113	0.01%
Cynomolgus monkey	2058	0.1%
Rhesus monkey	86	0%
Vervets (Chlorocebus spp.)	18	0%
Baboons	8	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	18	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1143	0.05%
Domestic fowl	29853	1.4%
Other birds	16554	0.78%
Reptiles	454	0.02%

Animal Species	Number of animals	Percentage
Rana	930	0.04%
Xenopus	5237	0.25%
Other Amphibians	2675	0.13%
Zebra fish	178224	8.37%
Other Fish	87759	4.12%
Cephalopods		
Total	**2128254**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1951771	94.31%
Animals born in the EU but not at a registered breeder	94479	4.57%
Animals born in rest of Europe	9258	0.45%
Animals born in rest of world	14101	0.68%
Total	**2069609**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	192	10.89%
Animals born in rest of Europe	2	0.11%
Animals born in Asia	1039	58.93%
Animals born in America		
Animals born in Africa	530	30.06%
Animals born elsewhere		
Total	**1763**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	403	22.86%
F2 or greater	895	50.77%
Self-sustaining colony	465	26.38%
Total	**1763**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1117731	52.52%
Translational and applied research	307138	14.43%
Regulatory use and Routine production	554982	26.08%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8101	0.38%
Preservation of species	40387	1.9%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	48931	2.3%
Forensic enquiries	28	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	50956	2.39%
Total	**2128254**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage

Basic Research	Number of uses	Percentage
Oncology	84836	7.59%
Cardiovascular Blood and Lymphatic System	101807	9.11%
Nervous System	168180	15.05%
Respiratory System	24355	2.18%
Gastrointestinal System including Liver	31097	2.78%
Musculoskeletal System	19328	1.73%
Immune System	220107	19.69%
Urogenital/Reproductive System	25928	2.32%
Sensory Organs (skin, eyes and ears)	28599	2.56%
Endocrine System/Metabolism	117143	10.48%
Multisystemic	137863	12.33%
Ethology / Animal Behaviour /Animal Biology	35228	3.15%
Other basic research	123260	11.03%
Total	**1117731**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	115230	37.52%
Human Infectious Disorders	22052	7.18%
Human Cardiovascular Disorders	14597	4.75%
Human Nervous and Mental Disorders	41343	13.46%
Human Respiratory Disorders	16124	5.25%
Human Gastrointestinal Disorders including Liver	10359	3.37%
Human Musculoskeletal Disorders	3572	1.16%
Human Immune Disorders	14685	4.78%
Human Urogenital/Reproductive Disorders	3773	1.23%
Human Sensory Organ Disorders (skin, eyes and ears)	5713	1.86%
Human Endocrine/Metabolism Disorders	14638	4.77%
Other Human Disorders	4223	1.37%
Animal Diseases and Disorders	23117	7.53%
Animal Welfare	7202	2.34%
Diagnosis of diseases	3412	1.11%
Plant diseases	17	0.01%
Non-regulatory toxicology and ecotoxicology	7081	2.31%
Total	**307138**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	186497	33.6%
Other efficacy and tolerance testing	45456	8.19%
Toxicity and other safety testing including pharmacology	228227	41.12%
Routine production	94802	17.08%
Total	**554982**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	27627	14.81%
Pyrogenicity testing	347	0.19%
Batch potency testing	155904	83.6%
Other quality controls	2619	1.4%
Total	**186497**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	7255	3.18%
Skin irritation/corrosion	758	0.33%
Skin sensitisation	8604	3.77%
Eye irritation/corrosion	200	0.09%
Repeated dose toxicity	18970	8.31%
Carcinogenicity	799	0.35%
Genotoxicity	2743	1.2%
Reproductive toxicity	14000	6.13%
Developmental toxicity	17916	7.85%
Neurotoxicity	166	0.07%
Kinetics	30657	13.43%
Pharmaco-dynamics (incl safety pharmacology)	92116	40.36%
Phototoxicity		
Ecotoxicity	27424	12.02%
Safety testing in food and feed area	86	0.04%
Target animal safety	3905	1.71%
Other toxicity/safety testing	2628	1.15%
Total	**228227**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4278	58.97%
Other lethal methods	301	4.15%
Non lethal methods	2676	36.88%
Total	**7255**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	12698	66.94%
29 - 90 days	4491	23.67%
> 90 days	1781	9.39%
Total	**18970**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	6189	22.57%
Chronic toxicity	10807	39.41%
Reproductive ecotoxicity	1465	5.34%
Endocrine activity	5940	21.66%
Bioaccumulation	2831	10.32%
Other ecotoxicity	192	0.7%
Total	**27424**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	88584	93.44%
Monoclonal antibody by mouse ascites method	2147	2.26%
Other product types	4071	4.29%
Total	**94802**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	389067	70.1%
Legislation on medicinal products for veterinary use and their residues	29785	5.37%
Medical devices legislation	56928	10.26%
Industrial chemicals legislation	36967	6.66%
Plant protection product legislation	33617	6.06%
Biocides legislation	2077	0.37%
Food legislation including food contact material	3	0%
Feed legislation including legislation for the safety of target animals, workers and environment	3068	0.55%
Cosmetics legislation		
Other legislation	3470	0.63%
Total	**554982**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	501983	90.45%
Legislation satisfying national requirements only [within EU]	51318	9.25%
Legislation satisfying Non-EU requirements only	1681	0.3%
Total	**554982**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2071372	97.33%
Yes	56882	2.67%
Total	**2128254**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	146265	6.87%
Mild [up to and including]	1324548	62.24%
Moderate	500009	23.49%
Severe	157432	7.4%
Total	**2128254**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2027088	95.25%
Yes	101166	4.75%
Total	**2128254**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1273498	59.84%
Genetically altered without a harmful phenotype	723600	34%
Genetically altered with a harmful phenotype	131156	6.16%
Total	**2128254**	**100.00%**

Germany: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term 'animal experiment'. The figures are virtually unchanged compared to the previous year. Approximately 80% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds. Here, too, the figures are virtually unchanged compared to the previous year.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Approximately 736,000 animals were used to this end in 2017, which means that overall approximately 11,000 more animals were used than in the previous year. Correspondingly, these animals are not included in the numbers of experimental animals submitted to the European Commission.

Genetically modified animals

The number of genetically modified animals has remained largely stable in comparison to the previous year. Approximately 1,150,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 41% (in 2016 this was approximately 42%). In particular mice (89%) and fish (10%) were used.

Primates

However, the number of primates used showed a definite increase. In 2017 a total of 3,525 primates were used, 1,063 more than in the previous year.

Simians have a genome that is comparable to that of humans, and their total bodily function is also more similar to that of humans. Therefore it is likely that some diseases that cannot be imitated well in the mouse by means of genetic modification can present well in simians in this way. These genetically modified simians could result in a major step towards better understanding very significant, hitherto incurable and terminal diseases and therefore put new therapies within our grasp.

Dogs and cats

The number of dogs and cats used amounted to 3,334 and 718 respectively, used in particular for statutory testing and for applied research. As compared to the previous year, there was an overall decrease in the number of dogs (3,977 in 2016) and cats (766 in 2016).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 50% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal diseases. Approximately 27% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 8% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2016 there was a slight decrease in the area of basic research (approximately 3%), while the other areas each saw a minimal increase of approximately 1%.

- **Basic research**
  Within basic research, research into the nervous system (approximately 21%) and the immune system (approximately 20%) was particularly important in 2017. As such, research into the nervous system showed an increase of approximately 6% compared to the previous year.
- **Human and animal diseases**
  Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 41% of test animals used in this field of research were utilised. This is a slight increase as compared to 2016 (approximately 37%).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'low' (approximately 59%). The share of animal experiments classified as 'medium' or 'severe' was approximately 27% and 5% respectively. Compared to the previous year, the number of experiments classified as 'medium' showed a slight increase of 4%, while the number of experiments classified as 'severe' showed a slight decrease of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 9% and thereby at a slightly higher level than the previous year (approximately 7%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The German Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) is endeavouring to reduce the number of animals used in experiments. For this reason various projects are initiated and supported with the goal of replacing animal experiments with alternative methods as soon as possible. These projects include establishing and operating the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R), promoting research by the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR), supporting the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur

Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments) and annually awarding the BMEL's Animal Welfare Research Prize. In 2016 the amount of the prize was increased from €15,000 to €25,000.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Category 'other animal species'

In this category, particularly in the areas 'other fish species' and 'other bird species', there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, brown trout) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was 'low'.

Among birds, primarily turkeys and local wild bird species (e.g. tit, duck, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was 'low'.

Moreover, in the areas 'other carnivores' and 'other amphibians' there were a smaller number of additional species. For instance, among carnivores minks were particularly used in the context of vaccine tolerability testing, while in the area of amphibians primarily the common toad, fire salamander, axolotl and common frog were used with the aim of protecting the natural environment in the interest of human and animal health or welfare.

Category 'other uses'

The emphasis in this category is in the areas 'basic research' and 'regulatory purposes'.

In the context of **basic research** there was particular emphasis on the following areas:

- creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
- molecular developmental genetics;
- research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
- research in the field of human and animal microbiology;
- research in the context of gerontology.

As a rule the severity classification for the animals involved was between 'low' and 'medium'.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- testing the effectiveness and mechanism of feed additives;
- pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was between 'low' and 'medium'.

Category 'other legal provisions'

In the context of this category the following other legal provisions are particularly referred to:

- test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
- test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);
- test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
- test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from 'low' to 'severe').

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 there were no experiments carried out in Germany in the context of which the classification exceeded 'severe'.

Germany: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1368447	66.15%
Rats	255449	12.35%
Guinea-Pigs	14851	0.72%
Hamsters (Syrian)	1222	0.06%
Hamsters (Chinese)	8	0%
Mongolian gerbil	4255	0.21%
Other Rodents	9950	0.48%
Rabbits	92661	4.48%
Cats	718	0.03%
Dogs	3330	0.16%
Ferrets	196	0.01%
Other carnivores	535	0.03%
Horses, donkeys and cross-breeds	1209	0.06%
Pigs	17347	0.84%
Goats	212	0.01%
Sheep	3053	0.15%
Cattle	6332	0.31%

Animal Species	Number of animals	Percentage
Prosimians	87	0%
Marmoset and tamarins	224	0.01%
Cynomolgus monkey	3002	0.15%
Rhesus monkey	117	0.01%
Vervets (Chlorocebus spp.)	15	0%
Baboons	14	0%
Squirrel monkey	1	0%
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	12	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1352	0.07%
Domestic fowl	24920	1.2%
Other birds	12000	0.58%
Reptiles	369	0.02%
Rana	377	0.02%
Xenopus	4546	0.22%
Other Amphibians	2652	0.13%
Zebra fish	141676	6.85%
Other Fish	97674	4.72%
Cephalopods		
Total	**2068813**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1900118	93.64%
Animals born in the EU but not at a registered breeder	100821	4.97%
Animals born in rest of Europe	15127	0.75%
Animals born in rest of world	13056	0.64%
Total	**2029122**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	360	13.39%
Animals born in rest of Europe		
Animals born in Asia	1699	63.21%
Animals born in America		
Animals born in Africa	628	23.36%
Animals born elsewhere	1	0.04%
Total	**2688**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	338	12.57%
F2 or greater	1786	66.44%
Self-sustaining colony	564	20.98%
Total	**2688**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1039225	50.23%
Translational and applied research	304599	14.72%
Regulatory use and Routine production	556946	26.92%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8491	0.41%
Preservation of species	41156	1.99%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	53121	2.57%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	65275	3.16%
Total	**2068813**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	91387	8.79%
Cardiovascular Blood and Lymphatic System	109053	10.49%
Nervous System	216128	20.8%
Respiratory System	23579	2.27%
Gastrointestinal System including Liver	33087	3.18%
Musculoskeletal System	25657	2.47%
Immune System	202581	19.49%
Urogenital/Reproductive System	23426	2.25%
Sensory Organs (skin, eyes and ears)	27801	2.68%
Endocrine System/Metabolism	57885	5.57%
Multisystemic	57475	5.53%
Ethology / Animal Behaviour /Animal Biology	46306	4.46%
Other basic research	124860	12.01%
Total	**1039225**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	125614	41.24%
Human Infectious Disorders	18388	6.04%
Human Cardiovascular Disorders	16923	5.56%
Human Nervous and Mental Disorders	38573	12.66%
Human Respiratory Disorders	13371	4.39%
Human Gastrointestinal Disorders including Liver	15898	5.22%
Human Musculoskeletal Disorders	3939	1.29%
Human Immune Disorders	11659	3.83%
Human Urogenital/Reproductive Disorders	4784	1.57%
Human Sensory Organ Disorders (skin, eyes and ears)	6500	2.13%
Human Endocrine/Metabolism Disorders	12138	3.98%
Other Human Disorders	1227	0.4%
Animal Diseases and Disorders	17368	5.7%
Animal Welfare	6271	2.06%
Diagnosis of diseases	2488	0.82%
Plant diseases	69	0.02%
Non-regulatory toxicology and ecotoxicology	9389	3.08%
Total	**304599**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	188089	33.77%
Other efficacy and tolerance testing	32991	5.92%
Toxicity and other safety testing including pharmacology	260473	46.77%
Routine production	75393	13.54%
Total	**556946**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	19382	10.3%
Pyrogenicity testing	5591	2.97%
Batch potency testing	161272	85.74%
Other quality controls	1844	0.98%
Total	**188089**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10357	3.98%
Skin irritation/corrosion	884	0.34%
Skin sensitisation	8711	3.34%
Eye irritation/corrosion	171	0.07%
Repeated dose toxicity	19136	7.35%
Carcinogenicity	1961	0.75%
Genotoxicity	3522	1.35%
Reproductive toxicity	21926	8.42%
Developmental toxicity	35887	13.78%
Neurotoxicity	86	0.03%
Kinetics	31782	12.2%
Pharmaco-dynamics (incl safety pharmacology)	79250	30.43%
Phototoxicity		
Ecotoxicity	38843	14.91%
Safety testing in food and feed area	1721	0.66%
Target animal safety	3423	1.31%
Other toxicity/safety testing	2813	1.08%
Total	**260473**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4136	39.93%
Other lethal methods	182	1.76%
Non lethal methods	6039	58.31%
Total	**10357**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13183	68.89%
29 - 90 days	4136	21.61%
> 90 days	1817	9.5%
Total	**19136**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	6957	17.91%
Chronic toxicity	16704	43%
Reproductive ecotoxicity	904	2.33%
Endocrine activity	5840	15.03%
Bioaccumulation	1807	4.65%
Other ecotoxicity	6631	17.07%
Total	**38843**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	73520	97.52%
Monoclonal antibody by mouse ascites method	384	0.51%
Other product types	1489	1.97%
Total	**75393**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	372333	66.85%
Legislation on medicinal products for veterinary use and their residues	23641	4.24%
Medical devices legislation	54817	9.84%
Industrial chemicals legislation	50724	9.11%
Plant protection product legislation	46229	8.3%
Biocides legislation	2366	0.42%
Food legislation including food contact material	14	0%
Feed legislation including legislation for the safety of target animals, workers and environment	3554	0.64%
Cosmetics legislation		
Other legislation	3268	0.59%
Total	**556946**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	543850	97.65%
Legislation satisfying national requirements only [within EU]	4078	0.73%
Legislation satisfying Non-EU requirements only	9018	1.62%
Total	**556946**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2031810	98.21%
Yes	37003	1.79%
Total	**2068813**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	178095	8.61%
Mild [up to and including]	1226990	59.31%
Moderate	548621	26.52%
Severe	115107	5.56%
Total	**2068813**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	1891562	91.43%
Yes	177251	8.57%
Total	**2068813**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1241283	60%
Genetically altered without a harmful phenotype	658801	31.84%
Genetically altered with a harmful phenotype	168729	8.16%
Total	**2068813**	**100.00%**

Greece

Greece: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

An increasing trend in the use of animals used for scientific purposes may be observed in 2015 compared to 2014. This is justified due to the fact that a lot of European research projects, which were funded by the European Union (ERC) were performed. 2015 has been a period where applications to receive funding from HORIZON 2020 were pending or were in the process to be approved.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

A) A significant use of fish is depicted in Greek statistical data in 2015 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 4-fold increase of use of domestic fowls is being recorded for 2015 and can be attributed the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2014, which can be attributed to the research projects performed

D) There is an increasing trend regarding the reuse of animals in the context of an attempt to reduce the number of animals used for scientific purposes.

E) A significant increase in the use of genetically altered animals without a harmful genotype by approximately 20% can be attributed to the HORIZON 2020 related projects.

F) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

G) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

An increase of “severe” use of animals is reported for 2015 compared to 2014 and is attributed to projects which included complicated surgical techniques, oncology and toxicology tests for regulatory use and routine production.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A significant proportion of other fish is reported in Greece for 2015. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

In one case legislation on medicinal products for veterinary use and their residues is recorded.

Rodents have been used for various ‘other” purposes in 2015, but not in an exceptional trend.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2015.

Greece: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	28849	53.67%
Rats	2205	4.1%
Guinea-Pigs	11	0.02%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	611	1.14%
Cats	47	0.09%
Dogs	4	0.01%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	430	0.8%
Goats		
Sheep	8	0.01%

Animal Species	Number of animals	Percentage
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	1606	2.99%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians	200	0.37%
Zebra fish	4675	8.7%
Other Fish	15099	28.09%
Cephalopods		
Total	**53748**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	53337	99.96%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world	20	0.04%
Total	**53357**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	1	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**1**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	1	100%
Self-sustaining colony		
Total	**1**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38599	71.81%
Translational and applied research	6463	12.02%
Regulatory use and Routine production	7589	14.12%
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	1097	2.04%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**53748**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4102	10.63%
Cardiovascular Blood and Lymphatic System	6710	17.38%
Nervous System	1541	3.99%
Respiratory System	124	0.32%
Gastrointestinal System including Liver	896	2.32%
Musculoskeletal System	908	2.35%
Immune System	3325	8.61%
Urogenital/Reproductive System	179	0.46%
Sensory Organs (skin, eyes and ears)	745	1.93%
Endocrine System/Metabolism	1110	2.88%
Multisystemic	1098	2.84%
Ethology / Animal Behaviour /Animal Biology	14299	37.05%
Other basic research	3562	9.23%
Total	**38599**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	915	14.16%
Human Infectious Disorders	470	7.27%
Human Cardiovascular Disorders	1	0.02%
Human Nervous and Mental Disorders	967	14.96%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	160	2.48%
Human Musculoskeletal Disorders	1825	28.24%
Human Immune Disorders	205	3.17%
Human Urogenital/Reproductive Disorders	12	0.19%
Human Sensory Organ Disorders (skin, eyes and ears)	90	1.39%
Human Endocrine/Metabolism Disorders	83	1.28%
Other Human Disorders	404	6.25%
Animal Diseases and Disorders		
Animal Welfare	165	2.55%
Diagnosis of diseases	788	12.19%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	378	5.85%
Total	**6463**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Toxicity and other safety testing including pharmacology	7580	99.88%
Routine production	9	0.12%
Total	**7589**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	800	10.55%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	6780	89.45%
Total	**7580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	800	100%
Other lethal methods		
Non lethal methods		
Total	**800**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	9	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**9**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	9	0.12%
Legislation on medicinal products for veterinary use and their residues	800	10.54%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	6780	89.34%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**7589**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7589	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**7589**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	53358	99.27%
Yes	390	0.73%
Total	**53748**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	949	1.77%
Mild [up to and including]	37804	70.34%
Moderate	11905	22.15%
Severe	3090	5.75%
Total	**53748**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	51409	95.65%
Yes	2339	4.35%
Total	**53748**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	40705	75.73%
Genetically altered without a harmful phenotype	11085	20.62%
Genetically altered with a harmful phenotype	1958	3.64%
Total	**53748**	**100.00%**

Greece: Narrative 2016

1. **General information on any changes in trends observed since the previous reporting period.**

Any significant changes of trends observed in 2016 compared to 2015 regarding the purpose of authorised projects can be attributed to their nature and number. This is directly related to funding resources and the choice of research purpose by user establishments.

A significant decrease in the use of animals for the creation of new genetic lines is reported and can be attributed to the lack of relevant funding by European research projects or absence of relevant application forms by researchers.

2**. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 2-fold increase of use of domestic fowls is being recorded for 2016 and can be attributed to the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2015, which can be attributed to the research projects performed during 2016.

D) A significant decrease in the use of genetically altered animals without a harmful phenotype by approximately 5% and an increase of genetically altered animals with a harmful phenotype can be attributed to relevant authorised projects.

E) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

F) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

No particular change in trends in actual severities are reported.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A significant proportion of other fish is reported in Greece for 2016. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

Rodents have been used for mouse development from epiblast derived cells in 2016, but not in an exceptional trend.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2016.

Greece: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	23946	52.65%
Rats	2222	4.89%
Guinea-Pigs	13	0.03%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	491	1.08%
Cats	13	0.03%
Dogs	3	0.01%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	333	0.73%
Goats		
Sheep	12	0.03%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0.01%

Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	3200	7.04%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	130	0.29%
Other Fish	15117	33.24%
Cephalopods		
Total	**45483**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	45127	99.83%
Animals born in the EU but not at a registered breeder	30	0.07%
Animals born in rest of Europe		
Animals born in rest of world	48	0.11%
Total	**45205**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**1**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	1	100%
Self-sustaining colony		
Total	**1**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	33690	74.07%
Translational and applied research	4514	9.92%
Regulatory use and Routine production	6630	14.58%
Protection of the natural environment in the interests of the health or welfare of human		

Purpose Category	Number of uses	Percentage
beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	649	1.43%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**45483**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	2377	7.06%
Cardiovascular Blood and Lymphatic System	2855	8.47%
Nervous System	1753	5.2%
Respiratory System	335	0.99%
Gastrointestinal System including Liver	915	2.72%
Musculoskeletal System	502	1.49%
Immune System	1300	3.86%
Urogenital/Reproductive System	97	0.29%
Sensory Organs (skin, eyes and ears)	1284	3.81%
Endocrine System/Metabolism	742	2.2%
Multisystemic	3075	9.13%
Ethology / Animal Behaviour /Animal Biology	14957	44.4%
Other basic research	3498	10.38%
Total	**33690**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1319	29.22%
Human Infectious Disorders	224	4.96%
Human Cardiovascular Disorders	385	8.53%
Human Nervous and Mental Disorders	526	11.65%
Human Respiratory Disorders	422	9.35%
Human Gastrointestinal Disorders including Liver	204	4.52%
Human Musculoskeletal Disorders	841	18.63%
Human Immune Disorders	135	2.99%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	67	1.48%
Human Endocrine/Metabolism Disorders	136	3.01%
Other Human Disorders	207	4.59%
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	48	1.06%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**4514**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		

Regulatory use and Routine production	Number of uses	Percentage
Routine production		
Toxicity and other safety testing including pharmacology	6630	100%
Total	**6630**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	6630	100%
Total	**6630**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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	6630	100%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**6630**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6630	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6630**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	45206	99.39%
Yes	277	0.61%
Total	**45483**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1873	4.12%
Mild [up to and including]	32156	70.7%
Moderate	8903	19.57%
Severe	2551	5.61%
Total	**45483**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	45053	99.05%
Yes	430	0.95%
Total	**45483**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	34912	76.76%
Genetically altered without a harmful phenotype	7683	16.89%
Genetically altered with a harmful phenotype	2888	6.35%
Total	**45483**	**100.00%**

Greece: Narrative 2017

1. **General information on any changes in trends observed since the previous reporting period.**

A significant increase in the use of animals for the creation of new genetic lines is reported and can be attributed to the increase of funding by European research projects.

A significant increase in the number of animals undergone "non-recovery" procedures has been reported. This is proportional to the number of animals used for higher education of training for the acquisition, training of improvement of vocational skills.

A new user establishment was authorised in 2017, which performs research projects on the protection of natural environment in the interests of the health of welfare of humans and animals. This is a new category of purposes in Greece.

2**. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as "mild".

B) A significant decrease in the use of domestic fowl is reported due to lack of relevant projects performed in 2017 by a user establishment.

C) Regarding the use of cephalopods (first time for Greece in 2017):

The application of the protocol had the objective to assess the sensitivity and immune response of *O. vulgaris* against common fish pathogens under different physicochemical water parameters (i.e. different temperatures). Animals are infected either intramuscularly or intravenously, hemolymph is collected for the assessment of immune stimulation and at the end of the experiment, organ samples are collected to assess immune responses and bacteria presence internally. All procedures are carried out under anesthesia, while organ sampling is performed after euthanasia with an overdose of anesthetic. In 2017, the protocol was applied once in 33 animals. From these, 9 individuals either died or used for the collection of samples and for 24 individuals, the protocol was characterized as mild. *O. vulgaris* were used by a newly authorised user establishment.

D) Regarding the use of animals for the protection of natural environment in the interests of the health or welfare of human beings or animals, that is recorded for the first time in 2017, these were used by a newly authorised user establishment.

E) It has to be noted that the use of various species differs among each year according to the protocols authorised and funding received by user establishments. Minor changing trends can be recorded.

F) It has to be noted that the use of animals for translational and applied research has increased by approximately 40% in total. This percentage in general differs among each year according to the protocols authorised and funding received by user establishments.

G) It has to be noted that the use of animals for various systems either for basic or translational and applied research varies among each year according to the nature of protocols chosen by researchers.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

A) Animals with “Non recovery” severity seem to have diminished due to a decrease in higher education trainings programs that are performed with the use of live animals in Greece.

B) The application of experimental protocols on teleosts by a newly authorised user establishment had the objective to assess either resistance of fish to fish pathogens or the efficacy of vaccines. These protocols were classified as severe because mortality is caused near to or more than > 70%. For 2017, gilthead sea bream and European sea bass were used.

C) A significant increase in the use of animals in translational/applied research for human cancer has been noted in 2017 compared to 2016 which has resulted in the relevant increase of the severe use of those animals. This can attributed to the increase of funding research programmes in this sector.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Laboratory animal science training courses are organised annually in Greece.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

A) A significant proportion of other fish is reported in Greece for 2017. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

B) A number of rodents have been reported under ‘Translational/ Applied research”: Other human disorders, as having been used in multisystemic protocols including arthritis and enteropathy.

C) A number of rodents have been reported for aging studies using “mild” procedures.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such case reported for 2017.

Greece: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	25479	54.52%
Rats	2438	5.22%
Guinea-Pigs	6	0.01%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	213	0.46%
Cats	8	0.02%
Dogs	41	0.09%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	289	0.62%
Goats		
Sheep	8	0.02%
Cattle	3	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	1	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	6	0.01%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	1859	3.98%
Other Fish	16346	34.98%
Cephalopods	33	0.07%
Total	**46730**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	45596	98.55%
Animals born in the EU but not at a registered breeder	33	0.07%
Animals born in rest of Europe		
Animals born in rest of world	640	1.38%
Total	**46269**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	27573	59%
Translational and applied research	8058	17.24%
Regulatory use and Routine production	6887	14.74%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3093	6.62%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1119	2.39%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**46730**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	923	3.35%
Cardiovascular Blood and Lymphatic System	1315	4.77%
Nervous System	1204	4.37%
Respiratory System		
Gastrointestinal System including Liver	428	1.55%
Musculoskeletal System	520	1.89%
Immune System	2225	8.07%
Urogenital/Reproductive System	242	0.88%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	988	3.58%
Endocrine System/Metabolism	843	3.06%
Multisystemic	99	0.36%
Ethology / Animal Behaviour /Animal Biology	14686	53.26%
Other basic research	4100	14.87%
Total	**27573**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2487	30.86%
Human Infectious Disorders	271	3.36%
Human Cardiovascular Disorders	967	12%
Human Nervous and Mental Disorders	1372	17.03%
Human Respiratory Disorders	291	3.61%
Human Gastrointestinal Disorders including Liver	363	4.5%
Human Musculoskeletal Disorders	710	8.81%
Human Immune Disorders	200	2.48%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	381	4.73%
Human Endocrine/Metabolism Disorders	34	0.42%
Other Human Disorders	648	8.04%
Animal Diseases and Disorders		
Animal Welfare	40	0.5%
Diagnosis of diseases	230	2.85%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	64	0.79%
Total	**8058**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	6887	100%
Total	**6887**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Pharmaco-dynamics (incl safety pharmacology)	10	0.15%
Safety testing in food and feed area	6877	99.85%
Total	**6887**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	10	0.15%
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	6877	99.85%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**6887**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6887	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6887**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	46269	99.01%
Yes	461	0.99%
Total	**46730**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3646	7.8%
Mild [up to and including]	29392	62.9%
Moderate	9198	19.68%
Severe	4494	9.62%
Total	**46730**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	42770	91.53%
Yes	3960	8.47%
Total	**46730**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	31622	67.67%
Genetically altered without a harmful phenotype	12982	27.78%
Genetically altered with a harmful phenotype	2126	4.55%
Total	**46730**	**100.00%**

Hungary

Hungary: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2015 was 195 603 which represents 2.7 % decrease compared to the same figure of 2014. The number of re-uses has been decreased by 56% (from 6584 to 2924).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The increase was 10.8% in the number of mice, 3.65% in case of rats, 23.22% for guinea-pigs and 29.08% in the case of rabbits. Both the number and the proportion of rodents increased since 2014 (hamsters and other rodents represents only a small percentage of rodents), the proportion of them is about 63% (it was 57% in 2014 and 61% in 2013).

The number of used birds is still very high (50 117), and the proportion of domestic fowls grew among them from 89.39% to 96.23% (mainly because of the decrease in the number of other poultry species).

The number of used cats was more than 4 times higher than in 2014 (60 compared to 14), in contrast the number of dogs decreased by 42% (from 859 to 495).

There was a 10% decrease in the number of pigs (in opposition to the growing tendency during the last few years). Notable changes can be observed also in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

The number of zebra fish and other fishes decreased by 83% and more than 25%. The number of amphibians also decreased by about 25% (form 8373 to 6286), but it is still high compared to the period between 2007 and 2012 (it was ranged between 340 and 1807). The number of reptiles is only 12 compared to 62 in 2014.

When analysed by the purposes of the use of animals a large decrease can be observed in the fundamental biological research segment (more than 47%), and the number of animals used in education has also decreased (by nearly 62%). On the other hand remarkable increase can be observed in applied and translational research (almost 28%) – which was a key reason for the increase in the number of used rodents –, in regulatory and routine production (16.59%), and also in the number of animals used for the preservation of species (more than 70%) and used for the protection of the natural environment (which is 133 times more than in 2014).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of non-recoveries was dropped from 21.61% to 12.78%, the proportion of severe uses from 6.90% to 6.01%, and the moderate uses from 16.55% to 14.12%. On the other hand mild uses increased from 54.95% to 67.10%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Xenopus spp., *Rana temporaria* or *Rana pipiens* were not used in 2015; therefore the ratio of other amphibians is 100%. High number of *Bufo bufo* (5400 individuals, 85.91% of all amphibians), and also *Lissotriton vulgaris* (526 individuals) and *Rana dalmatina* (360 individuals) used for the preservation of species and for the protection of the natural environment in the interest of the health or welfare of human beings or animals.

The ratio of other fish is 69.23% mainly due to the high number of *Poecilia reticulata* used in regulatory ecotoxicology tests (2250 individuals, 49.82% of other fish) and farm fish species (e.g. *Cyprinus carpio*).

The ratio of other category in routine production is 100% (it is worth to note that the total number of animals used for routine production is quite low, only 603 individuals, so a single project can greatly influence the ratio).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	84650	43.28%
Rats	35037	17.91%
Guinea-Pigs	4113	2.1%
Hamsters (Syrian)	1	0%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	36	0.02%
Rabbits	5256	2.69%
Cats	60	0.03%
Dogs	495	0.25%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	2884	1.47%
Goats		

Animal Species	Number of animals	Percentage
Sheep	110	0.06%
Cattle	20	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	3	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	48230	24.66%
Other birds	1887	0.96%
Reptiles	12	0.01%
Rana		
Xenopus		
Other Amphibians	6286	3.21%
Zebra fish	2007	1.03%
Other Fish	4516	2.31%
Cephalopods		
Total	**195603**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	174024	90.32%
Animals born in the EU but not at a registered breeder	15917	8.26%
Animals born in rest of Europe	2236	1.16%
Animals born in rest of world	499	0.26%
Total	**192676**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	3	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**3**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	3	100%
Self-sustaining colony		
Total	**3**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38544	19.71%
Translational and applied research	63815	32.62%
Regulatory use and Routine production	84310	43.1%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6006	3.07%
Preservation of species	960	0.49%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1968	1.01%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**195603**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	5013	13.01%
Cardiovascular Blood and Lymphatic System	2813	7.3%
Nervous System	12887	33.43%
Respiratory System	299	0.78%
Gastrointestinal System including Liver	2069	5.37%
Musculoskeletal System	382	0.99%
Immune System	3075	7.98%
Urogenital/Reproductive System	2459	6.38%
Sensory Organs (skin, eyes and ears)	239	0.62%
Endocrine System/Metabolism	2249	5.83%
Multisystemic	2259	5.86%
Ethology / Animal Behaviour /Animal Biology	2443	6.34%
Other basic research	2357	6.12%
Total	**38544**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2223	3.48%
Human Infectious Disorders	228	0.36%
Human Cardiovascular Disorders	499	0.78%
Human Nervous and Mental Disorders	43979	68.92%
Human Respiratory Disorders	81	0.13%
Human Gastrointestinal Disorders including Liver	278	0.44%
Human Musculoskeletal Disorders		
Human Immune Disorders	580	0.91%
Human Urogenital/Reproductive Disorders	179	0.28%
Human Sensory Organ Disorders (skin, eyes and ears)	74	0.12%
Human Endocrine/Metabolism Disorders	116	0.18%
Other Human Disorders	294	0.46%
Animal Diseases and Disorders	11335	17.76%
Animal Welfare	492	0.77%
Diagnosis of diseases	1981	3.1%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1476	2.31%
Total	**63815**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	49504	58.72%
Other efficacy and tolerance testing	192	0.23%
Toxicity and other safety testing including pharmacology	34011	40.34%
Routine production	603	0.72%
Total	**84310**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	17400	35.15%
Pyrogenicity testing	952	1.92%
Batch potency testing	30891	62.4%
Other quality controls	261	0.53%
Total	**49504**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16836	49.5%
Skin irritation/corrosion	336	0.99%
Skin sensitisation	4800	14.11%
Eye irritation/corrosion	329	0.97%
Repeated dose toxicity	3705	10.89%
Carcinogenicity		
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Genotoxicity	643	1.89%
Reproductive toxicity	1048	3.08%
Developmental toxicity	667	1.96%
Kinetics	486	1.43%
Pharmaco-dynamics (incl safety pharmacology)	392	1.15%
Ecotoxicity	3936	11.57%
Target animal safety	694	2.04%
Other toxicity/safety testing	139	0.41%
Total	**34011**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	15320	91%
Other lethal methods		
Non lethal methods	1516	9%
Total	**16836**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2226	60.08%
29 - 90 days	615	16.6%
> 90 days	864	23.32%
Total	**3705**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3936	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**3936**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	603	100%
Total	**603**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25232	29.93%
Legislation on medicinal products for veterinary use and their residues	51951	61.62%
Medical devices legislation	30	0.04%
Industrial chemicals legislation		
Plant protection product legislation	4664	5.53%
Biocides legislation	3	0%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	180	0.21%
Cosmetics legislation		
Other legislation	2250	2.67%
Total	**84310**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	83159	98.63%
Legislation satisfying national requirements only [within EU]	310	0.37%
Legislation satisfying Non-EU requirements only	841	1%
Total	**84310**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	192679	98.51%
Yes	2924	1.49%
Total	**195603**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	24993	12.78%
Mild [up to and including]	131240	67.1%
Moderate	27617	14.12%
Severe	11753	6.01%
Total	**195603**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	194120	99.24%
Yes	1483	0.76%
Total	**195603**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	188601	96.42%
Genetically altered without a harmful phenotype	6574	3.36%
Genetically altered with a harmful phenotype	428	0.22%
Total	**195603**	**100.00%**

Hungary: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2016 was 170 075 which represents about 13% decrease compared to the same figure of 2015 (there was also a downward trend in the last few years). The number of re-uses has also been decreased by 15% (from 2924 to 2493).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The vast majority (92.39%) of used animals – as in previous years – were warm-blooded vertebrates. There was increase in the proportion of mammals (form 67.82% to 75.14%) and amphibians (from 3.21% to 4.79%), while the proportion of birds and fish decreased (the birds from 25.62% to 17.25% and the fish from 3.30% to 2.82%).

The proportion of rodents among mammals is about the same as last year. The increase was 10.63% in the number of rats and 23.85% in case of guinea-pigs. On the other hand there was an about 11% decrease in the number of mice. Hamsters and other rodents represent only a small percentage of rodents. The number of rabbits decreased by 35.65%.

The number of used cats was more than 4 times lower than in 2015 (14 compared to 60), in contrast the number of dogs increased by 27.27% (from 495 to 630). No non-human primate was used in 2016 (compared to the 3 Rhesus monkeys in 2015).

There was a 25.83% increase in the number of pigs. Notable decrease can be observed in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

There was an about 41% decrease in the number of used birds. The number of domestic fowl decreased by 43.39%, while the number of other birds increased by 8 %.

The number of other fishes decreased by 35%. The proportion of zebra fish is almost the same as in 2015. The number of other amphibians increased by 29.45% (form 6286 to 8137). The number of reptiles is only 2 compared to 12 in 2015.

When analysed by the purposes of the use of animals a large decrease can be observed in regulatory and routine production (about 25%) and in the number of animals used for the protection of the natural environment (nearly 85%). On the other hand remarkable increase can be observed in the number of animals used for the preservation of species (which is more than 5 times more than in 2015), used in education (more than 36%) and in the fundamental biological research segment (5.53%). The proportion of animals in applied and translational research is almost the same as in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of mild uses was dropped from 67.10% to 48.80%. On the other hand moderate uses increased from 14.12% to 23.98%, severe uses from 6.01% to 8.19% and non-recoveries from 12.78% to 19.03%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Only 6 *Rana temporaria* or *Rana pipiens* were used in 2016; therefore the ratio of other amphibians is 99.93%. High number of *Bufo bufo* (4830 individuals, 59.31% of all amphibians) and *Rana dalmatina* (3270 individuals, 40.16% of all amphibians) were used.

The ratio of other fish is 61.11% mainly due to the high number of farm fish species (e.g. *Cyprinus carpio, Oncorhynchus mykiss*) and *Poecilia reticulata* used in regulatory ecotoxicology tests.

The ratio of other category in routine production is 45.15% (it is worth to note that the total number of animals used for routine production is quite low, only 846 individuals, so a single project can greatly influence the ratio).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	76079	44.73%
Rats	38762	22.79%
Guinea-Pigs	5094	3%
Hamsters (Syrian)	63	0.04%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	40	0.02%
Rabbits	3363	1.98%
Cats	14	0.01%
Dogs	630	0.37%
Ferrets	8	0%
Other carnivores		
Horses, donkeys and cross-breeds		

Animal Species	Number of animals	Percentage
Pigs	3629	2.13%
Goats		
Sheep	91	0.05%
Cattle	16	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	27304	16.05%
Other birds	2039	1.2%
Reptiles	2	0%
Rana	6	0%
Xenopus		
Other Amphibians	8137	4.78%
Zebra fish	1866	1.1%
Other Fish	2932	1.72%
Cephalopods		
Total	**170075**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	147713	88.14%
Animals born in the EU but not at a registered breeder	19479	11.62%
Animals born in rest of Europe	40	0.02%
Animals born in rest of world	350	0.21%
Total	**167582**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	40678	23.92%
Translational and applied research	57752	33.96%
Regulatory use and Routine production	62895	36.98%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	950	0.56%
Preservation of species	5112	3.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2688	1.58%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**170075**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3669	9.02%
Cardiovascular Blood and Lymphatic System	2451	6.03%
Nervous System	15998	39.33%
Respiratory System	993	2.44%
Gastrointestinal System including Liver	3428	8.43%
Musculoskeletal System	663	1.63%
Immune System	3088	7.59%
Urogenital/Reproductive System	1759	4.32%
Sensory Organs (skin, eyes and ears)	721	1.77%
Endocrine System/Metabolism	2204	5.42%
Multisystemic	2112	5.19%
Ethology / Animal Behaviour /Animal Biology	1634	4.02%
Other basic research	1958	4.81%
Total	**40678**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3290	5.7%
Human Infectious Disorders	1367	2.37%
Human Cardiovascular Disorders	508	0.88%
Human Nervous and Mental Disorders	26418	45.74%
Human Respiratory Disorders	239	0.41%
Human Gastrointestinal Disorders including Liver	758	1.31%
Human Musculoskeletal Disorders	29	0.05%
Human Immune Disorders	354	0.61%
Human Urogenital/Reproductive Disorders	3	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	50	0.09%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	36	0.06%
Animal Diseases and Disorders	15687	27.16%
Animal Welfare	478	0.83%
Diagnosis of diseases	4509	7.81%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	4026	6.97%
Total	**57752**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25445	40.46%
Other efficacy and tolerance testing	70	0.11%
Toxicity and other safety testing including pharmacology	36534	58.09%
Routine production	846	1.35%
Total	**62895**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	11247	44.2%
Pyrogenicity testing	646	2.54%
Batch potency testing	13252	52.08%
Other quality controls	300	1.18%
Total	**25445**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	19234	52.65%
Skin irritation/corrosion	184	0.5%
Skin sensitisation	5438	14.88%
Eye irritation/corrosion	131	0.36%
Repeated dose toxicity	3804	10.41%
Carcinogenicity		
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Genotoxicity	1272	3.48%
Reproductive toxicity	340	0.93%
Developmental toxicity	1656	4.53%
Kinetics	875	2.4%
Pharmaco-dynamics (incl safety pharmacology)	204	0.56%
Ecotoxicity	2555	6.99%
Target animal safety	130	0.36%
Other toxicity/safety testing	711	1.95%
Total	**36534**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	16581	86.21%
Other lethal methods		
Non lethal methods	2653	13.79%
Total	**19234**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	466	12.25%
29 - 90 days	126	3.31%
> 90 days	3212	84.44%
Total	**3804**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2555	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**2555**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	114	13.48%
Monoclonal antibody by mouse ascites method	350	41.37%
Other product types	382	45.15%
Total	**846**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	27171	43.2%
Legislation on medicinal products for veterinary use and their residues	31160	49.54%
Medical devices legislation	21	0.03%
Industrial chemicals legislation	2966	4.72%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	526	0.84%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	1051	1.67%
Total	**62895**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	61739	98.16%
Legislation satisfying national requirements only [within EU]	723	1.15%
Legislation satisfying Non-EU requirements only	433	0.69%
Total	**62895**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	167582	98.53%
Yes	2493	1.47%
Total	**170075**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	32367	19.03%
Mild [up to and including]	82993	48.8%
Moderate	40784	23.98%
Severe	13931	8.19%
Total	**170075**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	168864	99.29%
Yes	1211	0.71%
Total	**170075**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	162097	95.31%
Genetically altered without a harmful phenotype	7170	4.22%
Genetically altered with a harmful phenotype	808	0.48%
Total	**170075**	**100.00%**

Hungary: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The total number of animals used for experimental and other scientific purposes in 2017 was 141 183 which represents about 17% decrease compared to the same figure of 2016 (there was also a downward trend in the last few years). The number of re-uses has been increased by 300% (from 2493 to 7520).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The vast majority (97.58%) of used animals were warm-blooded vertebrates. There was increase in the proportion of mammals (form 75.14% to 78.28%) and birds (from 17.25% to 19.30%), while the proportion of amphibians and fish decreased (amphibians from 4.79% to 0.0% and the fish from 2.82% to 2.42%).

The proportion of rodents among mammals increased from 93.93% to 95.92%. There was 19% decrease in the number of mice and 30% in the number of rats. In case of guinea-pigs was 11% increase. On the other hand there was a dramatically increase at other rodents. Hamsters decreased to 0%. The number of rabbits decreased by 53%.

The number of used cats was a small increase (14 compared to 16). The number of dogs decreased by 36% (from 630 to 463). Two non-human primate was used in 2017 (compared to the 0 Rhesus monkeys in 2016).

There was 33.72% decrease in the number of pigs. Notable decrease can be observed in the proportion of other sheep, but increase in case of cattle, but their number is relatively low which could cause fluctuation.

The number of domestic fowl decreased by 7.82%, while the number of other birds increased by 2.2 %.

The proportion of zebra fish increased by 16.8% and other fish decreased by 59.95%. The number of other amphibians dramatically decreased to 0% (form 8137). The number of reptiles is 0 compared to 2 in 2016.

When analysed by the purposes of the use of animals a small increase can be observed in regulatory and routine production (about 6.3%) and in the number of animals used for the protection of the natural environment and preservation of species decreased to 0%. The proportion of basic research, animals in applied and translational research shows decrease than in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of mild uses was increased from 48.80% to 49.85%. and moderate uses also from 23.98% to 28.60%, severe uses from 8.19% to 12.76%. It means there was 30% increase in number of severe procedures. This increase was highly influented by two projects with animal diseases and disorders purpose. It contains 5071 Gallus gallus domesticus and 1224 Sus scrofa domesticus.

On the other hand non-recoveries decreased from 19.03% to 8.79%.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The number of other amphibians dramatically decreased from 8137 to 0 in 2017. The reason is there is an establishment, where in 2016 investigated *Rana dalmatina, Bufo bufo, Lissortion vulgaris*. There was mainly eggs collection at the natural habitat and after incubation investigated juvenils and natural predators. At the end of the project more than 3700 amphibians were released into their habitat. These projects were categorized into protection of the natural environment and preservation of species. It explains the dramatically decrease to 0 value in purpose category.

The number of used rabbits decreased by 53%. In 2016 there were projects a batch safety testing project with 1097 rabbits and a pyrogenicity testing with 606 rabbits. The reason for the 53% decrease is this 2 projects ended in 2016.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Cases where the 'severe' classification is exceeded did not occur.

Hungary: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	65876	46.8%
Rats	33946	24.12%
Guinea-Pigs	5765	4.1%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	1583	1.12%
Cats	16	0.01%
Dogs	463	0.33%
Ferrets	4	0%
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	2405	1.71%
Goats		

Animal Species	Number of animals	Percentage
Sheep		
Cattle	33	0.02%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	2	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	25169	17.88%
Other birds	2084	1.48%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	2243	1.59%
Other Fish	1174	0.83%
Cephalopods		
Total	**140763**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	126683	95.08%
Animals born in the EU but not at a registered breeder	5062	3.8%
Animals born in rest of Europe	1187	0.89%
Animals born in rest of world	309	0.23%
Total	**133241**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	2	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**2**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	2	100%
Self-sustaining colony		
Total	**2**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	38539	27.38%
Translational and applied research	41847	29.73%
Regulatory use and Routine production	58007	41.21%
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	2370	1.68%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**140763**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3346	8.68%
Cardiovascular Blood and Lymphatic System	3406	8.84%
Nervous System	16498	42.81%
Respiratory System	718	1.86%
Gastrointestinal System including Liver	1865	4.84%
Musculoskeletal System	189	0.49%
Immune System	4412	11.45%
Urogenital/Reproductive System	1678	4.35%
Sensory Organs (skin, eyes and ears)	488	1.27%
Endocrine System/Metabolism	1417	3.68%
Multisystemic	2369	6.15%
Ethology / Animal Behaviour /Animal Biology	526	1.36%
Other basic research	1627	4.22%
Total	**38539**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	4919	11.75%
Human Infectious Disorders	581	1.39%
Human Cardiovascular Disorders	293	0.7%
Human Nervous and Mental Disorders	20172	48.2%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	211	0.5%
Human Musculoskeletal Disorders	79	0.19%
Human Immune Disorders	89	0.21%
Human Urogenital/Reproductive Disorders	8	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	40	0.1%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders		
Other Human Disorders	224	0.54%
Animal Diseases and Disorders	9410	22.49%
Animal Welfare	4573	10.93%
Diagnosis of diseases	788	1.88%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	460	1.1%
Total	**41847**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	27156	46.82%
Other efficacy and tolerance testing	329	0.57%
Toxicity and other safety testing including pharmacology	29813	51.4%
Routine production	709	1.22%
Total	**58007**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	10102	37.2%
Pyrogenicity testing	29	0.11%
Batch potency testing	16682	61.43%
Other quality controls	343	1.26%
Total	**27156**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	17639	59.17%
Skin irritation/corrosion	293	0.98%
Skin sensitisation	4629	15.53%
Eye irritation/corrosion	137	0.46%
Repeated dose toxicity	1125	3.77%
Carcinogenicity	40	0.13%
Genotoxicity	562	1.89%
Reproductive toxicity	833	2.79%
Developmental toxicity	1286	4.31%
Neurotoxicity		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Kinetics	1207	4.05%
Pharmaco-dynamics (incl safety pharmacology)	569	1.91%
Ecotoxicity	1028	3.45%
Other toxicity/safety testing	465	1.56%
Total	**29813**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	14255	80.82%
Other lethal methods		
Non lethal methods	3384	19.18%
Total	**17639**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	438	38.93%
29 - 90 days	75	6.67%
> 90 days	612	54.4%
Total	**1125**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1028	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1028**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	40	5.64%
Monoclonal antibody by mouse ascites method	157	22.14%
Other product types	512	72.21%
Total	**709**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	25062	43.21%
Legislation on medicinal products for veterinary use and their residues	28770	49.6%
Medical devices legislation	516	0.89%
Industrial chemicals legislation	834	1.44%
Plant protection product legislation	2167	3.74%
Biocides legislation		
Food legislation including food contact material	461	0.79%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	197	0.34%
Total	**58007**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	56731	97.8%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	1276	2.2%
Total	**58007**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	133243	94.66%
Yes	7520	5.34%
Total	**140763**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	12410	8.82%
Mild [up to and including]	70383	50%
Moderate	39954	28.38%
Severe	18016	12.8%
Total	**140763**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	139882	99.37%
Yes	881	0.63%
Total	**140763**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	132229	93.94%
Genetically altered without a harmful phenotype	7898	5.61%
Genetically altered with a harmful phenotype	636	0.45%
Total	**140763**	**100.00%**

Ireland

Ireland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

- There was a 1% increase in animal uses from 2014 to 2015.
- There was a 31% drop in procedures reported as severe from 2014 to 2015.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

- Although the majority of animals are still used for regulatory purposes, basic research overtook translational research as the second most common project purpose. The increase in numbers used for basic research went from 34,512 in 2014 to 42,347 in 2015, an increase of 23%. The species that account for most of this increase in basic research were cattle, pigs and fish, in particular cattle of which there were 7,246 uses in 2015 compared to 2,712 uses in 2014. A significant amount of agricultural research is performed in Ireland, and much of this is reported (based on our advice) as 'Basic research – ethology/animal behaviour/animal biology' because it involves feeding trials and investigation into reproductive efficiency. For example, over 2000 cattle were used for a single epidemiological study of the key factors affecting reproductive efficiency of beef cattle herds. This could potentially also be considered as translational research but it doesn't quite fit into the categories 'animal diseases and disorders' nor 'animal welfare'.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

- Non-recovery: 1% (2014) to 2% (2015)
- Mild: 28% (2014) to 50% (2015)
- Moderate: 32% (2014) to 22% (2015)
- Severe: 40% (2014) to 27% (2015)
- Overall there was a drop in severe and moderate procedures and an increase in mild and non-recovery procedures. The reason for this is unknown; but we would be cautious about over-interpreting this as it may be due to people becoming more accustomed to recording actual severity properly, rather than recording what they were prospectively authorised for.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- In 2015 we made it mandatory for humane endpoints to be implemented for LD50 tests in Ireland; however progress is slow re-validating the different assays so this has not impacted on the statistics, and the eventual impact on the statistics will probably be minimal, as animals will

have already reached a 'severe' severity when they are culled. We have also been in frequent contact with pharmaceutical companies producing botulinum toxin products in relation to the replacement of animal tests with non-animal assays so we would hope to see a drop in LD50 testing over the next few years when more of these cell-based assays become available for use.

- In 2015 we also contacted all pharmaceutical companies using rabbit pyrogen testing for their products in Ireland requesting they switch to an alternative or provide robust scientific justification for the use of an animal test. This communication has not had a major impact on the statistics for 2015 with 570 rabbits used for pyrogen testing in 2015 (versus 597 in 2014) but we would hope that the positive impact of this dialogue becomes evident in the 2016 statistics..

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

- We did not have many animals reported under the 'other' category because we combed through each submission and made sure that if there was an appropriate pre-existing category available, that it was chosen. However, it should be noted that as previously mentioned, a lot of the agricultural research in Ireland could be considered translational, yet there is no appropriate translational category. Animal diseases and disorders is not accurate because these are healthy animals and animal welfare is not appropriate either as most of the research is not to benefit the animal, but to improve yields (e.g. milk, meat) and efficiency and therefore benefit the farmer and the economy. Perhaps there could be a translational category appropriate for this type of work?

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

- The severe classification was not exceeded in 2015.

Ireland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	190585	83.47%
Rats	9876	4.33%
Guinea-Pigs	1929	0.84%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	2490	1.09%
Cats	164	0.07%
Dogs	587	0.26%
Ferrets	621	0.27%
Other carnivores		
Horses, donkeys and cross-breeds	127	0.06%

Animal Species	Number of animals	Percentage
Pigs	2372	1.04%
Goats	71	0.03%
Sheep	1112	0.49%
Cattle	11119	4.87%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	20	0.01%
Domestic fowl	113	0.05%
Other birds	572	0.25%
Reptiles		
Rana		
Xenopus	420	0.18%
Other Amphibians		
Zebra fish	1489	0.65%
Other Fish	4672	2.05%
Cephalopods		
Total	**228339**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	209587	92.77%
Animals born in the EU but not at a registered breeder	15014	6.65%
Animals born in rest of Europe	129	0.06%
Animals born in rest of world	1195	0.53%
Total	**225925**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	42179	18.47%
Translational and applied research	22516	9.86%
Regulatory use and Routine production	157872	69.14%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	815	0.36%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	389	0.17%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	4568	2%
Total	**228339**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1061	2.52%
Cardiovascular Blood and Lymphatic System	429	1.02%
Nervous System	8542	20.25%
Respiratory System	473	1.12%
Gastrointestinal System including Liver	2943	6.98%
Musculoskeletal System	278	0.66%
Immune System	13168	31.22%
Urogenital/Reproductive System	2378	5.64%
Sensory Organs (skin, eyes and ears)	1543	3.66%
Endocrine System/Metabolism	578	1.37%
Multisystemic	1601	3.8%
Ethology / Animal Behaviour /Animal Biology	9185	21.78%
Other basic research		
Total	**42179**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1209	5.37%
Human Infectious Disorders	1413	6.28%
Human Cardiovascular Disorders	1002	4.45%
Human Nervous and Mental Disorders	4173	18.53%
Human Respiratory Disorders	562	2.5%
Human Gastrointestinal Disorders including Liver	300	1.33%
Human Musculoskeletal Disorders	1776	7.89%
Human Immune Disorders	540	2.4%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1133	5.03%
Human Endocrine/Metabolism Disorders	139	0.62%
Other Human Disorders		
Animal Diseases and Disorders	9656	42.89%
Animal Welfare	240	1.07%
Diagnosis of diseases	373	1.66%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**22516**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	156621	99.21%
Other efficacy and tolerance testing	640	0.41%
Toxicity and other safety testing including pharmacology	611	0.39%
Routine production		
Total	**157872**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	6021	3.84%
Pyrogenicity testing	570	0.36%
Batch potency testing	150030	95.79%
Other quality controls		
Total	**156621**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Ecotoxicity	559	91.49%
Target animal safety	52	8.51%
Total	**611**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	559	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**559**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	155248	98.34%
Legislation on medicinal products for veterinary use and their residues	2047	1.3%
Medical devices legislation	18	0.01%
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	559	0.35%
Total	**157872**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	157872	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**157872**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	225925	98.94%
Yes	2414	1.06%
Total	**228339**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	3020	1.32%
Mild [up to and including]	113368	49.65%
Moderate	49705	21.77%
Severe	62246	27.26%
Total	**228339**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	226472	99.18%
Yes	1867	0.82%
Total	**228339**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	212262	92.96%
Genetically altered without a harmful phenotype	15476	6.78%
Genetically altered with a harmful phenotype	601	0.26%
Total	**228339**	**100.00%**

Ireland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

- There was a 1% decrease on number of uses reported from 2015.
- There was 21% drop in reported reuse.
- Basic research has reduced by 33% and Translational and applied has increased by 14%.
- The number of uses for Maintenance of colonies of established GA animals not used in other procedures has dropped by 80%.

  It is difficult to say with certainty what the reasons for these changes are.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As in previous years, in 2016 mice were still the most commonly used species representing 85% of overall animal use. Significant changes in species from 2015 to 2016 include the drop in the number of uses of cattle by 46% and the increased use of 'other fish' (e.g. salmon, eels and trout) by 125%. The decrease in cattle use relates to the completion of a particularly large country-wide cattle study in 2015. The increase in the use of 'other fish' relates to the increased tracking of eel and salmon stocks in Ireland (using tagging methods) due to concerns regarding their conservation status.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

- Majority of procedures are still mild (44%)
- Moderate procedures have increased from 22 to 26% of use
- Severe procedures have increased from 27 to 29%
- Non-recovery procedures have dropped from 2% to 1%

Clear trends in relation to severity may take a few more years to emerge as users are still becoming acquainted with the new reporting requirements.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The HPRA has made specific proactive efforts in communicating with contract research organisations and pharmaceutical companies in relation to the introduction of non-animal alternatives for regulatory tests, e.g. rabbit pyrogen and LD50 testing, as well as the introduction of earlier humane endpoints (for LD50 testing). However, due to the complex and protracted process involved in gaining regulatory acceptance and approval for such changes to regulatory testing protocols, an impact on the annual statistics is not expected until the 2018 report at the earliest.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category 'other fish' represented 5% of animal use. This primarily represents wild fish being studied for conservation projects. For example, European eels are a critically endangered species and Irish salmon stocks are critically low, so monitoring projects are required to improve the survival of these species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This was not exceeded nor was exemption granted at all during 2016.

Ireland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	192121	84.66%
Rats	9892	4.36%
Guinea-Pigs	964	0.42%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	1228	0.54%
Cats	271	0.12%
Dogs	356	0.16%
Ferrets	404	0.18%
Other carnivores		
Horses, donkeys and cross-breeds	204	0.09%
Pigs	1209	0.53%
Goats	30	0.01%
Sheep	1323	0.58%
Cattle	6044	2.66%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	196	0.09%
Other birds	674	0.3%
Reptiles		
Rana		

Animal Species	Number of animals	Percentage
Xenopus	60	0.03%
Other Amphibians		
Zebra fish	1439	0.63%
Other Fish	10519	4.64%
Cephalopods		
Total	**226934**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	209821	93.28%
Animals born in the EU but not at a registered breeder	14166	6.3%
Animals born in rest of Europe	455	0.2%
Animals born in rest of world	487	0.22%
Total	**224929**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	28340	12.49%
Translational and applied research	26230	11.56%
Regulatory use and Routine production	170976	75.34%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	235	0.1%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	250	0.11%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	903	0.4%
Total	**226934**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	213	0.75%

Basic Research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	803	2.83%
Nervous System	3876	13.68%
Respiratory System	1081	3.81%
Gastrointestinal System including Liver	2388	8.43%
Musculoskeletal System	68	0.24%
Immune System	6667	23.53%
Urogenital/Reproductive System	4	0.01%
Sensory Organs (skin, eyes and ears)	553	1.95%
Endocrine System/Metabolism	101	0.36%
Multisystemic	717	2.53%
Ethology / Animal Behaviour /Animal Biology	11868	41.88%
Other basic research	1	0%
Total	**28340**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1566	5.97%
Human Infectious Disorders	947	3.61%
Human Cardiovascular Disorders	2086	7.95%
Human Nervous and Mental Disorders	9308	35.49%
Human Respiratory Disorders	80	0.3%
Human Gastrointestinal Disorders including Liver	369	1.41%
Human Musculoskeletal Disorders	538	2.05%
Human Immune Disorders	1130	4.31%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	1553	5.92%
Human Endocrine/Metabolism Disorders	584	2.23%
Other Human Disorders		
Animal Diseases and Disorders	7691	29.32%
Animal Welfare	360	1.37%
Diagnosis of diseases	18	0.07%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**26230**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	169714	99.26%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	1262	0.74%
Total	**170976**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1630	0.96%
Pyrogenicity testing	506	0.3%
Batch potency testing	167549	98.72%
Other quality controls	29	0.02%
Total	**169714**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Kinetics	12	0.95%
Pharmaco-dynamics (incl safety pharmacology)	30	2.38%
Ecotoxicity	1180	93.5%
Target animal safety	40	3.17%
Total	**1262**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1180	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total	**1180**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	167227	97.81%
Legislation on medicinal products for veterinary use and their residues	2540	1.49%
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	1209	0.71%
Total	**170976**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	139897	81.82%
Legislation satisfying national requirements only [within EU]	29	0.02%
Legislation satisfying Non-EU requirements only	31050	18.16%
Total	**170976**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	224929	99.12%
Yes	2005	0.88%
Total	**226934**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2357	1.04%
Mild [up to and including]	99442	43.82%
Moderate	58832	25.92%
Severe	66303	29.22%
Total	**226934**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	225555	99.39%
Yes	1379	0.61%
Total	**226934**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	216565	95.43%
Genetically altered without a harmful phenotype	8360	3.68%
Genetically altered with a harmful phenotype	2009	0.89%
Total	**226934**	**100.00%**

Ireland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

- There was a 7% increase in animal use from the previous year (2016)
- This increase is accounted for by an increase in regulatory testing which is 80% of all testing.
- The use of cattle has dropped by 46% from the previous year, cats have dropped by 100% and dogs by 75%.
- There was a 67% decrease on reuse from the previous year.
- Basic research has dropped by 70% and Translational and Applied research has increased by 14%.
- There is a 28% drop in number of uses reported for 'Maintenance of colonies of established GA animals not used in other procedures'.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

- The 7% increase in animal numbers is due to increased regulatory testing, largely due to increased batch potency testing. The main reason for this was a breakdown of a non-animal alternative test, resulting in increased animal testing. Another smaller proportion of this increase was due to the use of additional animals for the validation of humane endpoints for batch potency testing.
- The reduction in cattle was due to the completion of a very large country-wide agricultural project. The reduction in dogs and cats was due to the closure of a dog and cat facility.
- The drop in basic research and increase in translational is not likely due to a true change in the type of research being conducted, but likely more accurate reporting.
- The reason for the drop in uses reported for 'maintenance of colonies of established GA animals not used in other procedures' is not known, but could be due to more efficient GA breeding.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There was a very slight increase in mild procedures (44 to 47%) and a slight decrease in moderate procedures (26 to 23%) but otherwise the proportions remained the same.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

- We focused a lot of efforts in ensuring that there is a move to non-animal alternatives for batch potency testing; however this is not reflected in the figures in 2017, but it is expected that it will

be reflected in the 2018 figures on. For the animals that still must be used for this type of testing, we have also required the establishment to work on implementing humane endpoints for these tests. This should, over time, reduce the animals in the 'severe' actual severity category, but this is not yet reflected in the figures.

- We have also put efforts into ensuring that rabbit pyrogen testing is only carried out where justified, by contacting the pharmaceutical companies that employ this type of testing. Since 2014 there has been a 48% reduction in this type of testing.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

There was no significant use of the 'other' categories at all. With regards to species, 'other fish' account for 4% of animal use and 'other birds' less than 1%. These relates to studies of wild animals, such as tagging and conservation projects.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This was not exceeded during 2017.

Ireland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	206908	85.39%
Rats	16858	6.96%
Guinea-Pigs	518	0.21%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	400	0.17%
Cats		
Dogs	89	0.04%
Ferrets	442	0.18%
Other carnivores		
Horses, donkeys and cross-breeds	60	0.02%
Pigs	1547	0.64%
Goats	11	0%
Sheep	1321	0.55%
Cattle	3244	1.34%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		

Animal Species	Number of animals	Percentage
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	40	0.02%
Other birds	823	0.34%
Reptiles		
Rana		
Xenopus	18	0.01%
Other Amphibians		
Zebra fish	236	0.1%
Other Fish	9787	4.04%
Cephalopods		
Total	**242302**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	227994	94.36%
Animals born in the EU but not at a registered breeder	13065	5.41%
Animals born in rest of Europe	121	0.05%
Animals born in rest of world	447	0.18%
Total	**241627**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	8558	3.53%
Translational and applied research	29815	12.3%
Regulatory use and Routine production	194816	80.4%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8366	3.45%
Preservation of species		

Purpose Category	Number of uses	Percentage
Higher education or training for the acquisition, maintenance or improvement of vocational skills	274	0.11%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	473	0.2%
Total	**242302**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	391	4.57%
Cardiovascular Blood and Lymphatic System	5	0.06%
Nervous System	2068	24.16%
Respiratory System	724	8.46%
Gastrointestinal System including Liver	1111	12.98%
Musculoskeletal System	192	2.24%
Immune System	991	11.58%
Urogenital/Reproductive System	238	2.78%
Sensory Organs (skin, eyes and ears)	54	0.63%
Endocrine System/Metabolism	139	1.62%
Multisystemic	6	0.07%
Ethology / Animal Behaviour /Animal Biology	2635	30.79%
Other basic research	4	0.05%
Total	**8558**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	754	2.53%
Human Infectious Disorders	780	2.62%
Human Cardiovascular Disorders	1195	4.01%
Human Nervous and Mental Disorders	9381	31.46%
Human Respiratory Disorders	277	0.93%
Human Gastrointestinal Disorders including Liver	1114	3.74%
Human Musculoskeletal Disorders	747	2.51%
Human Immune Disorders	8230	27.6%
Human Urogenital/Reproductive Disorders	50	0.17%
Human Sensory Organ Disorders (skin, eyes and ears)	2057	6.9%
Human Endocrine/Metabolism Disorders	444	1.49%
Other Human Disorders		
Animal Diseases and Disorders	2115	7.09%
Animal Welfare	2553	8.56%
Diagnosis of diseases	118	0.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**29815**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	194247	99.71%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	540	0.28%
Routine production	29	0.01%
Total	**194816**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1920	0.99%
Pyrogenicity testing	312	0.16%
Batch potency testing	192015	98.85%
Other quality controls		
Total	**194247**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Ecotoxicity	500	92.59%
Target animal safety	40	7.41%
Total	**540**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	500	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**500**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	29	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**29**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	185727	95.33%
Legislation on medicinal products for veterinary use and their residues	8589	4.41%
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	500	0.26%
Total	**194816**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	194784	99.98%
Legislation satisfying national requirements only [within EU]	32	0.02%
Legislation satisfying Non-EU requirements only		
Total	**194816**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	241627	99.72%
Yes	675	0.28%
Total	**242302**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2283	0.94%
Mild [up to and including]	114261	47.16%
Moderate	55162	22.77%
Severe	70596	29.14%
Total	**242302**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	241716	99.76%
Yes	586	0.24%
Total	**242302**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	234806	96.91%
Genetically altered without a harmful phenotype	5737	2.37%
Genetically altered with a harmful phenotype	1759	0.73%
Total	**242302**	**100.00%**

Italy

Italy: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, the total number of animals used in testing was 581,935, the first time this figure had fallen below 600,000. In general, the decrease in 2015 as compared to the previous year reflects the downward trend in the total number of animals used in testing, which has consistently remained below the one million mark since 1999.

In 2015, rodents and rabbits accounted for 91.19% of the animal species used. Within these species, there was an increase in the number of rats, rabbits and 'other rodents' used, while on the other hand there was a marked decrease from 485,820 to 373,483 in the number of mice used.

On the whole there has been a decrease in the use of other animal species, except for a slight increase as regards domestic fowl (from 28,215 in 2014 to 30,984 in 2015).

The total number of animals used went from 691,666 in 2014 to 581,935 in 2015, a percentage decrease of -15.86%. (See Table 1)

Table 1

Animal species	2014	% of the 2014 total	2015	% of the 2015 total	DIFFERENCE IN THE NUMBER OF ANIMALS	% DIFFERENCE 2014 / 2015
Rodents and rabbits	639,914	92.52	530,677	91.19	-109,237	-17.07
Other animal species	51,752	7.48	51,258	8.81	-494	-0.95
Total (all species)	**691,666**	**100.00**	**581,935**	**100.00**	**-109,737**	**-15.86**

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

37.26% of the animals were used in basic biological studies.

24.92% of the animals were used in translational or applied research.

36.07% of the animals were used for regulatory use and routine production.

1.75% of the animals were used for other purposes.

No animals were used for forensic enquiries.

Table 2

Purpose of studies	2014 %	2015 %	% DIFFERENCE
Basic research	41.84	37.26	-4.58
Translational research	31.77	24.92	-6.85
Regulatory testing	25.45	36.07	10.62
Other	0.94	1.75	0.81

2015 saw an increase in the number of animals used for regulatory testing, while there was a decrease in the number of animals used for both basic research and translational research and a very slight increase for other purposes (see Table 2).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals was recorded for the second time in 2015. A comparison between 2014 and 2015 shows that more than 47% of the animals experienced a 'mild' level of suffering, followed by 39% of animals with 'moderate' suffering, with neither the 'non-recovery' nor 'severe' suffering levels exceeding 7% (see Table 3).

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2014	4.89	49.09	42.90	3.12
2015	6.16	47.58	39.44	6.82

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is €1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

Also worth noting is the work of the Animal Welfare Bodies (*Organismi Preposti al Benessere Animale* (OPBAs)) under Article 25 of Legislative Decree No 26/2014. OPBAs are required to issue a reasoned opinion on research projects that are to be submitted for ministerial authorisation, verifying the correct application of the Three Rs principle and assessing the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals used.

As far as staff training is concerned, various conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes. The Ministry of Health sends its own experts as lecturers to such training events.

The Ministry provided training at no fewer than ten training courses in 2015.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Nothing to report.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	373666	63.69%
Rats	130972	22.32%
Guinea-Pigs	16668	2.84%
Hamsters (Syrian)	488	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	494	0.08%
Rabbits	9775	1.67%
Cats		
Dogs	601	0.1%

Animal Species	Number of animals	Percentage
Ferrets	14	0%
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	1746	0.3%
Goats	4	0%
Sheep	235	0.04%
Cattle	733	0.12%
Prosimians		
Marmoset and tamarins	3	0%
Cynomolgus monkey	278	0.05%
Rhesus monkey	4	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	8	0%
Other species of New World Monkeys (Ceboidea)	24	0%
Apes		
Other Mammals	16	0%
Domestic fowl	33020	5.63%
Other birds	750	0.13%
Reptiles	100	0.02%
Rana		
Xenopus	422	0.07%
Other Amphibians	7	0%
Zebra fish	11331	1.93%
Other Fish	5328	0.91%
Cephalopods	12	0%
Total	**586699**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	544052	93.53%
Animals born in the EU but not at a registered breeder	35311	6.07%
Animals born in rest of Europe	1167	0.2%
Animals born in rest of world	1181	0.2%
Total	**581711**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	4	1.79%
Animals born in rest of Europe		
Animals born in Asia	112	50%
Animals born in America		
Animals born in Africa	108	48.21%
Animals born elsewhere		
Total	**224**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	54	24.11%
F2 or greater	169	75.45%
Self-sustaining colony	1	0.45%
Total	**224**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	218615	37.26%
Translational and applied research	146213	24.92%
Regulatory use and Routine production	211615	36.07%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	76	0.01%
Preservation of species	228	0.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1042	0.18%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	8910	1.52%
Total	**586699**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	61958	28.34%
Cardiovascular Blood and Lymphatic System	9112	4.17%
Nervous System	83400	38.15%
Respiratory System	4470	2.04%
Gastrointestinal System including Liver	7690	3.52%
Musculoskeletal System	5485	2.51%
Immune System	22940	10.49%
Urogenital/Reproductive System	2015	0.92%
Sensory Organs (skin, eyes and ears)	1556	0.71%
Endocrine System/Metabolism	4640	2.12%
Multisystemic	5293	2.42%
Ethology / Animal Behaviour /Animal Biology	7120	3.26%
Other basic research	2936	1.34%
Total	**218615**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	40751	27.87%
Human Infectious Disorders	17960	12.28%
Human Cardiovascular Disorders	2606	1.78%
Human Nervous and Mental Disorders	21148	14.46%
Human Respiratory Disorders	17944	12.27%
Human Gastrointestinal Disorders including Liver	2428	1.66%
Human Musculoskeletal Disorders	2809	1.92%
Human Immune Disorders	6644	4.54%
Human Urogenital/Reproductive Disorders	2842	1.94%
Human Sensory Organ Disorders (skin, eyes and ears)	1908	1.3%

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	7589	5.19%
Other Human Disorders	3820	2.61%
Animal Diseases and Disorders	365	0.25%
Animal Welfare	466	0.32%
Diagnosis of diseases	16369	11.2%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	564	0.39%
Total	**146213**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	108737	51.38%
Other efficacy and tolerance testing	36979	17.47%
Toxicity and other safety testing including pharmacology	62965	29.75%
Routine production	2934	1.39%
Total	**211615**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	26087	23.99%
Pyrogenicity testing	4007	3.69%
Batch potency testing	75036	69.01%
Other quality controls	3607	3.32%
Total	**108737**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	15574	24.73%
Skin irritation/corrosion	583	0.93%
Skin sensitisation	10312	16.38%
Eye irritation/corrosion	54	0.09%
Repeated dose toxicity	8137	12.92%
Carcinogenicity	873	1.39%
Genotoxicity	378	0.6%
Reproductive toxicity	6583	10.46%
Developmental toxicity	4162	6.61%
Neurotoxicity	200	0.32%
Kinetics	5513	8.76%
Pharmaco-dynamics (incl safety pharmacology)	504	0.8%
Phototoxicity	164	0.26%
Ecotoxicity	3985	6.33%
Safety testing in food and feed area	4970	7.89%
Target animal safety	196	0.31%
Other toxicity/safety testing	777	1.23%
Total	**62965**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	6296	40.43%
Other lethal methods	120	0.77%
Non lethal methods	9158	58.8%
Total	**15574**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4350	53.46%
29 - 90 days	2841	34.91%
> 90 days	946	11.63%
Total	**8137**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3319	83.29%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	666	16.71%
Total	**3985**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1115	38%
Monoclonal antibody by mouse ascites method	1520	51.81%
Other product types	299	10.19%
Total	**2934**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	133861	63.26%
Legislation on medicinal products for veterinary use and their residues	31907	15.08%
Medical devices legislation	16980	8.02%
Industrial chemicals legislation	8704	4.11%
Plant protection product legislation	734	0.35%
Biocides legislation	1749	0.83%
Food legislation including food contact material	11973	5.66%
Feed legislation including legislation for the safety of target animals, workers and environment	706	0.33%
Cosmetics legislation		
Other legislation	5001	2.36%
Total	**211615**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	204055	96.43%
Legislation satisfying national requirements only [within EU]	2085	0.99%
Legislation satisfying Non-EU requirements only	5475	2.59%
Total	**211615**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	581935	99.19%
Yes	4764	0.81%
Total	**586699**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	36159	6.16%
Mild [up to and including]	279151	47.58%
Moderate	231395	39.44%
Severe	39994	6.82%
Total	**586699**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	582552	99.29%
Yes	4147	0.71%
Total	**586699**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	463538	79.01%
Genetically altered without a harmful phenotype	110917	18.91%
Genetically altered with a harmful phenotype	12244	2.09%
Total	**586699**	**100.00%**

Italy: Narrative 2016

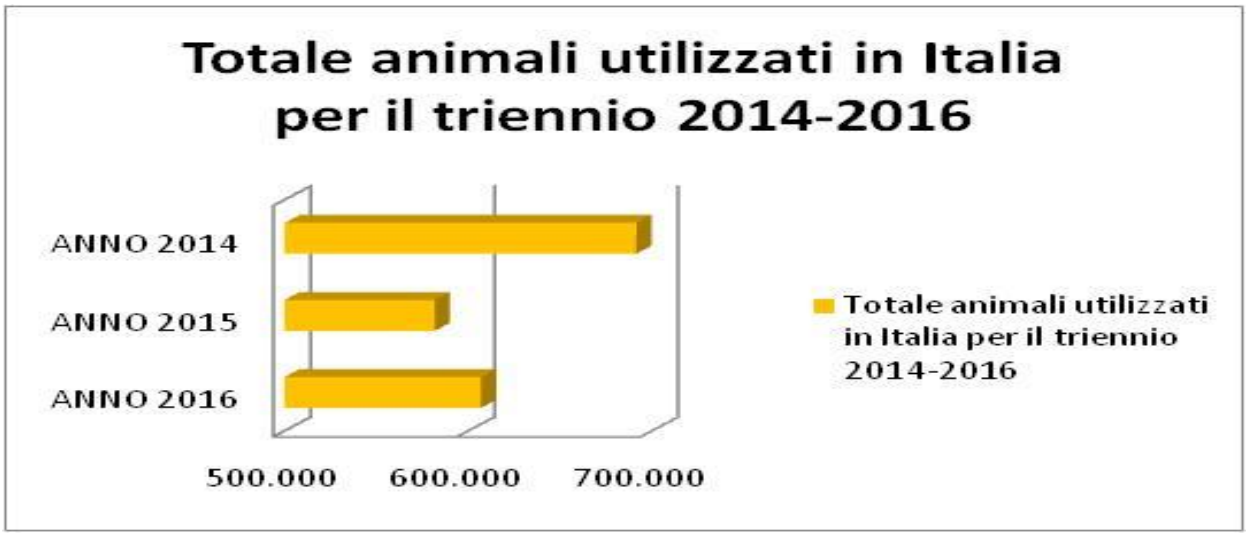
Introduction

The data for Italy for 2016 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

1. General information on any changes in trends observed since the previous reporting period.

In 2016, the total number of animals used in testing was 607,097, i.e. slightly more than 600,000. This was lower than in 2014 (691,666 animals; -12.23%) and slightly higher than in 2015 (581,935; +4.32%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

Figure 1



Translation of legend: Total number of animals used in Italy 2014-2016

In 2016, rodents and rabbits accounted for 90.36% of the animal species used. Within these species, there was an increase in the number of mice and rabbits as compared to 2015, while the use of rats decreased slightly.

For other animal species – which, in 2016, accounted for 9.64% of the total – there was an increase in the use of domestic fowl, fish (zebrafish) and amphibians (Xenopus). (See Table 1)

Table 1

Animal species	2014	% of the 2014 total	2015	% of the 2015 total	2016	% of the 2016 total	DIFFERENCE IN THE NUMBER OF ANIMALS 2014 / 2016	% DIFFERENCE 2014 / 2016
Rodents and rabbits	639,914	92.52	530,677	91.19	548,578	90.36	-91,336	-14.27
Other animal species	51,752	7.48	51,258	8.81	58,519	9.64	6,767	13.07
Total (all species)	**691,666**	**100.00**	**581,935**	**100.00**	**607,097**	**100.00**	**-84,569**	**-12.23**

2. Information on significant increase or decreases in use animals in any of the specific areas and analysis of the reasons thereof.

35.42% of the animals were used in basic biological studies.

26.54% were used in translational or applied research.

37.11% were used for regulatory use and routine production.

0.93% for other purposes.

No animals were used for forensic enquiries.

Table 2

Purpose of studies	2014 %	2016 %	DIFFERENCE 2014 / 2016 %
Basic research	41.84	35.42	-6.42
Translational research	31.77	26.54	-5.23
Regulatory testing	25.45	37.11	11.66
Other	0.94	0.93	-0.01

The downward trend in the number of animals used in basic research and translational research was confirmed in 2016.

The use of animals in regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose. (See Table 2)

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals was recorded for the third time in 2016. Comparing 2014, 2015 and 2016 shows that there were no material variations in the 'non-recovery' and 'mild' suffering levels, while there has been an increase in the 'severe' category (see Table 3).

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2014	4.89%	49.09%	42.90%	3.12%
2015	6.16%	47.58%	39.44%	6.82%
2016	4.81%	50.42%	34.11%	10.66%

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is € 1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

Animal Welfare Bodies (OPBAs)

In 2016, greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions made it possible to verify, to the best extent possible, the correct application of the Three Rs principle, particularly in the basic research and translational research sectors. The OPBAs' work enabled an assessment of the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals to be used, thus giving rise to a general downward trend in animal use except in the regulatory sector.

As far as staff skills are concerned, conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes, with experts from the Ministry of Health participating as lecturers. The Ministry provided training at a total of 15 training courses in 2016.

Lastly, it is worth stressing the importance of the first National Animal Welfare Conference, which was devised and organised by the Directorate-General for Animal Health and Veterinary Medicines (DGSAF) at the Ministry of Health. The Conference had the positive effect of putting the spotlight on the issue of animal welfare in all sectors. More specifically, one session was devoted entirely to the topic of protecting the animals used for scientific purposes. The speakers stressed the innovations and developments brought about by Legislative Decree No 26/2014, which transposed the European Directive, but also highlighted the problem areas in which it is necessary to keep working so as to ensure that projects are assessed ever more carefully while keeping to the deadlines set in the Directive.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

Nothing to report.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	388976	63.59%
Rats	128186	20.96%
Guinea-Pigs	16977	2.78%
Hamsters (Syrian)	553	0.09%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	143	0.02%
Rabbits	15245	2.49%
Cats		
Dogs	486	0.08%
Ferrets	7	0%
Other carnivores		
Horses, donkeys and cross-breeds	19	0%
Pigs	1534	0.25%
Goats	53	0.01%
Sheep	232	0.04%
Cattle	115	0.02%
Prosimians		

Animal Species	Number of animals	Percentage
Marmoset and tamarins	9	0%
Cynomolgus monkey	488	0.08%
Rhesus monkey	6	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	8	0%
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	36701	6%
Other birds	468	0.08%
Reptiles	57	0.01%
Rana		
Xenopus	771	0.13%
Other Amphibians	8	0%
Zebra fish	14664	2.4%
Other Fish	6001	0.98%
Cephalopods		
Total	**611707**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	557983	91.97%
Animals born in the EU but not at a registered breeder	46168	7.61%
Animals born in rest of Europe	835	0.14%
Animals born in rest of world	1690	0.28%
Total	**606676**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	139	33.02%
Animals born in America		
Animals born in Africa	282	66.98%
Animals born elsewhere		
Total	**421**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	94	22.33%
F2 or greater	327	77.67%
Self-sustaining colony		
Total	**421**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	216654	35.42%
Translational and applied research	162406	26.55%
Regulatory use and Routine production	226969	37.1%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1551	0.25%
Preservation of species	167	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1787	0.29%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2173	0.36%
Total	**611707**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	59961	27.68%
Cardiovascular Blood and Lymphatic System	9330	4.31%
Nervous System	82143	37.91%
Respiratory System	2755	1.27%
Gastrointestinal System including Liver	4929	2.28%
Musculoskeletal System	8391	3.87%
Immune System	20124	9.29%
Urogenital/Reproductive System	4933	2.28%
Sensory Organs (skin, eyes and ears)	1689	0.78%
Endocrine System/Metabolism	5655	2.61%
Multisystemic	7227	3.34%
Ethology / Animal Behaviour /Animal Biology	6098	2.81%
Other basic research	3419	1.58%
Total	**216654**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	45578	28.06%
Human Infectious Disorders	29058	17.89%
Human Cardiovascular Disorders	2074	1.28%
Human Nervous and Mental Disorders	19042	11.72%
Human Respiratory Disorders	17539	10.8%
Human Gastrointestinal Disorders including Liver	4221	2.6%
Human Musculoskeletal Disorders	6107	3.76%
Human Immune Disorders	5657	3.48%
Human Urogenital/Reproductive Disorders	1334	0.82%
Human Sensory Organ Disorders (skin, eyes and ears)	3540	2.18%
Human Endocrine/Metabolism Disorders	3441	2.12%
Other Human Disorders	6573	4.05%
Animal Diseases and Disorders	4309	2.65%
Animal Welfare	81	0.05%
Diagnosis of diseases	13214	8.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	638	0.39%
Total	**162406**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	111607	49.17%
Other efficacy and tolerance testing	48352	21.3%
Toxicity and other safety testing including pharmacology	65075	28.67%
Routine production	1935	0.85%
Total	**226969**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	24249	21.73%
Pyrogenicity testing	4352	3.9%
Batch potency testing	79363	71.11%
Other quality controls	3643	3.26%
Total	**111607**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	11131	17.1%
Skin irritation/corrosion	738	1.13%
Skin sensitisation	11885	18.26%
Eye irritation/corrosion	134	0.21%
Repeated dose toxicity	8838	13.58%
Carcinogenicity	229	0.35%
Genotoxicity	307	0.47%
Reproductive toxicity	955	1.47%
Developmental toxicity	8593	13.2%
Neurotoxicity	25	0.04%
Kinetics	6155	9.46%
Pharmaco-dynamics (incl safety pharmacology)	495	0.76%
Phototoxicity	66	0.1%
Ecotoxicity	3833	5.89%
Safety testing in food and feed area	11049	16.98%
Target animal safety	24	0.04%
Other toxicity/safety testing	618	0.95%
Total	**65075**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1003	9.01%
Other lethal methods	439	3.94%
Non lethal methods	9689	87.05%
Total	**11131**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2794	31.61%
29 - 90 days	4214	47.68%
> 90 days	1830	20.71%
Total	**8838**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3317	86.54%
Chronic toxicity	158	4.12%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	358	9.34%
Total	**3833**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1089	56.28%
Monoclonal antibody by mouse ascites method		
Other product types	846	43.72%
Total	**1935**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	147217	64.86%
Legislation on medicinal products for veterinary use and their residues	35207	15.51%
Medical devices legislation	18639	8.21%
Industrial chemicals legislation	9129	4.02%
Plant protection product legislation	401	0.18%
Biocides legislation	1119	0.49%
Food legislation including food contact material	11974	5.28%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation	3283	1.45%
Total	**226969**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	215219	94.82%
Legislation satisfying national requirements only [within EU]	1884	0.83%
Legislation satisfying Non-EU requirements only	9866	4.35%
Total	**226969**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	607097	99.25%
Yes	4610	0.75%
Total	**611707**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	29421	4.81%
Mild [up to and including]	308396	50.42%
Moderate	208660	34.11%
Severe	65230	10.66%
Total	**611707**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	604369	98.8%
Yes	7338	1.2%
Total	**611707**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	488643	79.88%
Genetically altered without a harmful phenotype	108952	17.81%
Genetically altered with a harmful phenotype	14112	2.31%
Total	**611707**	**100.00%**

Italy: Narrative 2017

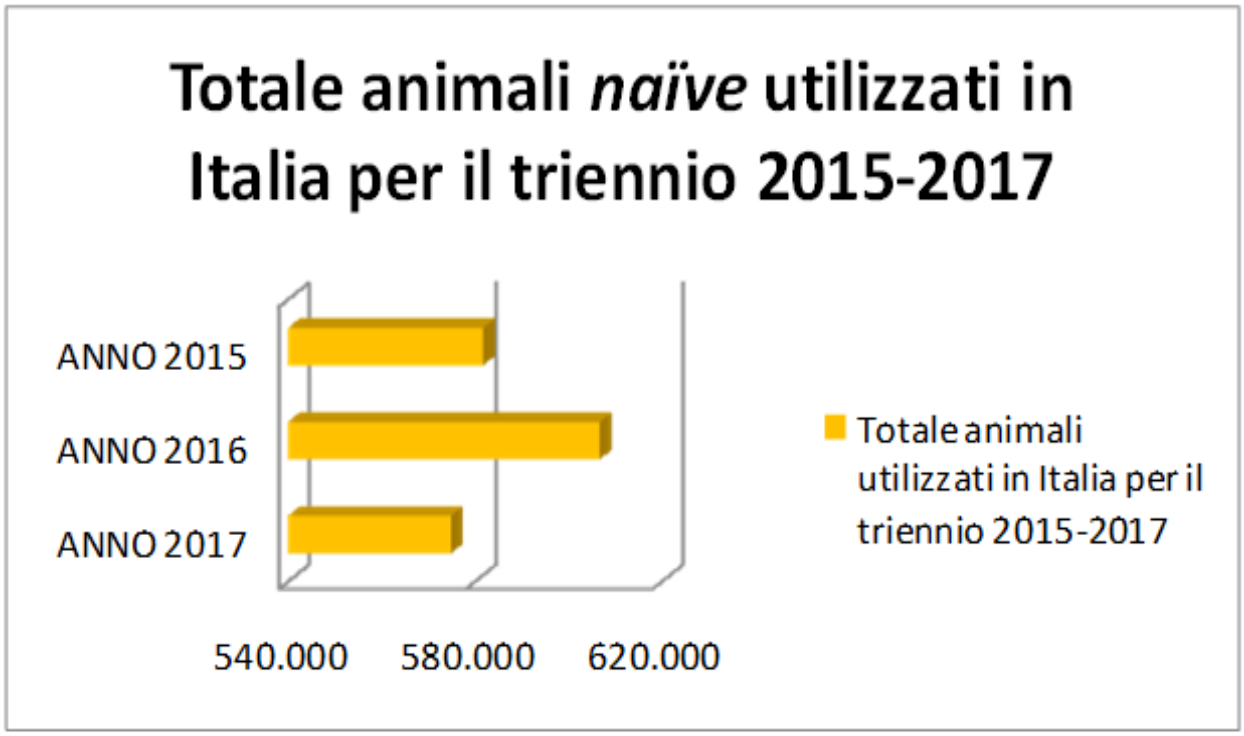
Introduction

The data for Italy for 2017 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the total number of animals used in testing for the first time ('naïve' animals) was 575,352, i.e. fewer than 600,000. This was lower than in 2015 (-1.20%) and 2016 (-5.54%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

Figure 1



Translation of legends:

- *Total number of naïve animals used in Italy 2015-2017*
- *Total number of animals used in Italy 2015-2017*

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015-2017 (see Table 1), rodents and animals accounted for 89.55% of the animal species used, including reused animals. Within these species, there was a decrease in the number of rodents and a significant increase in the number of rabbits. The increase in the number of rabbits is explained by the fact that around 95% of them are used in regulatory testing, i.e. tests that are compulsory under European or international law.

With regard to regulatory tests on rabbits, 78% of rabbits were used for quality controls on batches of medicines for human use, medical devices and veterinary medicines.

Another increase was in the use of non-human primates in regulatory tests (toxicity and other safety tests) required by European and international law (from 86.75% in 2015 to 97.27% in 2017). In consequence, there was a percentage decrease in non-human primates used in basic research in the three-year period concerned (from 11.67% in 2015 to 0.68% in 2017).

The most frequently used species was Macaca fascicularis; 2017 saw an increase in the use of generation F1 animals owing to reduced availability of generation F2 animals from breeding establishments and suppliers of non-human primates and the simultaneous increase in the number of regulatory tests.

For other animal species, there was a continuous increase in the 2015-2017 period in the use of:

- zebrafish in basic and translational research in the area of oncology and gastrointestinal diseases and in regulatory testing (ecotoxicity);
- other fish in translational research in the area of animal diseases.

Table 1

Animal species	% of the 2015 total	% of the 2016 total	% of the 2017 total	AVERAGE % - 2015-2017	% DIFFERENCE 2015 / 2017
Rodents	89.02%	87.43%	84.73%	87.06%	-4.82 %
Rabbits	1.66%	2.49%	3.33%	2.49%	+97.70%
Total rodents + rabbits	**90.68%**	**89.82%**	**88.06%**	**89.52%**	-2.89%
Other animal species	**9.32%**	**10.18%**	**11.94%**	**10.48%**	+28.11%
Total (all species)	**100.00%**	**100.00%**	**100.00%**	**100.00%**	

For 2017:
33.55% of the animals were used in basic biological studies.
26.48% were used in translational or applied research.
38.96% were used for regulatory use and routine production.
1.01% of the animals were used for other purposes.
No animals were used for forensic enquiries.

Table 2
Animal uses by purpose of studies

Purpose of studies	% 2015	% 2016	% 2017
Basic research	37.26%	35.42%	33.55%
Translational research	24.92%	26.54%	26.48%
Regulatory testing	36.07%	37.11%	38.96%
Other	1.75%	0.93%	1.01%

The downward trend in the number of animals used for basic research was confirmed in 2017.

The use of animals for regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose and is continually increasing (see Table 2).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Data collection on the level of suffering felt by animals (see Table 3) was recorded for the fourth time in 2017.

Table 3

Suffering level / Year	**Non-recovery**	**Mild (up to and including)**	**Moderate**	**Severe**
2015	6.16%	47.58%	39.44%	6.82%
2016	4.81%	50.42%	36.11%	10.66%
2017	5.49%	48.45%	30.55%	15.50%

Comparing the data for the 2015-2017 period shows that:
- there were no material variations in the 'non-recovery' and 'mild' suffering levels, which together represent 54%;
- there was a continuous decrease in the 'moderate' suffering level;
- there was an increase in the 'severe' category.

The animal species most concerned by the increase in the 'severe' suffering level is mice, at around 80%.

The correlation between the 'severe' suffering level and purpose is as follows:
- 46.62% for basic research (in particular for studies of central nervous system diseases and cancer);
- 37.14% for translational research (in particular for cancer);
- 15.89% for regulatory tests (in particular for toxicity);
- 0.35% for other purposes (maintenance of colonies of genetically altered animals).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal

Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarked funding for the development and validation of alternative methods and for staff training. The funding was € 1 million annually for the 2014-2016 period, broken down as follows:

- 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
- 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

National Committee for the Protection of Animals Used for Scientific Purposes

The National Committee for the Protection of Animals Used for Scientific Purposes was set up in February 2017. It is made up of members representing academia, public scientific research institutions, the Ministry of Health, the Italian National Institute of Health and the National Reference Centre for Alternative Methods and Welfare and Care of Laboratory Animals.

After drawing up its rules of procedure, its activities included providing the Ministry of Health with advice on preparing the draft ministerial decree on staff training.

Since October 2017 the National Committee has been working on organising the work of the Animal Welfare Bodies (OBPAs) with the aim of harmonising that work, particularly as regards preliminary assessment of research projects with a view to issuing the reasoned opinion needed for authorisation applications for such projects.

To that end, the National Committee has launched a major initiative to raise awareness among OPBAs so as to harmonise their activities in both logistical and technical terms, and in particular to encourage the sharing of project assessment criteria.

Animal Welfare Bodies (OPBAs)

In general terms, 2017 saw the consolidation of greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions. This made it possible to verify, to the best possible extent, the correct application of the Three Rs principle, particularly as regards the replacement or reduction of animal use, with clear results in the basic research and translational research sectors.

As far as staff skills are concerned, conferences, workshops and courses were organised by various public or private bodies, with experts from the Ministry of Health participating as lecturers/speakers in 14 events.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

The 'other' heading is used for the main sub-sectors, which mainly concern the regulatory field.

More specifically:

Animals used in routine production:

Other efficacy and tolerance testing (immunogenicity for human vaccines)

Other efficacy and tolerance testing (production of inactivated antigens for animal vaccines)

Animals used in the quality control sector:

Other quality controls (efficacy testing on rodenticides; testing for contaminants in veterinary medicines)

Animals used in the toxicity testing sector:

Other toxicity/safety testing (for drugs of abuse; for anomalous toxicity; for local tolerance)

Animals used in the acute and sub-acute toxicity methods sector:

Other lethal methods (testing in accordance with OECD 402 and OECD 423)

Animals used in the toxicity/ecotoxicity testing sector:

Other tests: (Diagnostic ecotoxicity testing)

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were no cases in which the 'severe' classification was exceeded.

Italy: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	358128	61.74%
Rats	118104	20.36%
Guinea-Pigs	14357	2.48%
Hamsters (Syrian)	277	0.05%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	647	0.11%
Rabbits	19325	3.33%
Cats		
Dogs	639	0.11%
Ferrets	42	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	17	0%
Pigs	1657	0.29%
Goats	23	0%
Sheep	192	0.03%
Cattle	279	0.05%
Prosimians		
Marmoset and tamarins	1	0%
Cynomolgus monkey	569	0.1%
Rhesus monkey	4	0%

Animal Species	Number of animals	Percentage
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	30	0.01%
Domestic fowl	34715	5.98%
Other birds	420	0.07%
Reptiles		
Rana		
Xenopus	401	0.07%
Other Amphibians		
Zebra fish	19508	3.36%
Other Fish	10715	1.85%
Cephalopods	10	0%
Total	**580060**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	507078	88.22%
Animals born in the EU but not at a registered breeder	65027	11.31%
Animals born in rest of Europe	874	0.15%
Animals born in rest of world	1825	0.32%
Total	**574804**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	0.18%
Animals born in rest of Europe		
Animals born in Asia	57	10.4%
Animals born in America		
Animals born in Africa	490	89.42%
Animals born elsewhere		
Total	**548**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	137	25%
F2 or greater	411	75%
Self-sustaining colony		
Total	**548**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	194642	33.56%
Translational and applied research	153743	26.5%
Regulatory use and Routine production	225842	38.93%
Protection of the natural environment in the interests of the health or welfare of human	1697	0.29%

Purpose Category	Number of uses	Percentage
beings or animals		
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1598	0.28%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	2538	0.44%
Total	**580060**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	58513	30.06%
Cardiovascular Blood and Lymphatic System	8635	4.44%
Nervous System	74343	38.19%
Respiratory System	1384	0.71%
Gastrointestinal System including Liver	5792	2.98%
Musculoskeletal System	6933	3.56%
Immune System	13667	7.02%
Urogenital/Reproductive System	2830	1.45%
Sensory Organs (skin, eyes and ears)	3892	2%
Endocrine System/Metabolism	4776	2.45%
Multisystemic	3858	1.98%
Ethology / Animal Behaviour /Animal Biology	5028	2.58%
Other basic research	4991	2.56%
Total	**194642**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	46470	30.23%
Human Infectious Disorders	21902	14.25%
Human Cardiovascular Disorders	1852	1.2%
Human Nervous and Mental Disorders	18498	12.03%
Human Respiratory Disorders	16658	10.83%
Human Gastrointestinal Disorders including Liver	2706	1.76%
Human Musculoskeletal Disorders	6007	3.91%
Human Immune Disorders	3875	2.52%
Human Urogenital/Reproductive Disorders	2992	1.95%
Human Sensory Organ Disorders (skin, eyes and ears)	2457	1.6%
Human Endocrine/Metabolism Disorders	3064	1.99%
Other Human Disorders	5288	3.44%
Animal Diseases and Disorders	7228	4.7%
Animal Welfare	918	0.6%
Diagnosis of diseases	13483	8.77%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	345	0.22%
Total	**153743**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	111851	49.53%
Other efficacy and tolerance testing	45856	20.3%
Toxicity and other safety testing including pharmacology	63786	28.24%
Routine production	4349	1.93%
Total	**225842**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	21535	19.25%
Pyrogenicity testing	2717	2.43%
Batch potency testing	84520	75.56%
Other quality controls	3079	2.75%
Total	**111851**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10612	16.64%
Skin irritation/corrosion	820	1.29%
Skin sensitisation	11983	18.79%
Eye irritation/corrosion	93	0.15%
Repeated dose toxicity	8757	13.73%
Carcinogenicity		
Phototoxicity		
Genotoxicity	291	0.46%
Reproductive toxicity	628	0.98%
Developmental toxicity	5554	8.71%
Neurotoxicity	300	0.47%
Kinetics	5976	9.37%
Pharmaco-dynamics (incl safety pharmacology)	1154	1.81%
Ecotoxicity	4224	6.62%
Safety testing in food and feed area	10807	16.94%
Target animal safety	1212	1.9%
Other toxicity/safety testing	1375	2.16%
Total	**63786**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1211	11.41%
Other lethal methods	755	7.11%
Non lethal methods	8646	81.47%
Total	**10612**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4157	47.47%
29 - 90 days	2782	31.77%
> 90 days	1818	20.76%
Total	**8757**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3930	93.04%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity	294	6.96%
Total	**4224**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	2861	65.79%
Monoclonal antibody by mouse ascites method		
Other product types	1488	34.21%
Total	**4349**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	143853	63.7%
Legislation on medicinal products for veterinary use and their residues	37188	16.47%
Medical devices legislation	19575	8.67%
Industrial chemicals legislation	8715	3.86%
Plant protection product legislation	595	0.26%
Biocides legislation	624	0.28%
Food legislation including food contact material	11492	5.09%
Feed legislation including legislation for the safety of target animals, workers and environment	1074	0.48%
Cosmetics legislation		
Other legislation	2726	1.21%
Total	**225842**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	209119	92.6%
Legislation satisfying national requirements only [within EU]	3418	1.51%
Legislation satisfying Non-EU requirements only	13305	5.89%
Total	**225842**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	575352	99.19%
Yes	4708	0.81%
Total	**580060**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	31875	5.5%
Mild [up to and including]	281069	48.46%
Moderate	177180	30.55%
Severe	89936	15.5%
Total	**580060**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	571715	98.56%
Yes	8345	1.44%
Total	**580060**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	448697	77.35%
Genetically altered without a harmful phenotype	112874	19.46%
Genetically altered with a harmful phenotype	18489	3.19%
Total	**580060**	**100.00%**

Latvia

Latvia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2014 competent authority has approved 8 projects, but in 2015 – 9, however since the previous year, animal amount used for scientific purposes have decreased from 13730 in 2014 to 5457 in 2015. During the 2014 active research was performed in 12 projects, but in 2015 – in 16 projects and one project was not realized because the lack of funding. Compeering previous period, in 2015 were realised more small projects with quite a small total animal amount not exceeding number of 100 animals per one project.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 new types of species were used in procedures – dogs (7), domestic fowl (40) and rabbits (35). Comparing 2014 and 2015 data using of pigs have decreased and wild birds have not been use because a lack of funding.

Animal species used in procedures in 2014 and 2015 are exposed on Figure 1. and Figure 2

Figure 1

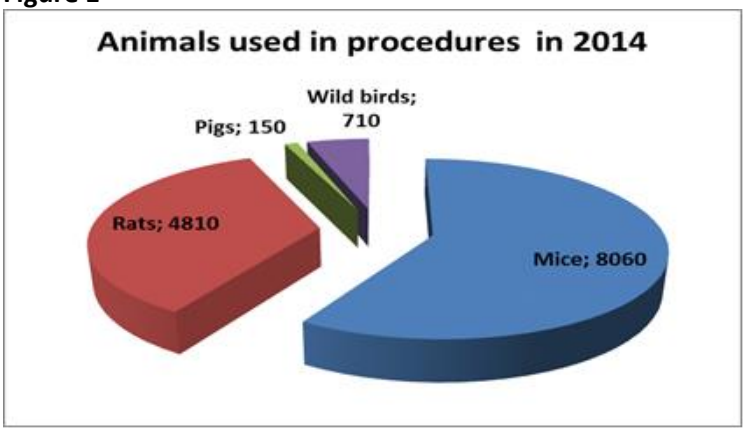
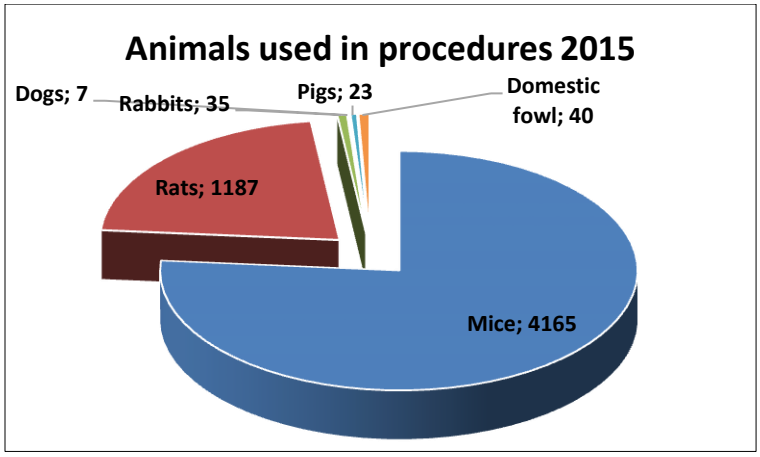


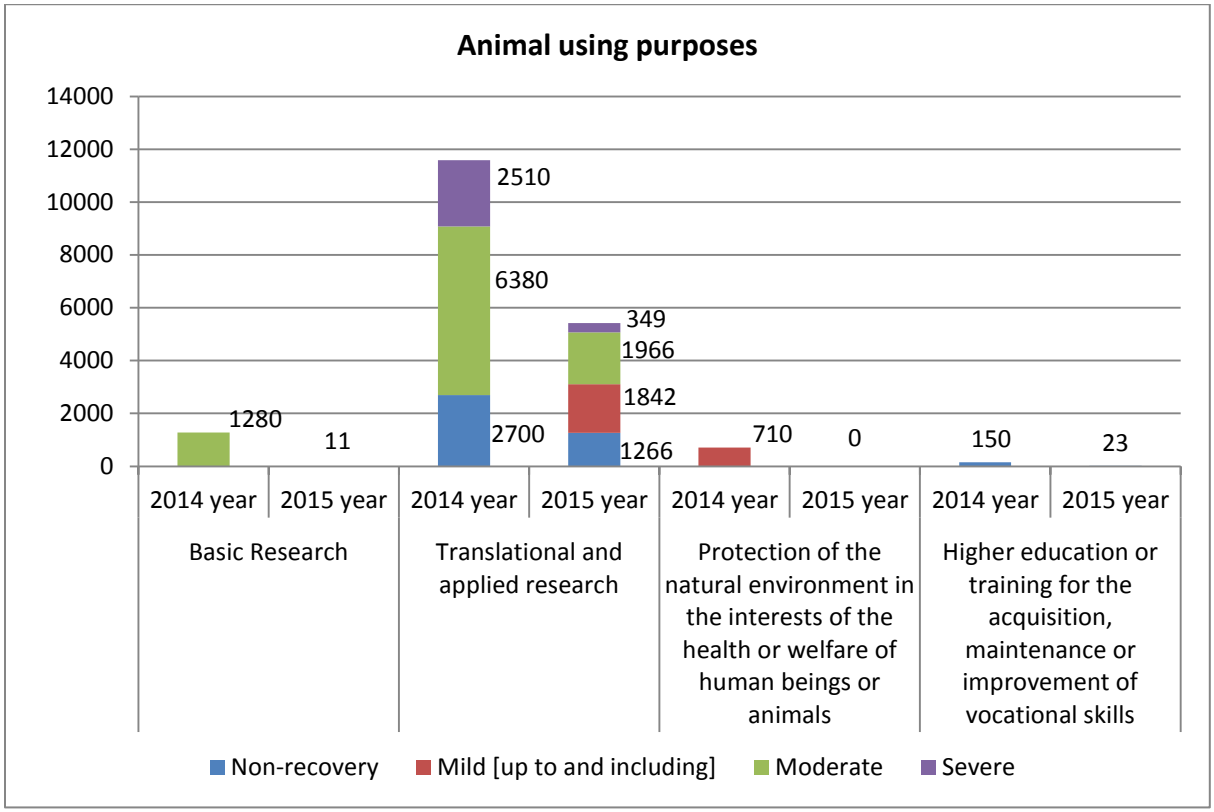
Figure 2



3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and biggest part 98.0% from the registered breeder.

Figure 3



In total 349 animals (6.40%) were used in planned severe procedures, including 81 mice and 182 rats for human nervous and mental disorders research. Procedures were appreciated as sever because of surgical intervention in brain cavity, but animals were not exposed to additional severe or moderate pain in long term. 74 mice and 12 rats from not planned severe procedures actually went through severe procedure because of individual reaction during surgery under anaesthesia (sudden death) and unexpected deterioration of health state (weight loss, hyperglycaemia), however mostly detecting heavier sufferings than were expected, animals were excluded from further steps of procedure and were humanely euthanized.

The biggest part 1977 (36.23%) of animals were exposed to planned moderate procedures, including 739 mice and 94 rats for human nervous and mental disorders research, 48 mice, 69 rats and 20 rabbits for human musculoskeletal disorders, 11 mice for nervous system (basic research), 37 mice for cancer, 78 mice for human immune disorders, 451 mice, 7 dogs and 15 rabbits for animal diseases and 367 mice for non-regulatory toxicology research (see Figure 3). 41 mice from not planned moderate procedures were exposed to moderate procedure because of individual reaction to adjuvant (not completed absorption and forming subcutaneous induration).
In mild procedures were used 1842 (33.75%) animals including 1565 mice for human nervous and mental disorders research, 62 mice for human immunes system disorders and 40 domestic fowl for

animal diseases research; 64 rats exposed to mild surgical intervention (sham operated animals) and 4 mice from procedures with harder character because of not desired effect and pathological state forming were excluded from further research process and underwent only mild manipulations
In non-recovery procedures were used 1289 (23.62%) animals including 520 mice and 746 rats for non-regulatory toxicology and ecotoxicology and 23 pigs for educational purposes
In general observation there are evident changes in the basic research, where animal using were decreased significantly from 1280 (9.32%) in 2014 to 11 (0.20%), also the number of animals used for educational purposes comparing previous year decreased from 150 (1.09%) to 23 (0.42%) in 2015 as well as in 2015 animals were not used in protection of natural environment in the interests of the health animal beings. The highest amount of animal using remain unchanged in translation and applied research. This year reaching 99.38% (5423) of all used animals and increasing for 14.97% comparing with previous year. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.
Reason for animal amount changes mentioned previous is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures and as it is seen from data in some projects animals are not used at all in this year instead of planned.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.
Scientific project authors strive to use *in silico* and *in vitro* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientist doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.
In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training). After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease used animal amount in procedures.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.
During the year 2015 users have reported to competent authority that 8 rats exposed to narcosis unexpectedly died during the surgical manipulation. In 2015 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4165	76.32%
Rats	1187	21.75%

Animal Species	Number of animals	Percentage
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	35	0.64%
Cats		
Dogs	7	0.13%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	23	0.42%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	40	0.73%
Other birds	0	0%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**5457**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5359	98.2%
Animals born in the EU but not at a registered breeder	98	1.8%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5457**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		

NHP Source (origin)	Number of animals	Percentage
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	11	0.2%
Translational and applied research	5423	99.38%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	0	0%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	23	0.42%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5457**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	11	100%
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	**11**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	52	0.96%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	2763	50.95%
Human Respiratory Disorders		

Translational and applied research	Number of uses	Percentage
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	141	2.6%
Human Immune Disorders	270	4.98%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders	564	10.4%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1633	30.11%
Total	**5423**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	5457	100%
Yes		
Total	**5457**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1289	23.62%
Mild [up to and including]	1842	33.75%
Moderate	1977	36.23%
Severe	349	6.4%
Total	**5457**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5457	100%
Yes		
Total	**5457**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5457	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**5457**	**100.00%**

Latvia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

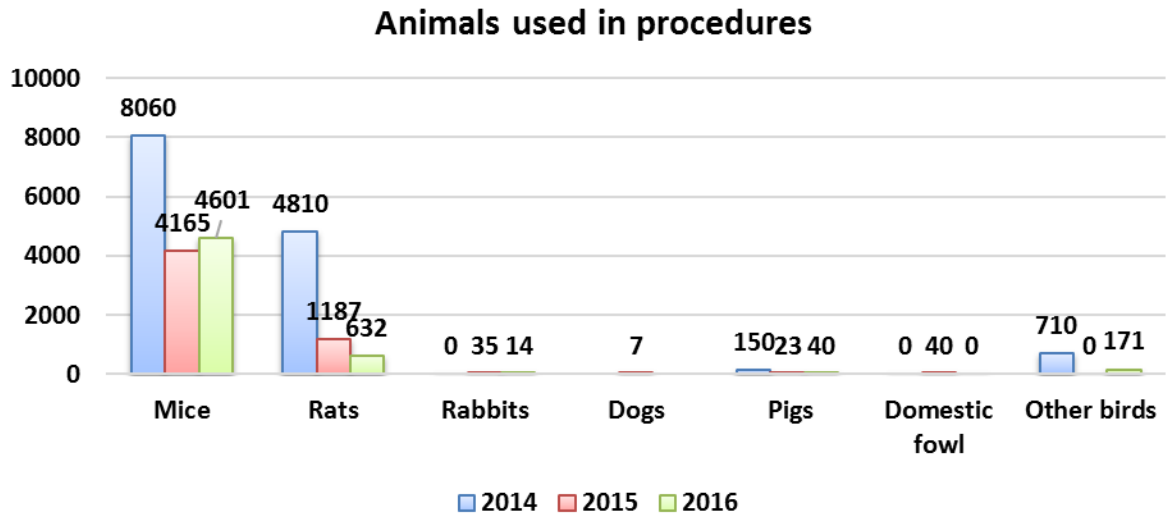
In 2015 competent authority has approved 9 projects, but in 2016 – 3. Since the previous year, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016). During the 2015 active research was performed in 16 projects, but in 2016 – in 17 projects. In 2016 the first time researchers started to use genetically altered animals – 60 mice in moderate procedures for basic research (human nervous system).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Compeering last two years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016, but total amount of used rats have decreased from 21.75% (n=1.187) in 2015 to 11.58% (n=632) in 2016. The reason for these changes is connected with economical (new synthesised substances are very expensive and therefore usually are synthesised in small amounts that leads to great need for smaller animals used in further *in vivo* tests) animal welfare and 3Rs considerations (suggestions from project evaluation commission). In 2016 dogs and domestic fowl were not used because the end of the projects in previous year, but after financial improvement the part of wild nature research project was realized and 171 wild birds were exposed to mild procedure.

Animal species used in procedures in 2014, 2015 and 2016 are exposed on Figure 1.

Figure 1



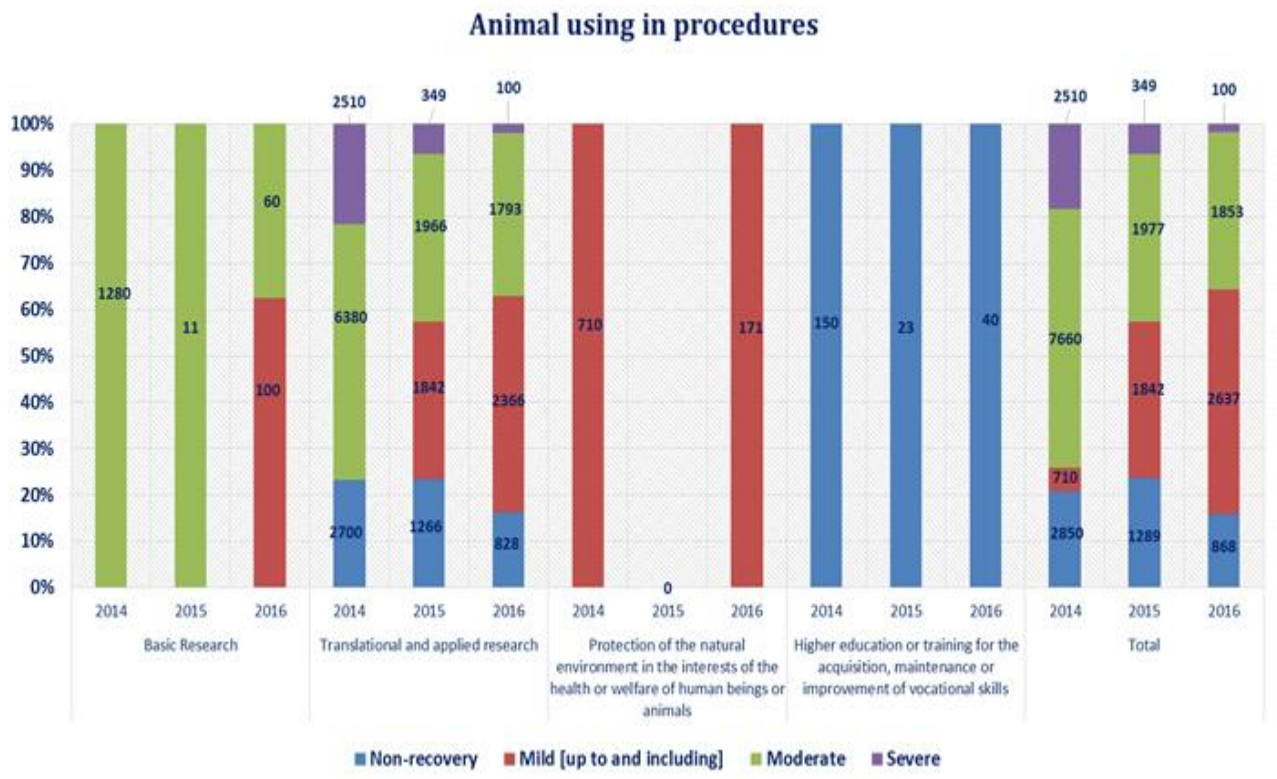
3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and biggest part 95.9% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2) – 48.3% (n=2637) from which 2516 were used for planned mild procedures, but 121, which came from a control groups and sham

operated groups of cardiovascular disease, human nervous and mental disorders research projects and in general were planned to expose to moderate procedures, but actually underwent easier or not all manipulations comparing to other experimental groups in the same procedure. Therefore previous mentioned animal (n=121) sufferings were evaluated as mild.

Figure 2



In total in 2016 animals were not used in planned severe procedures, but 100 animals (1.8%) in four projects actually went through severe procedure.

1. During mild procedure in human cardiovascular disease research project 4 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.

2. During moderate procedure in human cancer research project 35 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.

3. Because of specific individual features during moderate procedure in human infectious disorders research project 4 mice recovered very hard after long exposing to narcosis during electroporation and therefore animals were humanely killed and were not included in further manipulations.

4. During moderate procedure in human musculoskeletal disorders research project 1 rabbit died. The case was not convinced with procedure, but during the time of procedure previous unknown acquired digestion disorders exacerbated resulting with death.

5. During moderate procedure in animal diseases and disorders research, 56 mice died without previously detectable signs of suffering.

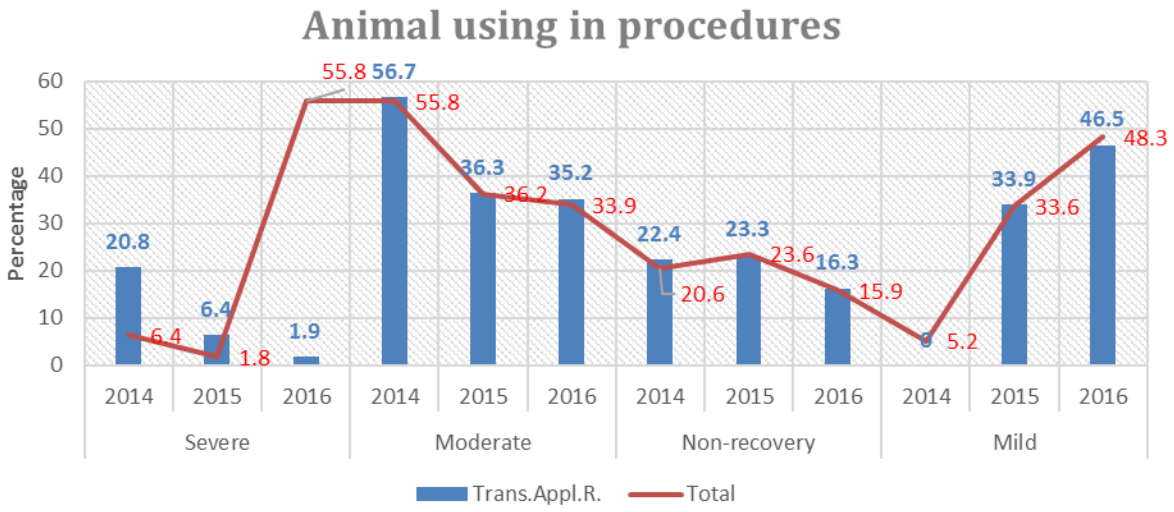
In moderate procedures in 2016 was used 1853 (33.95%) animals from which 1851 animals were exposed to planned moderate procedures, but 2 animals actually went through moderate procedures in human infections diseases research project because after using adjuvant (incomplete Freund's adjuvant) bad absorption in tissue was observed. Tissue thickening was remarked. It disappeared in 3-5days after injection was made. In moderate procedures 563 mice and 24 rats were used for trans/Appl human nervous and mental disorders, 48 mice, 418 mice for animal diseases and disorders research, 60 mice for basic nervous system research, 46 for human infectious and disorders research, 13 rabbits for musculoskeletal diseases and disorders and 158 mice for non-regulatory toxicology and ecotoxicology research (see Figure 3).

In 2016 868 (15.9%) animals were used in non-recovery procedures, including 260 mice and 560 rats in human cardiovascular disorders research projects and 40 pigs for higher education purposes (human and veterinary surgeons training).

In general observation there are evident changes in the basic research, where increased animal using in mild procedures (almost 2/3 form used animals for basic research), but still saving quite small amount – 3.2% (n=160) comparing with other research purposes.

The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect. In this research branch for the last three years decreased animal using, especially in harder procedures (see Fig.3), but increased animal using in mild procedures. In 2014 animals were not used in mild procedures. In 2014 and 2015 biggest amount of animals were used in severe and moderate procedures, but in 2016 – in mild procedures (46.4%) and in the same time animal using in severe procedures were low (1.9%).

Figure 3



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Scientific project authors strive to use *in silico, in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), but in 2016 – 40 pigs. After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease. Increase of pig using in non-recovery procedure probably is associated with more frequent training requests from surgeons.

Compeering previous year, in 2016 171 wild birds were used in wild nature research project. This project was authorized in previous year, but financial difficulties did not allow to realize project in 2015, but in 2016 after improvement of financial position, this project was resumed.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During the year 2016 users have not reported to competent authority that animals exposed to narcosis exceed classified “severe” procedure. In 2016 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4601	84.3%
Rats	632	11.58%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	14	0.26%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	40	0.73%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	171	3.13%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		

Animal Species	Number of animals	Percentage
Other Fish		
Cephalopods		
Total	**5458**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5233	95.88%
Animals born in the EU but not at a registered breeder	225	4.12%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5458**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	160	2.93%
Translational and applied research	5087	93.2%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	171	3.13%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	40	0.73%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5458**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular Blood and Lymphatic System		
Nervous System	160	100%
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	**160**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	604	11.87%
Human Infectious Disorders	108	2.12%
Human Cardiovascular Disorders	2277	44.76%
Human Nervous and Mental Disorders	1448	28.46%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	14	0.28%
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	478	9.4%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	158	3.11%
Total	**5087**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	5458	100%
Yes		
Total	**5458**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	868	15.9%
Mild [up to and including]	2637	48.31%
Moderate	1853	33.95%
Severe	100	1.83%
Total	**5458**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5458	100%
Yes		
Total	**5458**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5398	98.9%
Genetically altered without a harmful phenotype	60	1.1%
Genetically altered with a harmful phenotype		
Total	**5458**	**100.00%**

Latvia: Narrative 2017

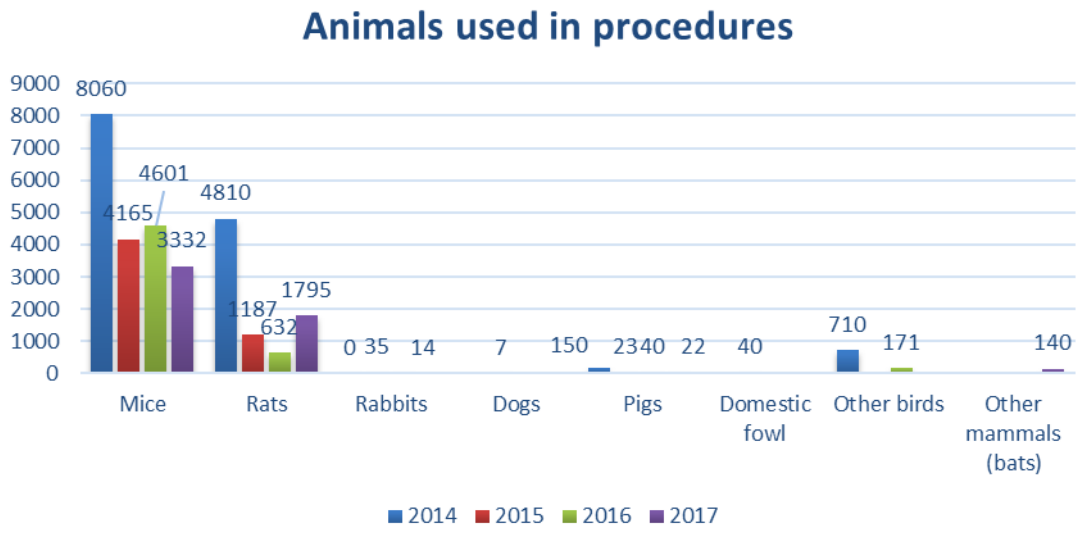
1. General information on any changes in trends observed since the previous reporting period.

In 2015 competent authority has approved 9 projects, in 2016 – 3, but in 2017 - 13. Since the previous years, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016), but slightly decreased – 5289 in 2017. During the 2015 active licence was for 16 projects, in 2016 – for 17, but in 2017 – for 25 projects. However it does not mean that in all projects all procedures were performed and projects realised as planned. In some cases projects or procedures were stopped for a while because the lack of financing or additional research before preclinical trials. Year by year the science quickly develops and that is why researchers after getting new information concerning their research topic uses *in vitro* methodology as much as possible, and it results with decreasing total amount of animals. In most of cases, especially in long lasting projects (5-year projects), researchers use less animals as they have written down in project licence application.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Comparing last three years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016 but in 2017 – decreased 63.0% (3332) (see Fig.1). Total amount of used rats have decreased from 21.75% (n=1187) in 2015 to 11.58% (n=632) in 2016, but increased in 2017 to 33.94% (1795). The reason for these changes is that in 2017 researchers have realized more projects where rats were included. In some specific investigations or testing of new substances rats were preferred because of their size. Rat's bigger size comparing to mice allow researchers to get more biological samples (for example – tissue, blood samples or tumour cells) for *in vitro* testing and in the same time also t allow to use less animals and get more necessary data. Compeering previous years in 2017 wild birds were not used for scientific purposes because of project ending however other wild species – bats (*Pipistrellus nathusii*) were used for mild procedures (basic research for white nose syndrome by taking blood samples for molecular analysis and investigation of their behaviour).

Figure 1



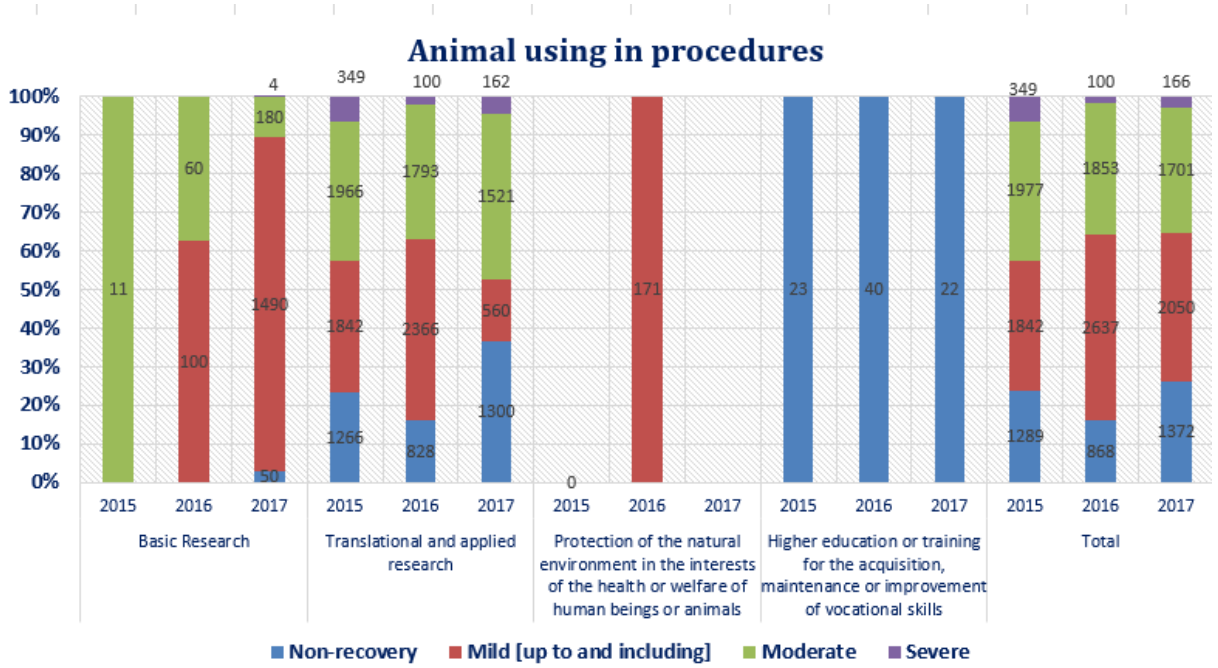
3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and the biggest part 96.4% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2 and Fig. 3) – 38.76% (n=2050) from which 1919 were used for planned mild procedures, but

a) 2 mice because the lack of tumour development were killed before the end of planned moderate procedure ((Trans/Appl Research) Human Cancer) and actually were exposed to mild procedure;
b) 24 rats and 65 mice were used as control group in moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) and were shame operated that finally did not cause further disabilities or dysfunctions except skin cut and finally resulted as mild procedure;
c) 40 rats were used in moderate procedure ((Basic Research) Nervous System) as animals of control group and did not underwent all manipulations comparing to other experimental groups, therefore actually were exposed to mild procedure.

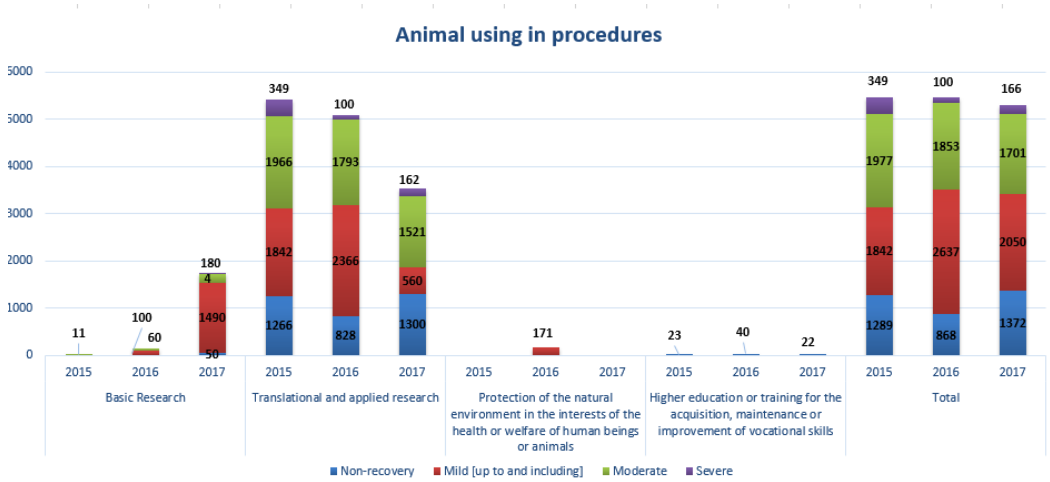
Figure 2



In total 166 (3.14%) animals in 2017 were used in severe procedures from which 114 animal were used for planned severe procedures (4 mice for (Basic Research) Oncology, and 110 mice for (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology) but 52 mice and 2 rats from three projects went through severe not planned procedure.

1. During moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) 18 mice died during the surgical manipulations and did not wake up after anaesthesia.
2. During moderate procedure ((Trans/Appl Research) Human Cancer) 34 animals lost weight more then 25% and therefore animals were humanely killed and were not included in further manipulations.

Figure 3

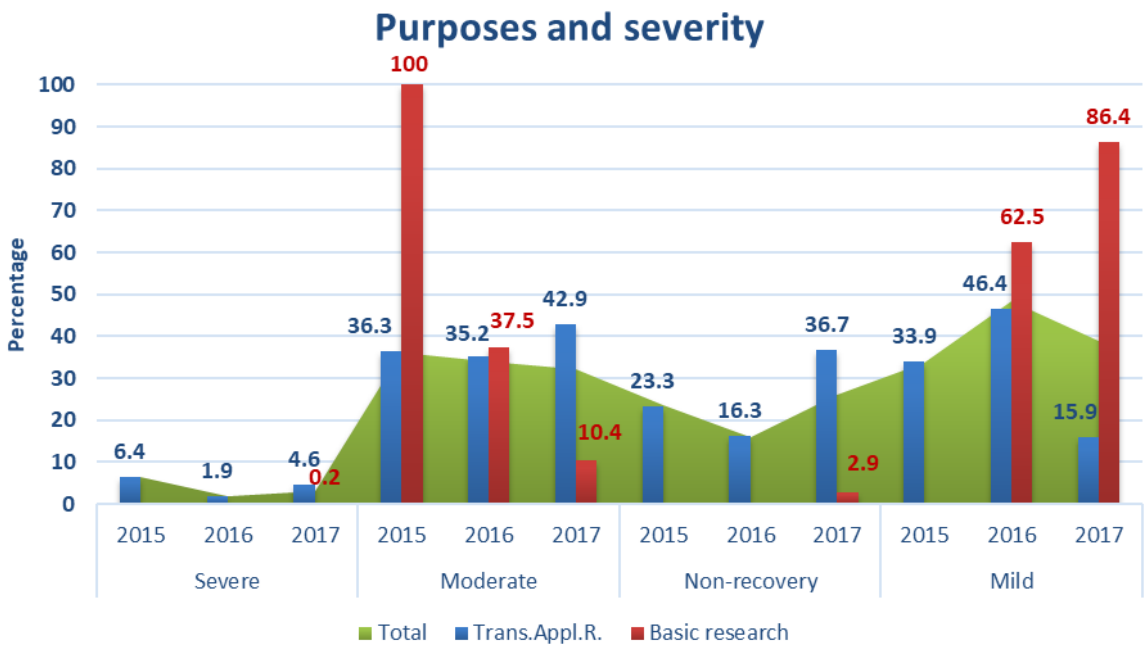


In moderate procedures in 2017 was used 1701 (32.16%) animals from which 804 mice were used in (Trans/Appl Research) Human Cancer research, 249 mice and 94 rats for (Trans/Appl Research) Human Nervous and Mental Disorders research, 59 rats for (Basic Research) Nervous System research and 374 mice for (Trans/Appl Research) Animal Diseases and Disorders research.

In 2017 1372 (25.94%) animals were used in non-recovery procedures, including 1300 rats for (Trans/Appl Research) Human Cardiovascular Disorders, 50 mice for (Basic Research) Nervous System and 22 pigs for Higher education or training for the acquisition, maintenance or improvement of vocational skills (human and veterinary surgeons training).

In general observation there are evident changes in severity of procedures. Comparing previous years in 2017 increased animal using in severe and non-recovery procedures. That is explained by long lasting projects (5-year projects) that were stopped for one or two year period for various reasons (lack of financing, additional *in vitro* research) but realized in 2017.
The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.
In this research branch for the last two years decreased animal using, especially in harder procedures (see Fig. 4), but in 2017 increased animal using in non-recovery, severe and moderate procedures.

Figure 4



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures in 2015 and 2016) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuous scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation

commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests. However increasing of animal using in non-recovery, moderate and severe procedures in 2017 is explained with interruption of long lasting projects (5-year lasting projects) and not fully realization during the time of first years authorization because of additional *in vitro* research and/or lack of finances.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Authors of scientific projects strive to use *in silico, in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan. If there are any possibility to decrease animal sufferings or to decrease a total amount of animals in procedures, applicants are strictly obligated to make changes in project before authorization. In addition – during inspections each project is checked according to approved methodology.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), 40 pigs – in 2016 and 22 pigs in 2017. After procedure (surgical intervention) pigs were euthanized. As much as possible manipulations (cuts, trainings of surgical techniques) were done with each animal under anaesthesia and narcosis to decrease a total amount of animals. Decrease of pig using in non-recovery procedure probably is associated with less frequent training requests from surgeons. In 2017 140 bats (*Pipistrellus nathusii*) were used for basic research (animal behaviour and infectious disease) in mild procedures. The procedure involved such a manipulations as blood and skin biopsy sample taking and observation of behaviour after animals were freed.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During the year 2017 users have reported two cases were animals did not awake after surgical intervention and narcosis (26 mice) and one case where 34 mice in cancer research where euthanized before the end of procedure because of weight lost more than 25%.

In 2017 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3332	63%
Rats	1795	33.94%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	22	0.42%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	140	2.65%
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**5289**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5127	96.94%
Animals born in the EU but not at a registered breeder	162	3.06%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5289**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1724	32.6%
Translational and applied research	3543	66.99%
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	22	0.42%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5289**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	4	0.23%
Cardiovascular Blood and Lymphatic System		
Nervous System	1580	91.65%
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	140	8.12%
Other basic research		
Total	**1724**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	840	23.71%
Human Infectious Disorders	135	3.81%
Human Cardiovascular Disorders	1406	39.68%
Human Nervous and Mental Disorders	605	17.08%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders		
Human Urogenital/Reproductive Disorders	70	1.98%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	0	0%
Other Human Disorders		
Animal Diseases and Disorders	377	10.64%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	110	3.1%
Total	**3543**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	5289	100%
Yes		
Total	**5289**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1372	25.94%
Mild [up to and including]	2050	38.76%
Moderate	1701	32.16%
Severe	166	3.14%
Total	**5289**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5289	100%
Yes		
Total	**5289**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	5229	98.87%
Genetically altered without a harmful phenotype	60	1.13%
Genetically altered with a harmful phenotype		
Total	**5289**	**100.00%**

Lithuania

Lithuania: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2015, there were 2451 laboratory animals employed for animal studies and other scientific purposes in Lithuania. In comparison to the previous year ~ 1000 less animals were used for the projects. Reduction can be justified due to the expiry date of more than 32 % projects in 2015.

The number of users increased from 8 in 2013 to 12 in 2015, however some establishments finished some projects in 2015.

Increase in use of birds is noticed.

Significant decrease in use of animals for the procedures classified as non-recovery.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The total number of animals used in specific areas is affected by many factors (i.e. active projects, funding, international projects ect.)

i. e. increase in use of animals for the purpose „Protection of the natural environment in the interests of the health or welfare of human beings or animals“ was directly related to one project where other birds (*Serinus canaria*) were used.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Most part of the animals (~64 %) were used for the procedures classified as mild [up to and including] severity, (~ 32 %) as moderate and (~4 %) as non-recovery.

Only Directive 2010/63/EU contains the requirement that all procedures should be classified, and no analogous to the system used in the Directives was introduced in the national legislation before, so this required additional input from users.

So significant decrease in use of animals for the procedures classified as non-recovery is mostly due to a better understanding of classification and better reporting of the actual severities by the users in 2015.

There was no exceeding of the ‘severe’ classification reported in 2015, because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category “Other”, only other birds (*Serinus canaria*) were used for one project during the reporting period.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period. No exemptions under article 6(4)(a) of the Directive 2010/63/EU were granted in 2015, either

Lithuania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1591	64.91%
Rats	572	23.34%
Guinea-Pigs	85	3.47%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	122	4.98%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	13	0.53%
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		

Animal Species	Number of animals	Percentage
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	64	2.61%
Reptiles	4	0.16%
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**2451**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2245	91.6%
Animals born in the EU but not at a registered breeder	206	8.4%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**2451**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2041	83.27%
Translational and applied research	302	12.32%
Regulatory use and Routine production		
Protection of the natural environment in the interests of the health or welfare of human beings or animals	64	2.61%

Purpose Category	Number of uses	Percentage
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	44	1.8%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**2451**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	388	19.01%
Cardiovascular Blood and Lymphatic System	275	13.47%
Nervous System	180	8.82%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	537	26.31%
Immune System	540	26.46%
Urogenital/Reproductive System	3	0.15%
Sensory Organs (skin, eyes and ears)	30	1.47%
Endocrine System/Metabolism		
Multisystemic	60	2.94%
Ethology / Animal Behaviour /Animal Biology		
Other basic research	28	1.37%
Total	**2041**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	22	7.28%
Human Infectious Disorders		
Human Cardiovascular Disorders	16	5.3%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	62	20.53%
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	20	6.62%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	182	60.26%
Total	**302**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		

Regulatory use and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	2451	100%
Yes		
Total	**2451**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	96	3.92%
Mild [up to and including]	1574	64.22%
Moderate	781	31.86%
Severe		
Total	**2451**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2451	100%
Yes		
Total	**2451**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2451	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**2451**	**100.00%**

Lithuania: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, there were 2660 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~200 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and (or) started performing projects. The number of users increased from 8 in 2013 to 14 in 2016.

The clearest trends in 2016 were increase in the use of farm animals for the purposes "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and "Regulatory use and Routine production".

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Almost 4 % of all the animals were used directly for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and it was almost twice as many in comparison to the previous year. Increase of animals used for this activity was related to an increased number of hospital type training centers due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2016 and other started or continued new projects in the end of the previous year.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Increase in use of animals for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" was partly related to the increased number of animals used for procedures classified as non-recovery.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

Substantial attention was given to 3R principles in personnel training. Training programmes were amended in terms of 3R theoretical and practical activities related to the search of animal alternatives by the organisers and approved by the competent authority.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category "Other", no other animals were used during the reporting period.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2016 as well as in 2015.

Lithuania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1759	66.13%
Rats	744	27.97%
Guinea-Pigs	30	1.13%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	51	1.92%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	48	1.8%
Goats		
Sheep	28	1.05%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		

Animal Species	Number of animals	Percentage
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**2660**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2602	97.82%
Animals born in the EU but not at a registered breeder	58	2.18%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**2660**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	2212	83.16%
Translational and applied research	117	4.4%
Regulatory use and Routine production	230	8.65%
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	101	3.8%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**2660**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	567	25.63%
Cardiovascular Blood and Lymphatic System	58	2.62%
Nervous System	69	3.12%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System	534	24.14%
Immune System	248	11.21%
Urogenital/Reproductive System	214	9.67%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	400	18.08%
Multisystemic	122	5.52%
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**2212**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	18	15.38%
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)	27	23.08%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	72	61.54%
Total	**117**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Toxicity and other safety testing including pharmacology	95	41.3%
Routine production	135	58.7%
Total	**230**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	40	42.11%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	15	15.79%
Pharmaco-dynamics (incl safety pharmacology)	40	42.11%
Total	**95**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	40	100%
Total	**40**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	135	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**135**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	175	76.09%
Legislation on medicinal products for veterinary use and their residues	55	23.91%
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	**230**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	230	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**230**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2660	100%
Yes		
Total	**2660**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	141	5.3%
Mild [up to and including]	1812	68.12%
Moderate	707	26.58%
Severe		
Total	**2660**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2660	100%
Yes		
Total	**2660**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2660	100%
Genetically altered without a harmful phenotype	0	0%
Genetically altered with a harmful phenotype		
Total	**2660**	**100.00%**

Lithuania: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, there were 2766 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~100 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and started performing projects. The number of users increased from 8 in 2013 to 12 in 2015 and to 14 in 2017.

The clearest trends in 2017 were the large increase in the use of fish for research, increase of use of farm animals (pigs) and use of animals for the purposes "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and "Translational and applied research".

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The most common primary purpose for using animals was basic research (in Immune System, Oncology, Nervous System) (~ 60 %), then (~ 22 %), for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" and (~ 18 %) for the purpose "Translational and applied research".

Increase in use of animals for the purpose "Higher education or training for the acquisition, maintenance or improvement of vocational skills" is noticed from ~ 4 % to ~ 22 %. Increase of animals used for this activity was related to increased number of hospital type training centres due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2017 and other started or continued new projects in the end of the previous year.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Most part of the animals (~79 %) were used for the procedures classified as mild [up to and including] severity, (~18 %) for the procedures classified as moderate and (~ 3 %) for non-recovery severity.

Decrease in use of animals for the procedures classified as moderate and non-recovery during year 2017-2015 is related to the fact that some establishment did not perform any projects due to reconstruction of premises for some time, so more animals were used for the procedures classified as mild.

There were no exceeding of the 'severe' classification reported in 2017 and previous year because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/Article_47_LT.pdf

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

As regards the category "Other", other birds (~ 1 %) and fish (~ 19 %) were used during the reporting period (~ 20 %) in total comparing to total amount of animals used in 2017.

The clearest trend in 2017 was the large increase in the use of fish for research. The main reason is, that new user was established and started performing projects with specific focus on fish.

Some other birds (Serinus canaria) were used.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2017.

Lithuania: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1718	62.11%
Rats	391	14.14%
Guinea-Pigs	15	0.54%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	13	0.47%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	68	2.46%
Goats		
Sheep	15	0.54%

Animal Species	Number of animals	Percentage
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds	26	0.94%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	520	18.8%
Cephalopods		
Total	**2766**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2683	97%
Animals born in the EU but not at a registered breeder	83	3%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**2766**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1659	59.98%
Translational and applied research	501	18.11%
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	606	21.91%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**2766**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	337	20.31%
Cardiovascular Blood and Lymphatic System	20	1.21%
Nervous System	284	17.12%
Respiratory System	103	6.21%
Gastrointestinal System including Liver		
Musculoskeletal System	10	0.6%
Immune System	873	52.62%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic	32	1.93%
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**1659**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	102	20.36%
Human Cardiovascular Disorders	8	1.6%
Human Nervous and Mental Disorders	107	21.36%
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)	17	3.39%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology	267	53.29%
Total	**501**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	2766	100%
Yes		
Total	**2766**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	83	3%
Mild [up to and including]	2186	79.03%
Moderate	497	17.97%
Severe		
Total	**2766**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2766	100%
Yes		
Total	**2766**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	2766	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**2766**	**100.00%**

Luxembourg

Luxembourg: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg an increase of about 50% of the use of animals was observed. Furthermore comparing the statistic of 2015, in 2015 the species “rat” was used in procedures.

More explanation will be indicated in part 2 of this questionnaire.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased during the last years. This trend will continue when reporting the following year (2016).

In Luxembourg two main institutions lead the laboratories and both modernised and increased their facilities during the last years. For example in 2016 a further facility was authorised, this will have a further impact on the number of animals used due to the fact of the little number of facilities (6 facilities) and the small size of the country.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 the first time the actual severity “severe” was reported. Initially for the concerned project the severity “mild” was prospected and consequently the responsible person stopped this project and they didn’t demanded any authorisation for modification .

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The particular efforts taken to promote the principle of the Three Rs were notably the enforcement and obligation of the training and the increased impact from the national committee.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

There is no significant proportion reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

During 2015 there was no case an exceedance of the ‘severe’ classification.

Luxembourg: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3078	87.34%
Rats	73	2.07%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	373	10.58%
Other Fish		
Cephalopods		
Total	**3524**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	3452	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**3452**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	3484	98.86%
Translational and applied research	40	1.14%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**3524**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	764	21.93%
Cardiovascular Blood and Lymphatic System	373	10.71%
Nervous System	1736	49.83%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	611	17.54%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**3484**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	39	97.5%
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	1	2.5%
Total	**40**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	3452	97.96%
Yes	72	2.04%
Total	**3524**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	151	4.28%
Mild [up to and including]	1654	46.94%
Moderate	1679	47.64%
Severe	40	1.14%
Total	**3524**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	3524	100%
Yes		
Total	**3524**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1721	48.84%
Genetically altered without a harmful phenotype	1657	47.02%
Genetically altered with a harmful phenotype	146	4.14%
Total	**3524**	**100.00%**

Luxembourg: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg there was an increase in the total number of uses from 3.524 in 2015 to 21.472 total uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total of 3.660 mammals were used in procedures in 2016. These figures represent an increase of 6% of the total use of mammals from 2015 to 2016.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015 to a total of 21.472 uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg, the two main institutions involved in animal testing both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2016.

Due to the small number of parties involved (6 facilities in total), this had a strong impact on the total number of animals used.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 the actual severity “severe” was reported the first time, when 1,14% of the uses were severe. In 2016 0,52% of the actual severities where classified as severe. As to the actual severities, no trend was observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics.

The particular efforts taken to promote the principle of the Three Rs were:

the focus on the education of the users,

the organisation of a workshop on the severity assessment and reporting

and additional care taken during the project evaluation.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category “other” was not reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2016 there was no case where the ‘severe-classification‘ has been exceeded.

Luxembourg: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	3493	16.27%
Rats	167	0.78%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	17812	82.95%
Other Fish		
Cephalopods		
Total	**21472**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	20987	98.81%
Animals born in the EU but not at a registered breeder	253	1.19%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**21240**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	21017	97.88%
Translational and applied research	455	2.12%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**21472**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	946	4.5%
Cardiovascular Blood and Lymphatic System	429	2.04%
Nervous System	18511	88.08%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	1131	5.38%
Urogenital/Reproductive System		

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**21017**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	372	81.76%
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	83	18.24%
Total	**455**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	21240	98.92%
Yes	232	1.08%
Total	**21472**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	341	1.59%
Mild [up to and including]	18628	86.75%
Moderate	2392	11.14%
Severe	111	0.52%
Total	**21472**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	21472	100%
Yes		
Total	**21472**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	18178	84.66%
Genetically altered without a harmful phenotype	1980	9.22%
Genetically altered with a harmful phenotype	1314	6.12%
Total	**21472**	**100.00%**

Luxembourg: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In Luxembourg there was an increase in the total number of uses from 3.524 total uses in 2015, 21.472 total uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total number of 5.668 mammals were used in procedures in 2017. These figures represent an increase of 54,86% of the total uses of mammals from 2016 to 2017.

Regarding the purpose of the animal uses, no trends ware observed during the last year. The main category is basic research, followed by translational and applied research, maintenance of colonies and higher education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015, 21.472 uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg two main institutions are involved in animal testing. Both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2017.

Due to the small number of the parties involved in animal experiments (6 facilities in total), the development of the animal facilities has a strong impact on the total number of animals used. In particular the majority of the animal uses (19.410 zebrafish larvae) represent a few projects.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Comparing the actual severities from 2016 to 2017 no trend were observed.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The particular efforts taken to promote the principle of the Three Rs have been:

- The focus is put on the education of the users. Notably additional minimum requirements have been adopted for the personal involved in animal experiment,

- A workshop on the severity assessment and reporting took place,

- Refinement of the housing and care of the animals is ensured, inter alia, by modernisation of the animal facilities and by a new animal facility. Another point is the environment enrichment of the cages

or aquariums, in particular, providing animals with appropriate housing that allows the expression of species-specific behaviours, such as nesting opportunities for mice.

- During the inspection attention is put on points such as that the staff follows the project protocol and in particularly that the humane endpoints are respected and the score sheets are reviewed. When procedures are conducted which involve pain or invasive procedures, it is verified that these procedures are carried out under general or local anaesthesia and that analgesia or another method is used to ensure that pain, suffering and distress are kept to a minimum.

- Additional care is taken during the project evaluation , inter alia, a review of the referenced literatures, a check of the most up to date references have been considered, a check whether there are alternative methods in place and the statistical calculation is reviewed. Regarding the alternative methods, it is checked if all measures are taken to reduce pain, suffering or lasting harms, if the humane endpoints are appropriate, if the housing, health checks of the animals are appropriate etc.

-Regarding the Reduction the national research institutes are collaborating with other research groups and are sharing data and resources (animals, tissue, organs and equipment) between research groups. Furthermore one institute owns an IRM, which enables longitudinal studies in the same animals and which is put at the disposal of the other institutes

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The category “other” was not reported.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 there was no case where the severe-classification has been exceeded.

Luxembourg: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	5572	21.56%
Rats	96	0.37%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		

Animal Species	Number of animals	Percentage
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	20173	78.07%
Other Fish		
Cephalopods		
Total	**25841**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	25617	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**25617**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	24562	95.05%
Translational and applied research	888	3.44%
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	144	0.56%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	247	0.96%
Total	**25841**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1861	7.58%
Cardiovascular Blood and Lymphatic System	374	1.52%
Nervous System	20265	82.51%
Respiratory System		
Gastrointestinal System including Liver		
Musculoskeletal System		
Immune System	2062	8.4%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**24562**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	526	59.23%
Human Infectious Disorders	326	36.71%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	36	4.05%
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	**888**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	25617	99.13%
Yes	224	0.87%
Total	**25841**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	519	2.01%
Mild [up to and including]	21938	84.9%
Moderate	3213	12.43%
Severe	171	0.66%
Total	**25841**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	25764	99.7%
Yes	77	0.3%
Total	**25841**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	22113	85.57%
Genetically altered without a harmful phenotype	3660	14.16%
Genetically altered with a harmful phenotype	68	0.26%
Total	**25841**	**100.00%**

Malta

Malta: Narrative 2015

1. **General information on any changes in trends observed since the previous reporting period.**

   During this year no changes have been observed in trends noted during the past years. This is due to the complete absence of scientific works involving animals.

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   N/A

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   N/A

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   N/A

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   N/A

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A

Malta: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	0	
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		

Animal Species	Number of animals	Percentage
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	0	100.00%

Malta: Narrative 2016

1. **General information on any changes in trends observed since the previous reporting period.**

   No changes have been noted from the previous year, so no animal experimentation have been carried out.

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   Not applicable

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   No

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   No

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   N/A

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A

Malta: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	0	
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		

Animal Species	Number of animals	Percentage
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	0	100.00%

Malta: Narrative 2017

1. **General information on any changes in trends observed since the previous reporting period.**

   This year an application has been received by the Competent authority and the approval has been granted to carry out research on fish (sea bass).

2. **Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.**

   The research program took to an increase in the number of animals used, from 0 to 250 fish.

3. **Information on any changes in trends in actual severities and analysis of the reasons thereof.**

   No severe procedures are involved in the study carried out.

4. **Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.**

   All the fish had to be been euthanized and incinerated.

5. **Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

   A significant proportion of animals is not used therefore it is not applicable

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

   N/A. This was an host specific parasite study interaction and did not involve severe procedures.

Malta: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice		
Rats		
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		

Animal Species	Number of animals	Percentage
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	250	100%
Cephalopods		
Total	**250**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
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	250	100%
Animals born in rest of world		
Total	**250**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research		
Translational and applied research	250	100%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**250**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology		
Cardiovascular 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		

Translational and applied research

Translational and applied research	Number of uses	Percentage
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	250	100%
Animal Welfare		
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**250**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology		
Total		

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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		

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total		

First uses and re-uses

Re-use	Number of uses	Percentage
No	250	100%
Yes		
Total	**250**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery		
Mild [up to and including]	250	100%
Moderate		
Severe		
Total	**250**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	250	100%
Yes		
Total	**250**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	250	100%
Genetically altered without a harmful phenotype		
Genetically altered with a harmful phenotype		
Total	**250**	**100.00%**

Netherlands

Netherlands: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

In 2014 and 2015, the Dutch collection of statistical information on the use of animals in procedures, was carried out according to the common format of Commission Implementing Decision 2012/707/EU. There are a big differences between the new data categories and the former Dutch data format. This makes it very difficult to compare the statistics of 2014 and 2015 with the data from previous years.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2015 528.159 animals were used in procedures. This is 92.868 (-14.9%) less than in 2014.

A decrease in numbers of animals has been observed in almost all data categories. Especially the number of mice (-32.701), cattle (-6.646), domestic fowl (-34.289), pigs (-4.777), rhesus monkeys (-47), and cats (-18) was reduced. In 2015 127.813 (26,7%) genetically altered animals were used in procedures, this is 17.574 (-12.1%) animals less than in 2014.

In 2015 animals were 8.514 times reused, which is 2.195 (+34.7%) more than in 2014 (6.319).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2015 1.971 (+12.9%) more procedures were reported in the severity category 'severe', compared to 2014. This increase was especially seen in the categories Translational and applied research (human) (+16.5%), Animal diseases and disorders / animal welfare (+6.3%), Higher education or training for the acquisition, maintenance or improvement of vocational skills (+0.5%), and Testing by legislation/feed legislation including legislation for the safety of target animals, works and environment (+1%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands continuous efforts have been taken to promote the principles of the 3R's. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Alures we have provided information on the 'other' categories in the required fields. Dutch users were asked to provide more information on the selected category when these information appeared to be insufficient. In some cases the users did realize that they could reclassify the animals uses in the predefined data categories. This is a continuous process of creating awareness to the authorized users.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2015 exceedance of the severity classification 'severe' has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	244804	51.05%
Rats	99602	20.77%
Guinea-Pigs	3433	0.72%
Hamsters (Syrian)	1518	0.32%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	1031	0.21%
Rabbits	9899	2.06%
Cats	61	0.01%
Dogs	750	0.16%
Ferrets	396	0.08%
Other carnivores	410	0.09%
Horses, donkeys and cross-breeds	213	0.04%
Pigs	8402	1.75%
Goats	239	0.05%
Sheep	2126	0.44%
Cattle	5240	1.09%
Prosimians		
Marmoset and tamarins	91	0.02%
Cynomolgus monkey	47	0.01%
Rhesus monkey	96	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	14	0%
Domestic fowl	51386	10.71%
Other birds	18248	3.8%
Reptiles	851	0.18%
Rana		
Xenopus	1181	0.25%
Other Amphibians	562	0.12%
Zebra fish	4909	1.02%
Other Fish	24071	5.02%
Cephalopods		
Total	**479580**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	378128	80.3%
Animals born in the EU but not at a registered breeder	90414	19.2%
Animals born in rest of Europe		
Animals born in rest of world	2350	0.5%
Total	**470892**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	166	95.4%
Animals born in rest of Europe		
Animals born in Asia	8	4.6%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**174**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	3	1.72%
F2 or greater	8	4.6%
Self-sustaining colony	163	93.68%
Total	**174**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	126592	26.4%
Translational and applied research	142675	29.75%
Regulatory use and Routine production	137291	28.63%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	364	0.08%
Preservation of species	1729	0.36%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	19628	4.09%
Forensic enquiries	42	0.01%
Maintenance of colonies of established genetically altered animals, not used in other procedures	51259	10.69%
Total	**479580**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	36560	28.88%
Cardiovascular Blood and Lymphatic System	12259	9.68%
Nervous System	20523	16.21%
Respiratory System	1763	1.39%
Gastrointestinal System including Liver	3499	2.76%
Musculoskeletal System	1890	1.49%
Immune System	15280	12.07%
Urogenital/Reproductive System	2261	1.79%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	234	0.18%
Endocrine System/Metabolism	6450	5.1%
Multisystemic	3318	2.62%
Ethology / Animal Behaviour /Animal Biology	17705	13.99%
Other basic research	4850	3.83%
Total	**126592**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13203	9.25%
Human Infectious Disorders	19623	13.75%
Human Cardiovascular Disorders	4985	3.49%
Human Nervous and Mental Disorders	11760	8.24%
Human Respiratory Disorders	3942	2.76%
Human Gastrointestinal Disorders including Liver	2677	1.88%
Human Musculoskeletal Disorders	1921	1.35%
Human Immune Disorders	3075	2.16%
Human Urogenital/Reproductive Disorders	965	0.68%
Human Sensory Organ Disorders (skin, eyes and ears)	281	0.2%
Human Endocrine/Metabolism Disorders	5034	3.53%
Other Human Disorders	882	0.62%
Animal Diseases and Disorders	42449	29.75%
Animal Welfare	28642	20.07%
Diagnosis of diseases	1877	1.32%
Plant diseases	436	0.31%
Non-regulatory toxicology and ecotoxicology	923	0.65%
Total	**142675**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	65122	47.43%
Other efficacy and tolerance testing	1023	0.75%
Toxicity and other safety testing including pharmacology	70723	51.51%
Routine production	423	0.31%
Total	**137291**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3162	4.86%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	61960	95.14%
Total	**65122**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1020	1.44%
Skin irritation/corrosion	316	0.45%
Skin sensitisation	3777	5.34%
Eye irritation/corrosion	85	0.12%
Repeated dose toxicity	6928	9.8%
Carcinogenicity	1538	2.17%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Genotoxicity	733	1.04%
Reproductive toxicity	23926	33.83%
Developmental toxicity	19323	27.32%
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Kinetics	986	1.39%
Ecotoxicity	9292	13.14%
Safety testing in food and feed area	960	1.36%
Target animal safety	1839	2.6%
Total	**70723**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	120	11.76%
Other lethal methods	425	41.67%
Non lethal methods	475	46.57%
Total	**1020**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	5024	72.52%
29 - 90 days	1904	27.48%
> 90 days		
Total	**6928**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	7821	84.17%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity	720	7.75%
Bioaccumulation	751	8.08%
Other ecotoxicity		
Total	**9292**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	294	69.5%
Monoclonal antibody by mouse ascites method		
Other product types	129	30.5%
Total	**423**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	44052	32.09%
Legislation on medicinal products for veterinary use and their residues	33821	24.63%
Medical devices legislation	2	0%
Industrial chemicals legislation	45992	33.5%
Plant protection product legislation	2764	2.01%
Biocides legislation		
Food legislation including food contact material	740	0.54%
Feed legislation including legislation for the safety of target animals, workers and environment	1045	0.76%
Cosmetics legislation		
Other legislation	8875	6.46%
Total	**137291**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	127695	93.01%
Legislation satisfying national requirements only [within EU]	521	0.38%
Legislation satisfying Non-EU requirements only	9075	6.61%
Total	**137291**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	471066	98.22%
Yes	8514	1.78%
Total	**479580**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	23323	4.86%
Mild [up to and including]	346271	72.2%
Moderate	92789	19.35%
Severe	17197	3.59%
Total	**479580**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	469439	97.89%
Yes	10141	2.11%
Total	**479580**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	351767	73.35%
Genetically altered without a harmful phenotype	63088	13.15%
Genetically altered with a harmful phenotype	64725	13.5%
Total	**479580**	**100.00%**

Netherlands: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period

In 2016, the Dutch registered establishments reported 403.370 animals used in procedures. This is 76.210 (-18.9%) less than in 2015. Especially the number of mice (-82.826), sheep (-1688), rabbits (-1320) and cattle (-1167) was reduced.

In 2016 animals were 10.819 times reused, which is which is 2305 more than in 2015 (8.514).
Reuse mainly takes place for the purpose of education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2016, 78.209 procedures were reported with the use of genetically altered animals. This is a decrease of 49.604 animals compared to 2015. This decrease in use of genetically altered animals can partially be explained with the observation that in the previous years a large numbers of lines of genetically altered animals were established. This after completion of a welfare assessment with a minimum of two generations. For a substantial amount of genetically altered lines, it was concluded in the welfare assessment that they are not expected to have a harmful phenotype. Therefore, breeding of these lines no longer needs to be reported.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severities reported in 2016 (mild 68.7%, moderate 21.7% severe 3.3%, and non-recovery: 6.3%) are generally in line with the actual severities reported in 2015 (non-recovery 4.9%, mild 72.2%, moderate 19.3% and severe 3.6%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R's. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other carnivores (main categories): European pine marten (*Martes martes*), harbour seals (*Phoca vitulina*), European (Russian) minks (*Mustela lutreola*), Toepaja (*Tupaia belangeri*), and wild boars (*Sus scrofa*).

Other birds (main categories): 4803 (23.8%) *Parus Major* (great tit), 3654 (18.1%) *Anas plathyrynchos* (common mallard), 1572 (7.8%) *Gallus gallus* (red junglefowl), 1363 (6.8%) *Limosa limosa (*black tailed godwit), 1055 (5.2%) *Cyanistes caeruleus* (Eurasian blue tit).

Other fish (main categories): 3087 (23.8%) *Anguilla Anguilla* (European eel), 2909 (22.5%) *Pimephales promelas* (fathead minnow), 2780 (21.5%) *Cyprinus carpio* (common carp)

All procedures (3257) reported in de category 'other basic research' were used for cell biology-research.

2756 out of 5008 procedures in the category 'other efficacy and tolerance testing' were used for tests concerning the European pharmacopeia.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2016 exceedance of the severity classification 'severe' has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	148406	38.38%
Rats	106876	27.64%
Guinea-Pigs	2763	0.71%
Hamsters (Syrian)	1443	0.37%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	472	0.12%
Rabbits	8579	2.22%
Cats	89	0.02%
Dogs	656	0.17%
Ferrets	294	0.08%
Other carnivores	216	0.06%
Horses, donkeys and cross-breeds	146	0.04%
Pigs	10129	2.62%
Goats	152	0.04%
Sheep	438	0.11%
Cattle	4073	1.05%
Prosimians		
Marmoset and tamarins	16	0%
Cynomolgus monkey	34	0.01%
Rhesus monkey	70	0.02%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1	0%
Domestic fowl	52237	13.51%
Other birds	20143	5.21%
Reptiles	207	0.05%

Animal Species	Number of animals	Percentage
Rana	20	0.01%
Xenopus	431	0.11%
Other Amphibians	63	0.02%
Zebra fish	15804	4.09%
Other Fish	12942	3.35%
Cephalopods		
Total	**386700**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	288771	76.84%
Animals born in the EU but not at a registered breeder	82417	21.93%
Animals born in rest of Europe		
Animals born in rest of world	4612	1.23%
Total	**375800**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	58	71.6%
Animals born in rest of Europe		
Animals born in Asia	23	28.4%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**81**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	25	30.86%
Self-sustaining colony	56	69.14%
Total	**81**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	115211	29.79%
Translational and applied research	107466	27.79%
Regulatory use and Routine production	142733	36.91%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	24	0.01%
Preservation of species	4257	1.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	14714	3.81%
Forensic enquiries	677	0.18%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1618	0.42%
Total	**386700**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	43795	38.01%
Cardiovascular Blood and Lymphatic System	7531	6.54%
Nervous System	17046	14.8%
Respiratory System	1498	1.3%
Gastrointestinal System including Liver	3351	2.91%
Musculoskeletal System	848	0.74%
Immune System	13063	11.34%
Urogenital/Reproductive System	1653	1.43%
Sensory Organs (skin, eyes and ears)	316	0.27%
Endocrine System/Metabolism	3670	3.19%
Multisystemic	3598	3.12%
Ethology / Animal Behaviour /Animal Biology	15585	13.53%
Other basic research	3257	2.83%
Total	**115211**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14122	13.14%
Human Infectious Disorders	18775	17.47%
Human Cardiovascular Disorders	4564	4.25%
Human Nervous and Mental Disorders	9646	8.98%
Human Respiratory Disorders	2664	2.48%
Human Gastrointestinal Disorders including Liver	2186	2.03%
Human Musculoskeletal Disorders	917	0.85%
Human Immune Disorders	2024	1.88%
Human Urogenital/Reproductive Disorders	107	0.1%
Human Sensory Organ Disorders (skin, eyes and ears)	430	0.4%
Human Endocrine/Metabolism Disorders	2444	2.27%
Other Human Disorders	30	0.03%
Animal Diseases and Disorders	18186	16.92%
Animal Welfare	29363	27.32%
Diagnosis of diseases	1339	1.25%
Plant diseases	43	0.04%
Non-regulatory toxicology and ecotoxicology	626	0.58%
Total	**107466**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	54947	38.5%
Other efficacy and tolerance testing	5008	3.51%
Toxicity and other safety testing including pharmacology	82616	57.88%
Routine production	162	0.11%
Total	**142733**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2603	4.74%
Pyrogenicity testing		
Batch potency testing	52206	95.01%
Other quality controls	138	0.25%
Total	**54947**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1903	2.3%
Skin irritation/corrosion	124	0.15%
Skin sensitisation	4086	4.95%
Eye irritation/corrosion	107	0.13%
Repeated dose toxicity	6386	7.73%
Carcinogenicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Genotoxicity	660	0.8%
Reproductive toxicity	25780	31.2%
Developmental toxicity	35853	43.4%
Kinetics	1001	1.21%
Ecotoxicity	4917	5.95%
Safety testing in food and feed area	1792	2.17%
Target animal safety	7	0.01%
Total	**82616**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods	112	5.89%
Non lethal methods	1791	94.11%
Total	**1903**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	2047	32.05%
29 - 90 days	3679	57.61%
> 90 days	660	10.34%
Total	**6386**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3777	76.82%
Chronic toxicity		
Reproductive ecotoxicity	240	4.88%
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	900	18.3%
Other ecotoxicity		
Total	**4917**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	2	1.23%
Monoclonal antibody by mouse ascites method		
Other product types	160	98.77%
Total	**162**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	38543	27%
Legislation on medicinal products for veterinary use and their residues	30184	21.15%
Medical devices legislation	62	0.04%
Industrial chemicals legislation	68172	47.76%
Plant protection product legislation	310	0.22%
Biocides legislation	86	0.06%
Food legislation including food contact material	438	0.31%
Feed legislation including legislation for the safety of target animals, workers and environment	2182	1.53%
Cosmetics legislation		
Other legislation	2756	1.93%
Total	**142733**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	140100	98.16%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	2633	1.84%
Total	**142733**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	375881	97.2%
Yes	10819	2.8%
Total	**386700**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	8732	2.26%
Mild [up to and including]	277205	71.68%
Moderate	87429	22.61%
Severe	13334	3.45%
Total	**386700**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	378070	97.77%
Yes	8630	2.23%
Total	**386700**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	308491	79.78%
Genetically altered without a harmful phenotype	67451	17.44%
Genetically altered with a harmful phenotype	10758	2.78%
Total	**386700**	**100.00%**

Netherlands: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

In 2017, the Dutch registered establishments reported 477.550 animals used in procedures. This is 74.180 (+18.4%) more than in 2016. Especially the number of mice (+44.015), and zebrafish (+36.220) was increased. The number of rats (-18.052) was reduced.

In 2017 animals were 11.138 times reused, which is 319 animal more than in 2016 (10.819). Reuse mainly takes place for the purpose of education and training.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2017 more experiments with zebrafish were carried out in the context of intensifying research into new possibilities for the screening of anti-cancer drugs. In addition, more experiments with zebrafish have been carried out as a result of research into hormone-disrupting substances in the context of a larger EU project.

In 2017, 133.365 procedures were reported with the use of genetically altered animals. This is a increase of 55.156 animals compared to 2016. Most animal testing on genetically modified animals have carried out on mice (84,908, 63.7% of the number of animal tests for genetically modified animals animals) and zebrafish (45,941, 34.4%).

After a significant increase in number of animal uses in 2014 and a temporary decrease in 2016, the number of animals uses appears to be stabilizing in 2017 and has reached the same level as in the reporting years 2013 and 2015. These fluctuations seem to be caused mainly by the adaptation of the user community to the new reporting and licensing system, introduced in 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The actual severities reported in 2017 (mild 64,9%, moderate 25,5%, severe 3.0%, and non-recovery: 6.6%) are generally in line with the actual severities reported in 2016 (mild 68.7%, moderate 21.7%, severe 3.3%, and non-recovery 6.3%).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R's. However, it is not possible to trace back these efforts to specific items in the statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other carnivores (main categories): 257 European (Russian) minks (Mustela lutreola), 6 harbour seals (Phoca vitulina), 6 badgers (Meles meles), and 2 European pine marten (Martes martes).

Other birds (main categories): 4618 Parus Major (great tit), 3822 Anas plathyrynchos (common mallard), 3160 Gallus gallus (red junglefowl), 1580 Limosa limosa (black tailed godwit).

Other fish (main categories): 5318 Pleuronectes platessa (European plaice), 4467 Anguilla Anguilla (European eel), 3571 Limanda limanda (common dab).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In 2017 exceedance of the severity classification 'severe' has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	205993	43.14%
Rats	91537	19.17%
Guinea-Pigs	5816	1.22%
Hamsters (Syrian)	1035	0.22%
Hamsters (Chinese)	12	0%
Mongolian gerbil		
Other Rodents	736	0.15%
Rabbits	9764	2.04%
Cats	200	0.04%
Dogs	909	0.19%
Ferrets	680	0.14%
Other carnivores	270	0.06%
Horses, donkeys and cross-breeds	173	0.04%
Pigs	9738	2.04%
Goats	259	0.05%
Sheep	558	0.12%
Cattle	3833	0.8%
Prosimians		
Marmoset and tamarins	41	0.01%
Cynomolgus monkey	42	0.01%
Rhesus monkey	234	0.05%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	3315	0.69%
Domestic fowl	55371	11.59%
Other birds	18322	3.84%
Reptiles	294	0.06%
Rana	9	0%
Xenopus	438	0.09%

Animal Species	Number of animals	Percentage
Other Amphibians	60	0.01%
Zebra fish	52024	10.89%
Other Fish	15887	3.33%
Cephalopods		
Total	**477550**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	363141	77.89%
Animals born in the EU but not at a registered breeder	94773	20.33%
Animals born in rest of Europe	44	0.01%
Animals born in rest of world	8263	1.77%
Total	**466221**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	189	98.95%
Animals born in rest of Europe		
Animals born in Asia	2	1.05%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**191**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	2	1.05%
Self-sustaining colony	189	98.95%
Total	**191**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	199245	41.72%
Translational and applied research	127385	26.67%
Regulatory use and Routine production	122247	25.6%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	873	0.18%
Preservation of species	3698	0.77%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	22074	4.62%
Forensic enquiries	361	0.08%
Maintenance of colonies of established genetically altered animals, not used in other procedures	1667	0.35%
Total	**477550**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	94460	47.41%
Cardiovascular Blood and Lymphatic System	6868	3.45%

Basic Research	Number of uses	Percentage
Nervous System	18175	9.12%
Respiratory System	758	0.38%
Gastrointestinal System including Liver	3203	1.61%
Musculoskeletal System	692	0.35%
Immune System	16582	8.32%
Urogenital/Reproductive System	1199	0.6%
Sensory Organs (skin, eyes and ears)	1030	0.52%
Endocrine System/Metabolism	4351	2.18%
Multisystemic	4115	2.07%
Ethology / Animal Behaviour /Animal Biology	20617	10.35%
Other basic research	27195	13.65%
Total	**199245**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	13920	10.93%
Human Infectious Disorders	22913	17.99%
Human Cardiovascular Disorders	5882	4.62%
Human Nervous and Mental Disorders	9692	7.61%
Human Respiratory Disorders	2410	1.89%
Human Gastrointestinal Disorders including Liver	2555	2.01%
Human Musculoskeletal Disorders	1587	1.25%
Human Immune Disorders	4179	3.28%
Human Urogenital/Reproductive Disorders	814	0.64%
Human Sensory Organ Disorders (skin, eyes and ears)	575	0.45%
Human Endocrine/Metabolism Disorders	2423	1.9%
Other Human Disorders	235	0.18%
Animal Diseases and Disorders	31368	24.62%
Animal Welfare	22221	17.44%
Diagnosis of diseases	1115	0.88%
Plant diseases	8	0.01%
Non-regulatory toxicology and ecotoxicology	5488	4.31%
Total	**127385**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	50082	40.97%
Other efficacy and tolerance testing	3235	2.65%
Toxicity and other safety testing including pharmacology	68753	56.24%
Routine production	177	0.14%
Total	**122247**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1948	3.89%
Pyrogenicity testing		
Batch potency testing	47934	95.71%
Other quality controls	200	0.4%
Total	**50082**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1886	2.74%
Skin irritation/corrosion	47	0.07%
Skin sensitisation	2378	3.46%
Eye irritation/corrosion	59	0.09%
Repeated dose toxicity	8739	12.71%
Carcinogenicity		
Neurotoxicity		
Other toxicity/safety testing		
Genotoxicity	106	0.15%
Reproductive toxicity	36568	53.19%
Developmental toxicity	9944	14.46%
Kinetics	1635	2.38%
Pharmaco-dynamics (incl safety pharmacology)	8	0.01%
Phototoxicity	4	0.01%
Ecotoxicity	4101	5.96%
Safety testing in food and feed area	2104	3.06%
Target animal safety	1174	1.71%
Total	**68753**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	1886	100%
Total	**1886**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3875	44.34%
29 - 90 days	4131	47.27%
> 90 days	733	8.39%
Total	**8739**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1368	33.36%
Chronic toxicity	2329	56.79%
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	404	9.85%
Other ecotoxicity		
Total	**4101**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	6	3.39%
Monoclonal antibody by mouse ascites method		
Other product types	171	96.61%
Total	**177**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	30227	24.73%
Legislation on medicinal products for veterinary use and their residues	31915	26.11%
Medical devices legislation		
Industrial chemicals legislation	57024	46.65%
Plant protection product legislation	312	0.26%
Biocides legislation	92	0.08%
Food legislation including food contact material	447	0.37%
Feed legislation including legislation for the safety of target animals, workers and environment	2164	1.77%
Cosmetics legislation		
Other legislation	66	0.05%
Total	**122247**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	119545	97.79%
Legislation satisfying national requirements only [within EU]	8	0.01%
Legislation satisfying Non-EU requirements only	2694	2.2%
Total	**122247**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	466412	97.67%
Yes	11138	2.33%
Total	**477550**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	31611	6.62%
Mild [up to and including]	310002	64.92%
Moderate	121739	25.49%
Severe	14198	2.97%
Total	**477550**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	466582	97.7%
Yes	10968	2.3%
Total	**477550**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	344185	72.07%
Genetically altered without a harmful phenotype	123939	25.95%
Genetically altered with a harmful phenotype	9426	1.97%
Total	**477550**	**100.00%**

Poland

Poland: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The report is the first submitted under the new rules.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The report is the first submitted under the new rules.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The report is the first submitted under the new rules.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Propagation and awareness of the need for replacement, reduction and refinement (3R) is one of the primary aims Polish National Ethics Committee on Animal Experimentation and is governed by a legal act of the highest importance, the Act on Experiments on Animals of 15 January 2015, in accordance to the Directive 2010/63/EU on the protection of animals used for scientific purposes.
Propagation of list of alternative methods designed to replace some routine animal tests and reduction of number of animals in routine testing is accessible at the webpage of the Committee.
Application of alternative methods to replace animals from routine tests is one of the major criteria in assessment of animal study applications by the Local Ethics Committees in Poland. Description of replacement, reduction and refinement application is also an indispensable part of each application.
The Committee supports the 3R courses for scientists and caretakers, which are obligatory to receive any permission to perform or plan experiments. All these issues are also propagate during the meetings organized with the local committees and disseminate to the bodies on animal welfare, which operate in all breeders, suppliers and users. At the webpage of the Committee there are documents concerning 3R rules prepared by European Commission and the guides prepared by the Committee describing how to assess the invasiveness procedures and how to make them milder to animals. All these documents are publicly accessible.
In our opinion, it is too early to assess its impacts on statistics.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In the 2015 report under the category "other animals" there are:

- Other carnivores (other Carnivora) are Meles meles, Mustela nivalis, Neovison vison, Nyctereutes procyonoides, Ursus arctos, Vulpes vulpes used in the purposes of Ethology /

Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals. They represent 96,24 % of all carnivores.

- Other birds (other Aves) are Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Calidris alba, Calidris ferruginea, Calidris canutus, Canistes caerules, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Cisticola chubbi, Coturnix japonica, Columba livia, Cyanistes caeruleus, Dromaiinae, Emberiza hortulana, Falco peregrinus, Fulica atra, Gerygone flavolateralis, Hirundo rustica, Laniarus atroflavus, Larus canus, Meleagris gallopavo gallopavo var. Domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sternula albiforns, Sterna hirundo, Sylvia communis, Turdus philomelos, Taeniopygia guttata, , Turdus merula used in the purposes of Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, Higher education or training for the acquisition, maintenance or improvement of vocational skills. They represent 34,31% of all birds.

- Other fish (other Pisces) are Acipenser baeri, Acipenser guldenstaedtii, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Carassius carassius, Cobitis taenia, Coregonus lavaretus, Cyprinus carpio, Gasterosteus aculeatus, Leuciscus idus, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Platichthys flesus, Poecilia reticulata, Poecilia sphenops, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta, Salmonidae, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Tinca tinca used in the purposes of (Regulatory use/Toxicity and../Ecotoxicity) Acute toxicity, (Basic Research) Immune System, (Basic Research) Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, (Basic Research) Urogenital/Reproductive System, (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology, Higher education or training for the acquisition, maintenance or improvement of vocational skills, Preservation of species, (Basic Research) Multisystemic , (Trans/Appl Research) Animal Welfare. They represent 94,85 % of all fish.

- Other amphibians (other Amphibia) are Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus, Slalamandra salamandra, used in the purposes of Basic Research: Urogenital/Reproductive System and Ethology / Animal Behaviour /Animal Biology. They represent 36,7 % of all amphibians.

In Regulatory use / Routine production as „Other" are specified medicinal products and quality controls.

In Regulatory use as „Other efficacy and tolerance testing" are specified study of local tolerance and study of skin sensitization.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There are no such cases.

Poland: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	88776	50.16%
Rats	36073	20.38%
Guinea-Pigs	5756	3.25%
Hamsters (Syrian)	22	0.01%
Hamsters (Chinese)		
Mongolian gerbil	178	0.1%
Other Rodents	8445	4.77%
Rabbits	1606	0.91%
Cats	8	0%
Dogs	24	0.01%
Ferrets		
Other carnivores	818	0.46%
Horses, donkeys and cross-breeds	232	0.13%
Pigs	1718	0.97%
Goats	8	0%
Sheep	566	0.32%
Cattle	1637	0.92%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1195	0.68%
Domestic fowl	11099	6.27%
Other birds	5798	3.28%
Reptiles	110	0.06%
Rana	224	0.13%
Xenopus	102	0.06%
Other Amphibians	189	0.11%
Zebra fish	639	0.36%
Other Fish	11757	6.64%
Cephalopods		
Total	**176980**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	145779	83.75%
Animals born in the EU but not at a registered breeder	27864	16.01%
Animals born in rest of Europe	21	0.01%
Animals born in rest of world	398	0.23%
Total	**174062**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	126089	71.24%
Translational and applied research	14826	8.38%
Regulatory use and Routine production	29475	16.65%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3126	1.77%
Preservation of species	664	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2688	1.52%
Forensic enquiries	100	0.06%
Maintenance of colonies of established genetically altered animals, not used in other procedures	12	0.01%
Total	**176980**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	9925	7.87%
Cardiovascular Blood and Lymphatic System	7537	5.98%
Nervous System	53294	42.27%
Respiratory System	236	0.19%
Gastrointestinal System including Liver	4076	3.23%
Musculoskeletal System	1107	0.88%
Immune System	6579	5.22%
Urogenital/Reproductive System	5662	4.49%
Sensory Organs (skin, eyes and ears)	495	0.39%
Endocrine System/Metabolism	3322	2.63%
Multisystemic	15835	12.56%
Ethology / Animal Behaviour /Animal Biology	6463	5.13%
Other basic research	11558	9.17%
Total	**126089**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	2906	19.6%
Human Infectious Disorders	468	3.16%
Human Cardiovascular Disorders	207	1.4%
Human Nervous and Mental Disorders	2399	16.18%
Human Respiratory Disorders	80	0.54%
Human Gastrointestinal Disorders including Liver	244	1.65%
Human Musculoskeletal Disorders	164	1.11%
Human Immune Disorders	338	2.28%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	410	2.77%
Human Endocrine/Metabolism Disorders	96	0.65%
Other Human Disorders	429	2.89%
Animal Diseases and Disorders	1642	11.08%
Animal Welfare	2418	16.31%
Diagnosis of diseases	577	3.89%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	2448	16.51%
Total	**14826**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16708	56.69%
Other efficacy and tolerance testing	36	0.12%
Toxicity and other safety testing including pharmacology	11766	39.92%
Routine production	965	3.27%
Total	**29475**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4710	28.19%
Pyrogenicity testing	234	1.4%
Batch potency testing	10089	60.38%
Other quality controls	1675	10.03%
Total	**16708**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	5385	45.77%
Skin irritation/corrosion	259	2.2%
Skin sensitisation	1284	10.91%
Eye irritation/corrosion	50	0.42%
Repeated dose toxicity	183	1.56%
Carcinogenicity	140	1.19%
Developmental toxicity		
Genotoxicity		
Kinetics		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Reproductive toxicity	1425	12.11%
Neurotoxicity	142	1.21%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	164	1.39%
Ecotoxicity	2718	23.1%
Other toxicity/safety testing	16	0.14%
Total	**11766**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	4525	84.03%
Other lethal methods		
Non lethal methods	860	15.97%
Total	**5385**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	183	100%
29 - 90 days		
> 90 days		
Total	**183**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2718	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**2718**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	383	39.69%
Monoclonal antibody by mouse ascites method		
Other product types	582	60.31%
Total	**965**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19733	66.95%
Legislation on medicinal products for veterinary use and their residues	3025	10.26%
Medical devices legislation	867	2.94%
Industrial chemicals legislation	2022	6.86%
Plant protection product legislation	3150	10.69%
Biocides legislation		
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	12	0.04%

Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation	666	2.26%
Total	**29475**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	28709	97.4%
Legislation satisfying national requirements only [within EU]	607	2.06%
Legislation satisfying Non-EU requirements only	159	0.54%
Total	**29475**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	174062	98.35%
Yes	2918	1.65%
Total	**176980**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	16523	9.34%
Mild [up to and including]	67288	38.02%
Moderate	64396	36.39%
Severe	28773	16.26%
Total	**176980**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	176187	99.55%
Yes	793	0.45%
Total	**176980**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	166850	94.28%
Genetically altered without a harmful phenotype	6489	3.67%
Genetically altered with a harmful phenotype	3641	2.06%
Total	**176980**	**100.00%**

Poland: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The 2016 report is only the second one made in accordance with the new rules. This makes it impossible to identify real trends in the use of animals for experiments. In addition, the drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. On the one hand, this has resulted in an increase in the number of animals used, due to rapidly completed 'old' experiments. On the other hand, some experiments which are not considered procedures under the new rules continue to take place (and be reported). The reports for 2015 could also contain errors resulting from a misunderstanding of the new rules and reporting rules. Users' awareness is increasing thanks to numerous training courses held in 2015-2016 and other forms of disseminating information, with the consequence that subsequent reports are correct and more consistent.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The observed differences in the number of animals used in each area, as reflected in the 2015 and 2016 reports, may be the consequence of the trends described above. In addition, they seem to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016, a clear decline is observed in the number of mice used in 'non-recovery' experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes. Certainty of the accuracy of the data reported was only achieved in the subsequent report for 2016.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website.
When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for

authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged by law to set up monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users' reporting in this area on an annual basis.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the 'other' group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2016, the animal species included in the 'other' category were:

- 'Other' species of carnivore (other Carnivora), namely Mustela nivalis and Neovison vison. These are used in fundamental research relating to biology and species behaviour and translational research on animal welfare. They account for 18.25% of all carnivorous animal species used in research.
- 'Other' bird species (other Aves), namely Acrocephalus arundinaceus, Acrocephalus dumetorum, Acrocephalus palustris, Acrocephalus schoenobaenus, Acrocephalus scirpaceus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris ferruginea, Canistes caerules, Chlidonias hybrid, Columba livia, Coturnix japonica, Cyanistes caeruleus, Dromaiinae, Ficedula hypoleuca, Fringilla coelebs, Hippolais icterina, Hirundo rustica, Lanius collurio, Larus canus, Locustella fluviatilis, Locustella luscinioides, Locustella naevia, Meleagris gallopavo gallopavo var. domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sterna albifrons, Sterna hirundo, Sylvia borin, Sylvia communis, Sylvia curruca, Sylvia nisoria, Tetrao urogallus, Turdus merula and Turdus philomelos. These are mainly used in fundamental research relating to biology and species behaviour, tests of gastrointestinal systems, including liver and multisystemic tests, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 66.61% of all bird species used in research.
- 'Other' fish species (other Pisces), namely Acipenser baeri, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Barbus barbus, Carassius auratus, Carassius carassius, Carassius gibelio, Chondrostoma nasus, Clarias gariepinus, Cobitis taenia, Cobitis elongatoides, Cobitis hybrids, Coregonus albula, Coregonus lavaretus, Cyprinus carpio, Esox lucius, Gasterosteus aculeatus, Gymnocephalus cernua, Neogobius fluviatilis, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Poecilia reticulate, Platichthys flesus, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta m. trutta, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Squalius cephalus and Tinca tinca. These are mainly used in fundamental research relating to biology and species behaviour, tests of immune systems,

reproductive systems and multisystemic tests, translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature, but also in some acute toxicity studies. They account for 97.16% of all fish species used in research.

- 'Other' amphibian species (other Amphibia), namely Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus and Slalamandra salamandra. These are used in fundamental research relating to biology and species behaviour and reproductive system tests, and translational research on animal diseases and disorders. They account for 97.32% of all amphibian species used in research.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees.

Poland: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	89105	47.22%
Rats	32370	17.15%
Guinea-Pigs	6639	3.52%
Hamsters (Syrian)	212	0.11%
Hamsters (Chinese)		
Mongolian gerbil	88	0.05%
Other Rodents	1263	0.67%
Rabbits	998	0.53%
Cats	15	0.01%
Dogs	88	0.05%
Ferrets		
Other carnivores	23	0.01%
Horses, donkeys and cross-breeds	220	0.12%
Pigs	1068	0.57%
Goats	36	0.02%
Sheep	1143	0.61%
Cattle	492	0.26%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	578	0.31%
Domestic fowl	3612	1.91%

Animal Species	Number of animals	Percentage
Other birds	7207	3.82%
Reptiles	526	0.28%
Rana	20	0.01%
Xenopus		
Other Amphibians	727	0.39%
Zebra fish	1203	0.64%
Other Fish	41086	21.77%
Cephalopods		
Total	**188719**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	129825	69.26%
Animals born in the EU but not at a registered breeder	57519	30.69%
Animals born in rest of Europe		
Animals born in rest of world	104	0.06%
Total	**187448**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	142463	75.49%
Translational and applied research	17140	9.08%
Regulatory use and Routine production	26157	13.86%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	321	0.17%
Preservation of species	893	0.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1597	0.85%
Forensic enquiries	30	0.02%
Maintenance of colonies of established genetically altered animals, not used in other procedures	118	0.06%
Total	**188719**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	7378	5.18%
Cardiovascular Blood and Lymphatic System	5558	3.9%
Nervous System	52700	36.99%
Respiratory System	134	0.09%
Gastrointestinal System including Liver	5032	3.53%
Musculoskeletal System	843	0.59%
Immune System	6012	4.22%
Urogenital/Reproductive System	3597	2.52%
Sensory Organs (skin, eyes and ears)	193	0.14%
Endocrine System/Metabolism	7697	5.4%
Multisystemic	7232	5.08%
Ethology / Animal Behaviour /Animal Biology	40710	28.58%
Other basic research	5377	3.77%
Total	**142463**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	5061	29.53%
Human Infectious Disorders	1207	7.04%
Human Cardiovascular Disorders	505	2.95%
Human Nervous and Mental Disorders	2261	13.19%
Human Respiratory Disorders	10	0.06%
Human Gastrointestinal Disorders including Liver	160	0.93%
Human Musculoskeletal Disorders	70	0.41%
Human Immune Disorders	115	0.67%
Human Urogenital/Reproductive Disorders	31	0.18%
Human Sensory Organ Disorders (skin, eyes and ears)	178	1.04%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	30	0.18%
Animal Diseases and Disorders	398	2.32%
Animal Welfare	3287	19.18%
Diagnosis of diseases	3325	19.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	502	2.93%
Total	**17140**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	18221	69.66%
Other efficacy and tolerance testing	363	1.39%
Toxicity and other safety testing including pharmacology	7261	27.76%
Routine production	312	1.19%
Total	**26157**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3876	21.27%
Pyrogenicity testing	202	1.11%
Batch potency testing	13177	72.32%
Other quality controls	966	5.3%
Total	**18221**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1721	23.7%
Skin irritation/corrosion	195	2.69%
Skin sensitisation	1571	21.64%
Eye irritation/corrosion	50	0.69%
Repeated dose toxicity	120	1.65%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Target animal safety		
Developmental toxicity	164	2.26%
Kinetics	40	0.55%
Pharmaco-dynamics (incl safety pharmacology)	38	0.52%
Ecotoxicity	3338	45.97%
Other toxicity/safety testing	24	0.33%
Total	**7261**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	371	21.56%
Other lethal methods		
Non lethal methods	1350	78.44%
Total	**1721**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	120	100%
> 90 days		
Total	**120**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3123	93.56%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity	215	6.44%
Total	**3338**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	312	100%
Total	**312**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	18178	69.5%
Legislation on medicinal products for veterinary use and their residues	2651	10.13%
Medical devices legislation	310	1.19%
Industrial chemicals legislation	265	1.01%
Plant protection product legislation	4597	17.57%
Biocides legislation	122	0.47%
Food legislation including food contact material		
Feed legislation including legislation for the safety of target animals, workers and environment	34	0.13%
Cosmetics legislation		
Other legislation		
Total	**26157**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	25604	97.89%
Legislation satisfying national requirements only [within EU]	487	1.86%
Legislation satisfying Non-EU requirements only	66	0.25%
Total	**26157**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	187448	99.33%
Yes	1271	0.67%
Total	**188719**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	7963	4.22%
Mild [up to and including]	87965	46.61%
Moderate	47593	25.22%
Severe	45198	23.95%
Total	**188719**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	188426	99.84%
Yes	293	0.16%
Total	**188719**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	180608	95.7%
Genetically altered without a harmful phenotype	5577	2.96%
Genetically altered with a harmful phenotype	2534	1.34%
Total	**188719**	**100.00%**

Poland: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. This is the case because some experiments which are not considered procedures under the new rules continue to take place and be reported. Despite this, the number of animals used decreased markedly in 2017. Thanks to the training provided, a better understanding can be seen of the definition of a procedure and the reporting rules, resulting in the more precise identification of animal numbers. One example is that the number of fish other than zebrafish used in 2017 fell significantly.
A steady and significant decrease was also noted in the number of animals reused.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The observed variation in the number of animals used of certain species seems to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties. One good example is the appearance in 2017 of a group of 17 monkeys from Ceboidea and Cercopitecoidea species used in connection with a single experiment on their behaviour in zoo conditions. It is also likely that single experiments on dogs and horses ended in 2017 for this same reason, and the number of dogs and horses used therefore decreased significantly.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2017, a decrease is observed in the number of rats used in 'non-recovery' experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website, and organises training for LECs once per year.

When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged to set up by law monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users' reporting in this area on an annual basis.
In 2017 the NEC also took the initiative to organise a cooperation network between units and bodies involved in the implementation of alternative methods.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the 'other' group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2017, the animal species included in the 'other' category were:

- 'Other' species of carnivore (other Carnivora), namely Mustela nivalis and Mustela lutreola. These are used mainly in fundamental research relating to biology and species behaviour. They account for 92.86% of all carnivorous animal species used in research.

- 'Other' bird species (other Aves), namely Acrocephalus paludicola, Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris alpine, Calidris canutus, Calidris falcinellus, Calidris ferruginea, Calidris minuta, Calidris pugnax, Charadrius dubius, Charadrius hiaticula, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Columba livia, Coturnix japonica, Cyanistes caeruleus, Cygnus olor, Ficedula hypoleuca, Fringilla coelebs, Fulica atra, Gallinago gallinago, Haliaeetus albicilla, Hirundo rustica, Meleagris gallopavo, Motacilla alba, Motacilla flava, Lanius collurio, Larus canus, Parus major, Passer domesticus, Passer montanus, Phasianus colchicus, Serinus canaria, Sterna hirundo, Taeniopygia guttata, Tetrao urogallus, Tringa erythropus, Tringa glareola, Tringa nebularia, Tringa ochropus, Tringa totanus, Turdus merula and Vanellus vanellus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 56.44% of all bird species used in research.

- 'Other' fish species (other Pisces), namely Acipenser baeri, Acipenser gueldenstadtii, Acipenser ruthenus, Babka gymnotrachelus, Coregonus lavaretus, Cottus gobio, Cyprinus carpio, Eudontomyzon mariae, Gobio gobio, Lampetra planeri, Neogobius fluviatilis, Oncorhynchus mykiss, Perca fluviatilis, Poecilia reticulata, Proterorhinus semilunaris, Rutilus rutilus, Sander

lucioperca and Scardinius erythrophthalmus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders, and also in some acute toxicity studies. They account for 84.99% of all fish species used in research.

- 'Other' amphibian species (other Amphibia), namely Bufotes viridis in the adult and larval stages, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus. These are mainly used in fundamental research relating to reproductive and metabolism studies, and translational research on animal diseases and disorders, as well as population genetics and phylogeography. They account for 95.8% of all amphibian species used in research.

- 'Other' monkey species, namely 17 monkeys from Ceboidea and Cercopithecoidea species used in connection with a single experiment on their behaviour in zoo conditions.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees.

Poland: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	89880	57.53%
Rats	28982	18.55%
Guinea-Pigs	5235	3.35%
Hamsters (Syrian)	150	0.1%
Hamsters (Chinese)		
Mongolian gerbil	120	0.08%
Other Rodents	8108	5.19%
Rabbits	820	0.52%
Cats		
Dogs	10	0.01%
Ferrets		
Other carnivores	130	0.08%
Horses, donkeys and cross-breeds	73	0.05%
Pigs	1517	0.97%
Goats	24	0.02%
Sheep	1301	0.83%
Cattle	413	0.26%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		

Animal Species	Number of animals	Percentage
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)	14	0.01%
Other species of New World Monkeys (Ceboidea)	3	0%
Apes		
Other Mammals	700	0.45%
Domestic fowl	5067	3.24%
Other birds	6566	4.2%
Reptiles	314	0.2%
Rana	20	0.01%
Xenopus		
Other Amphibians	456	0.29%
Zebra fish	950	0.61%
Other Fish	5381	3.44%
Cephalopods		
Total	**156234**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	135878	87.43%
Animals born in the EU but not at a registered breeder	18496	11.9%
Animals born in rest of Europe	361	0.23%
Animals born in rest of world	674	0.43%
Total	**155409**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	17	100%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**17**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	17	100%
Self-sustaining colony		
Total	**17**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	113639	72.74%
Translational and applied research	16135	10.33%
Regulatory use and Routine production	24762	15.85%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	43	0.03%
Preservation of species	25	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational	1129	0.72%

Purpose Category	Number of uses	Percentage
skills		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	501	0.32%
Total	**156234**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	8173	7.19%
Cardiovascular Blood and Lymphatic System	6727	5.92%
Nervous System	52548	46.24%
Respiratory System	784	0.69%
Gastrointestinal System including Liver	3070	2.7%
Musculoskeletal System	673	0.59%
Immune System	7755	6.82%
Urogenital/Reproductive System	2929	2.58%
Sensory Organs (skin, eyes and ears)	225	0.2%
Endocrine System/Metabolism	5992	5.27%
Multisystemic	5956	5.24%
Ethology / Animal Behaviour /Animal Biology	10531	9.27%
Other basic research	8276	7.28%
Total	**113639**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	3081	19.1%
Human Infectious Disorders	366	2.27%
Human Cardiovascular Disorders	815	5.05%
Human Nervous and Mental Disorders	1176	7.29%
Human Respiratory Disorders	943	5.84%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	64	0.4%
Human Immune Disorders	120	0.74%
Human Urogenital/Reproductive Disorders	44	0.27%
Human Sensory Organ Disorders (skin, eyes and ears)	20	0.12%
Human Endocrine/Metabolism Disorders	316	1.96%
Other Human Disorders	35	0.22%
Animal Diseases and Disorders	678	4.2%
Animal Welfare	3852	23.87%
Diagnosis of diseases	3088	19.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1537	9.53%
Total	**16135**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16493	66.61%
Other efficacy and tolerance testing	195	0.79%
Toxicity and other safety testing including pharmacology	7784	31.44%
Routine production	290	1.17%
Total	**24762**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3982	24.14%
Pyrogenicity testing	236	1.43%
Batch potency testing	11482	69.62%
Other quality controls	793	4.81%
Total	**16493**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1050	13.49%
Skin irritation/corrosion	139	1.79%
Skin sensitisation	707	9.08%
Eye irritation/corrosion	9	0.12%
Repeated dose toxicity	807	10.37%
Carcinogenicity		
Genotoxicity		
Neurotoxicity		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Safety testing in food and feed area		
Target animal safety		
Reproductive toxicity	669	8.59%
Developmental toxicity	1694	21.76%
Kinetics	30	0.39%
Ecotoxicity	2364	30.37%
Other toxicity/safety testing	315	4.05%
Total	**7784**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	180	17.14%
Other lethal methods		
Non lethal methods	870	82.86%
Total	**1050**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	387	47.96%
29 - 90 days	420	52.04%
> 90 days		
Total	**807**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2364	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total	**2364**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types	290	100%
Total	**290**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16523	66.73%
Legislation on medicinal products for veterinary use and their residues	2251	9.09%
Medical devices legislation	916	3.7%
Industrial chemicals legislation	2652	10.71%
Plant protection product legislation	2276	9.19%
Biocides legislation	24	0.1%
Food legislation including food contact material	120	0.48%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**24762**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	24221	97.82%
Legislation satisfying national requirements only [within EU]	514	2.08%
Legislation satisfying Non-EU requirements only	27	0.11%
Total	**24762**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	155426	99.48%
Yes	808	0.52%
Total	**156234**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	4791	3.07%
Mild [up to and including]	50260	32.17%
Moderate	50013	32.01%
Severe	51170	32.75%
Total	**156234**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	155876	99.77%
Yes	358	0.23%
Total	**156234**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	146889	94.02%
Genetically altered without a harmful phenotype	5905	3.78%
Genetically altered with a harmful phenotype	3440	2.2%
Total	**156234**	**100.00%**

Portugal

Portugal: Narrative 2015 – no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	13175	63.88%
Rats	2399	11.63%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits		
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats	46	0.22%
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	250	1.21%
Other Fish	4752	23.04%
Cephalopods	1	0%
Total	**20623**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	16287	85.59%
Animals born in the EU but not at a registered breeder	1896	9.96%
Animals born in rest of Europe		
Animals born in rest of world	847	4.45%
Total	**19030**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	11853	57.47%
Translational and applied research	7288	35.34%
Regulatory use and Routine production	1382	6.7%
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	3	0.01%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	97	0.47%
Total	**20623**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	266	2.24%
Cardiovascular Blood and Lymphatic System	576	4.86%
Nervous System	1859	15.68%
Respiratory System		
Gastrointestinal System including Liver	230	1.94%
Musculoskeletal System	330	2.78%
Immune System	5965	50.32%
Urogenital/Reproductive System	19	0.16%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	100	0.84%
Endocrine System/Metabolism		
Multisystemic	8	0.07%
Ethology / Animal Behaviour /Animal Biology	347	2.93%
Other basic research	2153	18.16%
Total	**11853**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	10	0.14%
Human Infectious Disorders	1019	13.98%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	2002	27.47%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	88	1.21%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	350	4.8%
Human Endocrine/Metabolism Disorders	89	1.22%
Other Human Disorders	230	3.16%
Animal Diseases and Disorders		
Animal Welfare	3500	48.02%
Diagnosis of diseases		
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**7288**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	1382	100%
Total	**1382**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	200	14.47%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	750	54.27%
Safety testing in food and feed area	432	31.26%
Total	**1382**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	200	100%
Total	**200**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity	750	100%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**750**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues		
Medical devices legislation		
Industrial chemicals legislation	750	54.27%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	632	45.73%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**1382**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements		
Legislation satisfying national requirements only [within EU]	1382	100%
Legislation satisfying Non-EU requirements only		
Total	**1382**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	19030	92.28%
Yes	1593	7.72%
Total	**20623**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	213	1.03%
Mild [up to and including]	11207	54.34%
Moderate	6832	33.13%
Severe	2371	11.5%
Total	**20623**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	20573	99.76%
Yes	50	0.24%
Total	**20623**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	15339	74.38%
Genetically altered without a harmful phenotype	2116	10.26%
Genetically altered with a harmful phenotype	3168	15.36%
Total	**20623**	**100.00%**

Portugal: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	28892	91.11%
Rats	2251	7.1%
Guinea-Pigs	4	0.01%
Hamsters (Syrian)	6	0.02%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	39	0.12%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep		
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl		
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	451	1.42%
Other Fish	69	0.22%
Cephalopods		
Total	**31712**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	30784	97.64%
Animals born in the EU but not at a registered breeder	623	1.98%
Animals born in rest of Europe		
Animals born in rest of world	120	0.38%
Total	**31527**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	14894	46.97%
Translational and applied research	9548	30.11%
Regulatory use and Routine production	185	0.58%
Protection of the natural environment in the interests of the health or welfare of human beings or animals		
Preservation of species	37	0.12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	102	0.32%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	6946	21.9%
Total	**31712**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	680	4.57%
Cardiovascular Blood and Lymphatic System	159	1.07%
Nervous System	2982	20.02%
Respiratory System	95	0.64%
Gastrointestinal System including Liver	307	2.06%
Musculoskeletal System	240	1.61%
Immune System	7543	50.64%
Urogenital/Reproductive System	90	0.6%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	562	3.77%
Multisystemic	92	0.62%
Ethology / Animal Behaviour /Animal Biology	1074	7.21%
Other basic research	1070	7.18%
Total	**14894**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	505	5.29%
Human Infectious Disorders	5782	60.56%
Human Cardiovascular Disorders	300	3.14%
Human Nervous and Mental Disorders	477	5%
Human Respiratory Disorders	82	0.86%
Human Gastrointestinal Disorders including Liver	161	1.69%
Human Musculoskeletal Disorders	72	0.75%
Human Immune Disorders	784	8.21%
Human Urogenital/Reproductive Disorders	10	0.1%
Human Sensory Organ Disorders (skin, eyes and ears)	221	2.31%
Human Endocrine/Metabolism Disorders	151	1.58%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare	99	1.04%
Diagnosis of diseases	904	9.47%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**9548**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	185	100%
Total	**185**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Safety testing in food and feed area	185	100%
Total	**185**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
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	185	100%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**185**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	185	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**185**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	31527	99.42%
Yes	185	0.58%
Total	**31712**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	369	1.16%
Mild [up to and including]	14043	44.28%
Moderate	9487	29.92%
Severe	7813	24.64%
Total	**31712**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	31438	99.14%
Yes	274	0.86%
Total	**31712**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19723	62.19%
Genetically altered without a harmful phenotype	9795	30.89%
Genetically altered with a harmful phenotype	2194	6.92%
Total	**31712**	**100.00%**

Portugal: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

Portugal: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	46107	88.04%
Rats	3135	5.99%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	140	0.27%
Rabbits	36	0.07%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	155	0.3%
Goats		
Sheep	30	0.06%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	32	0.06%
Domestic fowl	120	0.23%
Other birds	56	0.11%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish	1280	2.44%
Other Fish	829	1.58%
Cephalopods	450	0.86%
Total	**52370**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	49301	96.09%
Animals born in the EU but not at a registered breeder	1678	3.27%
Animals born in rest of Europe		
Animals born in rest of world	329	0.64%
Total	**51308**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	36663	70.01%
Translational and applied research	5202	9.93%
Regulatory use and Routine production	298	0.57%
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	392	0.75%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	9815	18.74%
Total	**52370**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3230	8.81%
Cardiovascular Blood and Lymphatic System	1205	3.29%
Nervous System	4952	13.51%
Respiratory System	83	0.23%
Gastrointestinal System including Liver	683	1.86%
Musculoskeletal System	173	0.47%
Immune System	20968	57.19%
Urogenital/Reproductive System	36	0.1%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	1437	3.92%
Multisystemic	153	0.42%
Ethology / Animal Behaviour /Animal Biology	1277	3.48%
Other basic research	2466	6.73%
Total	**36663**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	162	3.11%
Human Infectious Disorders	403	7.75%
Human Cardiovascular Disorders	68	1.31%
Human Nervous and Mental Disorders	2058	39.56%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	102	1.96%
Human Musculoskeletal Disorders	127	2.44%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	233	4.48%
Human Endocrine/Metabolism Disorders	36	0.69%
Other Human Disorders		
Animal Diseases and Disorders	3	0.06%
Animal Welfare	604	11.61%
Diagnosis of diseases	914	17.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	492	9.46%
Total	**5202**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Other efficacy and tolerance testing		
Quality control (incl batch safety and potency testing)		
Routine production		
Toxicity and other safety testing including pharmacology	298	100%
Total	**298**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	126	42.28%
Safety testing in food and feed area	172	57.72%
Total	**298**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	126	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**126**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use		
Legislation on medicinal products for veterinary use and their residues	126	42.28%
Medical devices legislation		
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	172	57.72%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**298**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	298	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**298**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	51308	97.97%
Yes	1062	2.03%
Total	**52370**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2017	3.85%
Mild [up to and including]	27397	52.31%
Moderate	12540	23.95%
Severe	10416	19.89%
Total	**52370**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	51836	98.98%
Yes	534	1.02%
Total	**52370**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	30557	58.35%
Genetically altered without a harmful phenotype	20466	39.08%
Genetically altered with a harmful phenotype	1347	2.57%
Total	**52370**	**100.00%**

Romania

Romania: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Compared to the last report, the one from 2014, there was a decrease in the number of total animals used for scientific purposes, with 0,53%, from 19735 in 2014 to 19632 in 2015.

To the purpose of use has been a decrease in the use of animals for higher education or training and an increased use of animals in research.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The difference between 2014 and 2015 is minim, given the fact that is less de 1%.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Some changes were observed in severity trend. 26% severe in 2015 vs 0.05% in 2014. 0.59% non-recovery in 2015 vs 17.31% in 2014. 39.27% mild in 2015 vs 62.344 in 2014. 34.14% moderate vs 20.30% in 2014.

The reason is that now, in this year, our colleague learned to done a severity assessment.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The animals use under “other" categories are 0.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Such a kind of analysis was not made yet.

Romania: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	10876	55.4%
Rats	6322	32.2%
Guinea-Pigs	1108	5.64%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	380	1.94%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs	10	0.05%
Goats		
Sheep	167	0.85%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	565	2.88%
Other birds		
Reptiles		
Rana	200	1.02%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**19632**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	18162	94.22%
Animals born in the EU but not at a registered breeder	1115	5.78%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**19277**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	7752	39.49%
Translational and applied research	3240	16.5%
Regulatory use and Routine production	7498	38.19%
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	1142	5.82%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**19632**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	3499	45.14%
Cardiovascular Blood and Lymphatic System	800	10.32%
Nervous System	289	3.73%
Respiratory System	200	2.58%
Gastrointestinal System including Liver	20	0.26%
Musculoskeletal System	188	2.43%
Immune System	162	2.09%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic	84	1.08%
Ethology / Animal Behaviour /Animal Biology	50	0.64%
Other basic research	2460	31.73%
Total	**7752**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	32	0.99%
Human Infectious Disorders	20	0.62%
Human Cardiovascular Disorders	110	3.4%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	85	2.62%
Human Immune Disorders		
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	69	2.13%
Human Endocrine/Metabolism Disorders		
Other Human Disorders	30	0.93%
Animal Diseases and Disorders	102	3.15%
Animal Welfare	66	2.04%
Diagnosis of diseases	2726	84.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**3240**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	6184	82.48%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	927	12.36%
Routine production	387	5.16%
Total	**7498**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	5456	88.23%
Pyrogenicity testing	58	0.94%
Batch potency testing	670	10.83%
Other quality controls		
Total	**6184**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	187	20.17%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	740	79.83%
Total	**927**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	187	100%
Total	**187**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	740	100%
29 - 90 days		
> 90 days		
Total	**740**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	321	82.95%
Monoclonal antibody by mouse ascites method		
Other product types	66	17.05%
Total	**387**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	6404	85.41%
Legislation on medicinal products for veterinary use and their residues	731	9.75%
Medical devices legislation	363	4.84%
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	**7498**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	7438	99.2%
Legislation satisfying national requirements only [within EU]	2	0.03%
Legislation satisfying Non-EU requirements only	58	0.77%
Total	**7498**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	19277	98.19%
Yes	355	1.81%
Total	**19632**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	88	0.45%
Mild [up to and including]	9958	50.72%
Moderate	5550	28.27%
Severe	4036	20.56%
Total	**19632**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	19632	100%
Yes		
Total	**19632**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	19032	96.94%
Genetically altered without a harmful phenotype	600	3.06%
Genetically altered with a harmful phenotype		
Total	**19632**	**100.00%**

Romania: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Compared to the last report, the one from 2015, there was a decrease in the number of total animals used for scientific purposes (around 20.000 in 2015 and around 13.000 in 2016).

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

To the purpose of use has been a decrease in the use of animals for higher education or training and diagnosis of the disease and an increased use of animals in research.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Some changes were observed in severity trend. The main category of severity was moderate followed by mild and severe. It have been reduced non - recovery category.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The animals use under “other" categories are not in a significant proportion.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Such a kind of analysis was not made yet.

Romania: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	9079	64.08%
Rats	2685	18.95%
Guinea-Pigs	1076	7.59%
Hamsters (Syrian)	146	1.03%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	222	1.57%

Animal Species	Number of animals	Percentage
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs		
Goats		
Sheep	211	1.49%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	555	3.92%
Other birds		
Reptiles		
Rana	190	1.34%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**14168**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12592	90.95%
Animals born in the EU but not at a registered breeder	1253	9.05%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**13845**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	4011	28.31%
Translational and applied research	3183	22.47%
Regulatory use and Routine production	5402	38.13%
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	1572	11.1%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**14168**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	935	23.31%
Cardiovascular Blood and Lymphatic System	485	12.09%
Nervous System	190	4.74%
Respiratory System		
Gastrointestinal System including Liver	261	6.51%
Musculoskeletal System	92	2.29%
Immune System	334	8.33%
Urogenital/Reproductive System	170	4.24%
Sensory Organs (skin, eyes and ears)	120	2.99%
Endocrine System/Metabolism	70	1.75%
Multisystemic	884	22.04%
Ethology / Animal Behaviour /Animal Biology	200	4.99%
Other basic research	270	6.73%
Total	**4011**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	15	0.47%
Human Infectious Disorders	4	0.13%
Human Cardiovascular Disorders	86	2.7%
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		

Translational and applied research	Number of uses	Percentage
Other Human Disorders		
Animal Diseases and Disorders	277	8.7%
Animal Welfare		
Diagnosis of diseases	2742	86.15%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	59	1.85%
Total	**3183**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4913	90.95%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	171	3.17%
Routine production	318	5.89%
Total	**5402**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4260	86.71%
Pyrogenicity testing	27	0.55%
Batch potency testing	584	11.89%
Other quality controls	42	0.85%
Total	**4913**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	74	43.27%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	97	56.73%
Total	**171**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	74	100%
Total	**74**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	303	95.28%
Monoclonal antibody by mouse ascites method		
Other product types	15	4.72%
Total	**318**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	3992	73.9%
Legislation on medicinal products for veterinary use and their residues	1096	20.29%
Medical devices legislation	314	5.81%
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	**5402**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	5364	99.3%
Legislation satisfying national requirements only [within EU]	11	0.2%
Legislation satisfying Non-EU requirements only	27	0.5%
Total	**5402**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	13845	97.72%
Yes	323	2.28%
Total	**14168**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	169	1.19%
Mild [up to and including]	7693	54.3%
Moderate	5498	38.81%
Severe	808	5.7%
Total	**14168**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	14168	100%
Yes		
Total	**14168**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	13885	98%
Genetically altered without a harmful phenotype	283	2%
Genetically altered with a harmful phenotype		
Total	**14168**	**100.00%**

Romania: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

Since the previous reporting year, there was a slight increase in the number of total animals used for scientific purposes, from 14168 in 2016 to 14642 in 2017.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

There was a significant decrease in the diagnosis of diseases within the translational and applied research due to the reduced number of samples received.

There was a decrease in regulatory use and routine production, with a significant drop in blood based products and batch safety testing and an increase in batch potency testing. The latter occurred due to an increase in the vaccines production

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

There were some variations in terms of severity, namely a decrease in mild and an increase in non-recovery, according to those who evaluated the projects.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

There was a joint effort from the competent authority and the scientific organizations to promote the principle of replacement, reduction and refinement through briefings and workshops.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No significant proportion of animal use was reported under “other" categories.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There were not cases where “severe” classification was exceeded.

Romania: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	7975	54.47%
Rats	4367	29.83%
Guinea-Pigs	792	5.41%
Hamsters (Syrian)	150	1.02%
Hamsters (Chinese)		

Animal Species	Number of animals	Percentage
Mongolian gerbil		
Other Rodents		
Rabbits	504	3.44%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.01%
Pigs	58	0.4%
Goats		
Sheep	209	1.43%
Cattle	2	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	330	2.25%
Other birds	23	0.16%
Reptiles		
Rana	230	1.57%
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**14642**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12356	86.54%
Animals born in the EU but not at a registered breeder	1922	13.46%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**14278**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	5381	36.75%
Translational and applied research	5500	37.56%
Regulatory use and Routine production	2522	17.22%
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	1239	8.46%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**14642**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	1525	28.34%
Cardiovascular Blood and Lymphatic System	539	10.02%
Nervous System	634	11.78%
Respiratory System		
Gastrointestinal System including Liver	165	3.07%
Musculoskeletal System	339	6.3%
Immune System	1349	25.07%
Urogenital/Reproductive System	70	1.3%
Sensory Organs (skin, eyes and ears)	10	0.19%
Endocrine System/Metabolism	318	5.91%
Multisystemic	342	6.36%
Ethology / Animal Behaviour /Animal Biology	90	1.67%
Other basic research		
Total	**5381**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	114	2.07%
Human Cardiovascular Disorders	211	3.84%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	286	5.2%
Human Musculoskeletal Disorders	260	4.73%
Human Immune Disorders	275	5%

Translational and applied research	Number of uses	Percentage
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	121	2.2%
Human Endocrine/Metabolism Disorders	690	12.55%
Other Human Disorders		
Animal Diseases and Disorders	74	1.35%
Animal Welfare		
Diagnosis of diseases	3040	55.27%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	429	7.8%
Total	**5500**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1789	70.94%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	106	4.2%
Routine production	627	24.86%
Total	**2522**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	721	40.3%
Pyrogenicity testing	234	13.08%
Batch potency testing	753	42.09%
Other quality controls	81	4.53%
Total	**1789**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	20	18.87%
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Ecotoxicity	86	81.13%
Total	**106**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	20	100%
Total	**20**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity	86	100%
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**86**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	587	93.62%
Monoclonal antibody by mouse ascites method		
Other product types	40	6.38%
Total	**627**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1078	42.74%
Legislation on medicinal products for veterinary use and their residues	1253	49.68%
Medical devices legislation	170	6.74%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	20	0.79%
Feed legislation including legislation for the safety of target animals, workers and environment	1	0.04%
Cosmetics legislation		
Other legislation		
Total	**2522**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2138	84.77%
Legislation satisfying national requirements only [within EU]	2	0.08%
Legislation satisfying Non-EU requirements only	382	15.15%
Total	**2522**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	14278	97.51%
Yes	364	2.49%
Total	**14642**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	2110	14.41%
Mild [up to and including]	5061	34.56%
Moderate	6094	41.62%
Severe	1377	9.4%
Total	**14642**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	14642	100%
Yes		
Total	**14642**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	14289	97.59%
Genetically altered without a harmful phenotype	353	2.41%
Genetically altered with a harmful phenotype		
Total	**14642**	**100.00%**

Slovakia

Slovakia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

New information on keeping GM (genetically modified) animal lines appeared in the Report from year 2015. In SK the new GM lines were not established, just were kept on the basis of approved Project.

In comparison to the previous year, 3213 less animals were used in the projects. It was caused also by the fact, that more of the approved establishments did not perform any projects in 2015. Some of the establishments informed in advance about the closure of their establishment, because they were not able to assure the compliance with the requirements for placing and treatment of the animals, appointed by the Directive.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Red numbers appeared in the column “other birds” of the Report, in particular in Zebra finch (Taeniopygia guttata) species, with the information on consumption of used animals of 13,95 % , which compared to the previous year, is more. It concerns one approved project for one applicant, approved for performance from15.05.2014 to 31.12.2017. Each year, the applicant consumed 36 birds on the average. It is allowed to use 80 male and 15 female animals within this approved project. By the time of duration of the project, 72 animals were already used. In comparison to the previous year, we did not record significant increase in use of the animals of this category in the project. The same number of animals were used in 2015 as in previous year 2014.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

During year 2015, any significant changes in evaluation of cruelty did not appear in the projects, comparing to the year 2014.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Observance of 3R principles is established in our legislation, it is required to observe 3R principles in performance of the projects and breeding and treating of the animals. Great attention is given to 3R principles in trainings of the assigned persons, stated in Article 23 of the Directive.

5. Further breakdown on the use of "other"categories if a significant proportion of animal use is reported under this category.

In SK any other more significant animal categories are used, just those already stated in the Report.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In SK, there is an Act (No.: 71/67 Coll. on Administrative Order), establishing that the issued decisions are obligatory for the applicant. Any kind of arbitrary change against the project is illegal. This defect, according to the its importance, can be considered as an administrative offence and a penalty can be imposed for it. Each project is classified according to the level of severity, due to the Annex VIII of the Directive. The level of severity of the procedures is stated in the Decision for authorisation of the projects. In SK any situation of arbitrary change of the level of severity towards it increase, cannot appear. It is not possible to use in the projects a different number of animals as those approved, without permission. Within annual reports, CA would see the changes of the levels of severity and the numbers of used animals on the contrary to the Decisions for authorisation of the projects, issued by CA. There is also feed-back in performance of the controls in the approved establishments.

Slovakia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6046	44.66%
Rats	5841	43.15%
Guinea-Pigs	1026	7.58%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	33	0.24%
Other Rodents		
Rabbits	228	1.68%
Cats	29	0.21%
Dogs	34	0.25%
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	16	0.12%
Goats		
Sheep	26	0.19%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	222	1.64%

Animal Species	Number of animals	Percentage
Other birds	36	0.27%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**13537**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	13537	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**13537**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	9870	72.91%
Translational and applied research	788	5.82%
Regulatory use and Routine production	2048	15.13%
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	8	0.06%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	823	6.08%
Total	**13537**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	796	8.06%
Cardiovascular Blood and Lymphatic System	1371	13.89%
Nervous System	2192	22.21%
Respiratory System	992	10.05%
Gastrointestinal System including Liver	194	1.97%
Musculoskeletal System	106	1.07%
Immune System	421	4.27%
Urogenital/Reproductive System	2596	26.3%
Sensory Organs (skin, eyes and ears)	40	0.41%
Endocrine System/Metabolism	496	5.03%
Multisystemic	138	1.4%
Ethology / Animal Behaviour /Animal Biology	11	0.11%
Other basic research	517	5.24%
Total	**9870**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	134	17.01%
Human Infectious Disorders		
Human Cardiovascular Disorders	79	10.03%
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	314	39.85%
Human Urogenital/Reproductive Disorders	80	10.15%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders		
Other Human Disorders	75	9.52%
Animal Diseases and Disorders	62	7.87%
Animal Welfare		
Diagnosis of diseases	44	5.58%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**788**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1462	71.39%
Other efficacy and tolerance testing	6	0.29%
Toxicity and other safety testing including pharmacology	580	28.32%
Routine production		
Total	**2048**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1262	86.32%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	200	13.68%
Total	**1462**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	253	43.62%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	35	6.03%
Repeated dose toxicity	292	50.34%
Total	**580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	253	100%
Other lethal methods		
Non lethal methods		
Total	**253**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days	90	30.82%
> 90 days	202	69.18%
Total	**292**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1385	67.63%
Legislation on medicinal products for veterinary use and their residues	126	6.15%
Medical devices legislation	90	4.39%
Industrial chemicals legislation	245	11.96%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	202	9.86%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**2048**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2048	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2048**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	13537	100%
Yes		
Total	**13537**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1402	10.36%
Mild [up to and including]	8226	60.77%
Moderate	3639	26.88%
Severe	270	1.99%
Total	**13537**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	13537	100%
Yes		
Total	**13537**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	12679	93.66%
Genetically altered without a harmful phenotype	99	0.73%
Genetically altered with a harmful phenotype	759	5.61%
Total	**13537**	**100.00%**

Slovakia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

In 2016, in SK 5% less animals were used in the projects than in 2015. From the total number of used animals the most were used rats (46, 6%). There were 40, 9% of mice, 7,4% of guinea-pigs, 2,8% of rabbits, 2% of poultry used. As many as 96% of rodentials were used in the scientific programs. The rest was poultry. On 31 December 2016, the transition period for implementation of the requirements established in Annex III of the Directive 2010/63/EU finished.
Since 2013, in SK re-accreditation of all approved establishments of the users, breeders and suppliers, according to new legislative requirements, was carried out. In 2016, 4 (four) establishments of the users asked the Competent Authority for their withdrawal and discard from the list of approved establishments of the users, for the reason of technical and economical demandingness. 5 (five) users asked for withdrawal of the approval of their establishment for the reason of change of the legal person and the change of address in order to merge into one legal subject. In SK, general reconstruction of several establishments for placement of animals used in the procedures or kept for the reason of their use in the procedures, was carried out. Therefore, the total number of used procedures and subsequently the number of used animals has decreased. In comparison to 2015, the number of approved establishments has changed. In 2015, 54 establishments overall were approved and in 2016, only 40 establishments were approved. Therefore, only 79 projects were approved in 2016 in comparison to 2015, when SVFA SR as the competent authority has issued 102 decisions on the approval of the projects. The most common use of the animals was the basic research (71,3%), subsequently the use in regulated projects with common production (23,4%), then (3,1%) was used in keeping of GMO breeding colonies, and (2,2%) in translation/applied research. In frame of the basic research, mainly nervous system (30%), reproductive system (16%) and immunity system (14%) were declared as the common research areas. 99,67% of used animals were kept/breeded within EU. None of the animals were reused again. 93% of the used animals were without GM and 7% of all used animals were GM.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In comparison to 2015, the changes in % are as follows: the number of used mice has decreased by 13% and quinea-pigs by 7%. Increase of the number of used rats has been proved by 2% and rabbits by 59%. In 2016 comparing to the last year, domestic dogs have not been used in any of the procedures. In 2015, 34 dogs were used. The number of used cats decreased from 29 to 11 cats only. In comparison to the last year, the use of other mammals (cattle, pigs, sheep) decreased by 80%. According to withdrawal of the decisions for approval of some of the users establishments and with respect to reduction or stopping of the procedures of some of the users establishments, a significant decrease of the animals used in the procedures namely in mice and quinea-pigs occurred. Decreased number of used mice and quinea-pigs is related to the research procedures of some establishments, which ceased or suspended from their activities by the reason of reconstruction in 2016. The cause is also that minimum 5 users have merged into one legal subject and they had to abolish their establishments. Reconstructions of the establishments had been performed in the establishments using dogs and cats, therefore their number has been reduced or decreased to minimum.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In 2016, 52% of projects were classified as “non-recovery” or “,mild”, 46% of the total number were projects classified as ”moderate”, (in 2015, the “moderate” projects were represented only by 27% of all approved establishments), and projects classified as “severe” were represented by 1,2% of the total number of the approved projects. The number of severe projects decreased from 2% in 2015. The reason of increased number of the projects classified as “moderate” can be that the applicants for the approval of projects, performing projects classified as “severe” last year, have refined their procedures, therefore their projects automatically came into category “moderate”.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The obligation to comply with 3R principles is established by the legislation. This topics is presented in details at trainings of staff carrying functions referred to in Article 23 of the Directive. During controls of the establishments of the users, breeders and suppliers carried out in a frequency established by the law, a great attention is taken to observance of the 3R principles during performance of the projects and in animal placement and animal care. There is a great space in SK for the performance of “in-vitro” projects, using alternative methods and providing information of 3R principles, also declared in up-dating of the activities in the table due to the Article 47 of the Directive, published on web site of the Competent Authority SVFA SR.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In the category „other basic research” a significant increase of the used animals has occurred. The number of 517 animals from 2015 increased to 1875 animals in 2016, which represents almost 20% more animals used in this area. It was found out after the additional control, that some users have incorrectly assigned the objective of the project to the concerned performed type of the project. No significant increase of the number of used animals was recorded in other areas.

In category “other birds” increased number of used animals by 12,45% in comparison to the last year was indicated. 32 pcs of Zebra finch was used in the approved project in 2016. This is not a significant increase whereas the project is approved for the period of 5 (five) years and annualy approximately 30-40 birds are used

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In the process of authorisation of the project of the user, breeder or supplier in SK, an Authorization Decision is issued. In the Authorization Decision all necessary detailed information, including classification of severity, authorized exemptions within the frame of performance of the project or breeding or animal supplies are specified. According to the seriousness of the infringement it is

possible to resolve the infringement of any type of the decision either by issuing veterinary measures in the administrative procedure, or by issuing veterinary measures on site. A penalty on site or financial penalty through administrative procedure can also be imposed. If shortcomings are not eliminated up to the stated deadline, it is possible to increase the penalty, or abolish the decision on authorization of the project or establishment.

Such a case has not happened in SK yet. All establishments are regularly controlled due to the specified frequency. In 2016, altogether 38 controls of the establishments were carried out. Included 2 controls which were follow-up – additional for the purpose of control of elimination of found shortcomings. 29 controls were carried out for the purpose of authorisation of the establishments of the users, breeders or suppliers and 7 controls for the reason of control of the compliance of requirements in the approved establishments. During retrospective assessment, an Advisory Body and the Competent Authority reviewed that each of the projects intended for the reverse control was resent and evaluated. In each "severe" project, several available possibilities for its refinement were used in order to assure that the animals would not feel cruelty/severity. In several projects submitted to the reverse assessment was found out that after their severity was classified as "moderate". If a pain classified as "severe" occurred, all available possible measures were carried out for its refinement

Slovakia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	5263	41.01%
Rats	5973	46.55%
Guinea-Pigs	955	7.44%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	14	0.11%
Other Rodents		
Rabbits	358	2.79%
Cats	11	0.09%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	1	0.01%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		

Animal Species	Number of animals	Percentage
Apes		
Other Mammals		
Domestic fowl	225	1.75%
Other birds	32	0.25%
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**12832**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	12789	99.66%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world	43	0.34%
Total	**12832**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	8366	65.2%
Translational and applied research	1085	8.46%
Regulatory use and Routine production	2987	23.28%
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		
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other	394	3.07%

Purpose Category	Number of uses	Percentage
procedures		
Total	**12832**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	146	1.75%
Cardiovascular Blood and Lymphatic System	808	9.66%
Nervous System	2746	32.82%
Respiratory System	478	5.71%
Gastrointestinal System including Liver	58	0.69%
Musculoskeletal System	52	0.62%
Immune System	1350	16.14%
Urogenital/Reproductive System	1454	17.38%
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	230	2.75%
Multisystemic	23	0.27%
Ethology / Animal Behaviour /Animal Biology	40	0.48%
Other basic research	981	11.73%
Total	**8366**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders	40	3.69%
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders		
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver	72	6.64%
Human Musculoskeletal Disorders		
Human Immune Disorders	103	9.49%
Human Urogenital/Reproductive Disorders		
Human Sensory Organ Disorders (skin, eyes and ears)	57	5.25%
Human Endocrine/Metabolism Disorders		
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	7	0.65%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	806	74.29%
Total	**1085**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1533	51.32%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	1412	47.27%
Routine production	42	1.41%
Total	**2987**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1298	84.67%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	235	15.33%
Total	**1533**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	388	27.48%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	632	44.76%
Repeated dose toxicity	392	27.76%
Total	**1412**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	388	100%
Other lethal methods		
Non lethal methods		
Total	**388**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	392	100%
29 - 90 days		
> 90 days		
Total	**392**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	42	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**42**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1340	44.86%
Legislation on medicinal products for veterinary use and their residues	235	7.87%
Medical devices legislation		
Industrial chemicals legislation	1002	33.55%
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	410	13.73%
Feed legislation including legislation for the safety of target animals, workers and environment		
Cosmetics legislation		
Other legislation		
Total	**2987**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2987	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2987**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	12832	100%
Yes		
Total	**12832**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1149	8.95%
Mild [up to and including]	5588	43.55%
Moderate	5947	46.35%
Severe	148	1.15%
Total	**12832**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	12832	100%
Yes		
Total	**12832**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	11920	92.89%
Genetically altered without a harmful phenotype	43	0.34%
Genetically altered with a harmful phenotype	869	6.77%
Total	**12832**	**100.00%**

Slovakia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the number of animals used in projects increased by 17,66% for the different reasons. The first reason was authorisation of two big establishments of users breeding animals for their own need, offering their establishments for performing projects also for the other users. Thereby, the space for performance of the projects in the Slovak Republic has amplified. The second reason was that by the end of year 2016, all existing establishments of users, breeders, suppliers have finished reconstructions in their establishments and therefore in 2017 they could involve in performing of the projects. In 2016, all existing establishments were newly authorised in compliance with Annex 3 of the Directive 2010/63/EU. Since 2017, scientific activities have fully developed, all authorised establishments have started to perform them. Project Agencies in SK (VEGA, APVV) have allocated financial grants for realisation of several projects authorised by the Competent Authority of SR in the area of protection of animals used for scientific purposes. Increased number of animals used in 2017 is deeply connected with this. After finishing transition period for standards of treating and housing animals until 01.01.2017, performance of the projects in establishments has developed in SK. Purpose of the projects in performance of regulated projects has increased. In comparison to year 2016, in performance of the project with the purpose non-regulatory toxicology and ecotoxicology was not reported in 2017. In the area of regulatory use and routine production a type of regulated project - reproductive toxicity occurred and a test with 29-90 days period of administration was added in the area of repeated dose toxicity. Due to the Act, in vitro methods or alternative methods are used preferentially in the regulated projects. In vivo project shall be carried out only if it is not possible to use an alternative method, if there is any. The reason is that the tested substance e.g. is not dissoluble in the dissolution reagent determined for given alternative method.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

In 2017, the number of animals used in the projects increased by 17, 66% in comparison to the year 2016. This relates also to the increase of use animals in particular areas or their decrease depending on the area of the research. Significant increase occurred in use of „other birds“, whereas in the approved project No. 2982/17-221 apart from the species Zebra finch the other species Bangalese finch has also started to be used, whereby the number of use animals increased by 7,8%. The number of animals used for maintenance GM animal colonies without their further use in the project increased by 3%. The number of used animals in basic research in the area multisystemic has increased. A project with use of 782 (7,23%) of animals for the purpose of carcinogenicity research was authorised. The project was focused on safety testing of genetically modified plants by means of toxicology methods. The number of animals used in translational and applied research has increased significantly by 50, 48%, whereas in 2016 no project with this purpose had been carried out. The number of used animals in Animal Diseases and Disorders has increased by 36 % relating to increased number of used animals in one year. In 2017, the purpose of regulated projects increased and simultaneously, the number of animals used in regulated projects decreased in general by 5%. At the same time, the number of animals used in the

basic research increased by 4 % related to starting research activities of several useres establishments of the Slovak Academy of Science and Universities.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In comparison to the year 2016, significant increase occured in classification of severity. The number of animals used in category „mild“ decreased by 10%, whereas the number of animals used in category „moderate“ increased by 11%. This is also related to the purpose of executed projects which have increased significantly in the basic research mainly in the area of „other basic research“, as stated in the table for obligatory report of the Member States. The projects in „other basic reaserch“ had been carried out for the purposes of microbiology, virology and diabetes. By using these methods also the level of severity is increasing.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Slovak Republic annually completes and sends referred templates of the tables for reporting of support and achievements in the area of observing the principles of 3R. The tables are published at the web site of the State Veterinary and Food Administration of SR. Applicants for any kind of authorisation, whether the establishment or the project, in compliance with the Act, are obliged to describe observance of 3R principles. During controls of establishments in the area of observance of legislative requirements, inspectors of animal protection are focused mainly on the area of observance of 3R in keeping and using animals. Several users attend trainings for implementation of in vitro methods in performance of the regulated projects. In 2017, Slovakia organized an International Conference of in vitro methods EUROTOX. The subject of the observance of 3R principles is highly emphasized at the obligational training of specified functions carried out by the staff of authorised establishments of users, breeders and suppliers. Moreover, the members of Animal Welfare Body, which is established in each establishment or its services are used externally, have to supervise the compliance of these principles in the establishments.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The number of used animals has changed significantly in basic research in the area „ other basic research“ as listed in the purpose of projects in the table for obligatory report of the Member States. The projects in „other basic research“ were carried out in the area of microbiology, virology and diabetes. Simultaneously, increase of animals category „ other birds“ from 32 in 2016 to 59 in 2017 was notified. It was caused by the use of other bird species, i.e. Bengalese finch (Lonchura striata domestica).

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

The Competent Authority of the Slovak Republic does not register exceed of classification specified as „severe“ in 2017. In the Slovak Republic the projects classified as „severe“ are authorised. The real number of animals that have experienced pain in the projects classified as „severe“ is notified in every obligatory report sent to EU Commission. Exceed is not possible because the establishments are annually controlled by a physical control on site in the establishments by inspectors of animal protection of the District Veterinary and Food Administrations. At the same time, users are obliged to notify real severity caused to animals in the projects according to the submitted template of the tables from EU Commission. The Competent Authority of SR has got all relevant information about the projects and in case of suspicion can impose execution of a targeted control in the establishment of the respective user. Inspector of animal protection shall carry out control focused on observance of severity in the project in comparison to the Decision of authorisation of the project. In case of found incompliances, the veterinary measures or penalties are imposed.

Slovakia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6087	39.01%
Rats	7939	50.88%
Guinea-Pigs	1036	6.64%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil	9	0.06%
Other Rodents		
Rabbits	226	1.45%
Cats	11	0.07%
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs		
Goats		
Sheep	2	0.01%
Cattle	1	0.01%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	233	1.49%
Other birds	59	0.38%
Reptiles		
Rana		

Animal Species	Number of animals	Percentage
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**15603**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	15565	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**15565**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	10819	69.34%
Translational and applied research	1046	6.7%
Regulatory use and Routine production	2822	18.09%
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	56	0.36%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	860	5.51%
Total	**15603**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	316	2.92%
Cardiovascular Blood and Lymphatic System	932	8.61%
Nervous System	4076	37.67%
Respiratory System	607	5.61%
Gastrointestinal System including Liver	180	1.66%
Musculoskeletal System	19	0.18%
Immune System	424	3.92%
Urogenital/Reproductive System	1175	10.86%
Sensory Organs (skin, eyes and ears)	9	0.08%
Endocrine System/Metabolism	610	5.64%
Multisystemic	782	7.23%
Ethology / Animal Behaviour /Animal Biology	595	5.5%
Other basic research	1094	10.11%
Total	**10819**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer		
Human Infectious Disorders		
Human Cardiovascular Disorders	20	1.91%
Human Nervous and Mental Disorders	528	50.48%
Human Respiratory Disorders		
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders		
Human Immune Disorders	21	2.01%
Human Urogenital/Reproductive Disorders	10	0.96%
Human Sensory Organ Disorders (skin, eyes and ears)	27	2.58%
Human Endocrine/Metabolism Disorders	60	5.74%
Other Human Disorders		
Animal Diseases and Disorders	374	35.76%
Animal Welfare		
Diagnosis of diseases	6	0.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1046**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1014	35.93%
Other efficacy and tolerance testing		
Toxicity and other safety testing including pharmacology	1777	62.97%
Routine production	31	1.1%
Total	**2822**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	867	85.5%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	147	14.5%
Total	**1014**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	653	36.75%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Target animal safety		
Skin sensitisation	542	30.5%
Repeated dose toxicity	460	25.89%
Reproductive toxicity	122	6.87%
Total	**1777**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	603	92.34%
Other lethal methods		
Non lethal methods	50	7.66%
Total	**653**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	280	60.87%
29 - 90 days	180	39.13%
> 90 days		
Total	**460**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	31	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**31**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1300	46.07%
Legislation on medicinal products for veterinary use and their residues	133	4.71%
Medical devices legislation	64	2.27%
Industrial chemicals legislation	946	33.52%
Plant protection product legislation	9	0.32%
Biocides legislation		
Food legislation including food contact material	190	6.73%
Feed legislation including legislation for the safety of target animals, workers and environment	180	6.38%
Cosmetics legislation		
Other legislation		
Total	**2822**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2822	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2822**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	15565	99.76%
Yes	38	0.24%
Total	**15603**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	1101	7.06%
Mild [up to and including]	5185	33.23%
Moderate	8963	57.44%
Severe	354	2.27%
Total	**15603**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	15603	100%
Yes		
Total	**15603**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	14104	90.39%
Genetically altered without a harmful phenotype	260	1.67%
Genetically altered with a harmful phenotype	1239	7.94%
Total	**15603**	**100.00%**

Slovenia

Slovenia: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

Number of animals used for scientific purposes in 2015 is slightly lower in comparison with numbers reported in 2014. In 2014, approximately 12.000 animals were used and in 2015, the number of animals used for scientific purposes is slightly over 9.000.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

More than 95% of all used animals in 2015 are rodents and rabbits. Mice is the most commonly used species (95%), following rats (2%) and rabbits (1, 4%). 477 animals (rodents) were reported as GA animals, 58 of them with a harmful phenotype (39 mice and 19 rats). Animals were used in basic research (endocrine system/metabolism and cardiovascular/lymphatic system).
No cats, dogs and non-human primates were used for scientific purposes in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The majority of all animals (74,17%) were used for the purpose of regulatory use and routine production. Out of this percentage, over 40% of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

In 2015, 57 fish (*Onchorhynchus mykiss*) were used in higher education or training for the acquisition, maintenance or improvement of vocational skills. Severity of procedures was classified as non-recovery or mild.

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No information submitted.

Slovenia: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	8621	95.63%
Rats	184	2.04%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	127	1.41%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.02%
Pigs	8	0.09%
Goats		
Sheep	3	0.03%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	13	0.14%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	57	0.63%
Cephalopods		
Total	**9015**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	5400	98.58%
Animals born in the EU but not at a registered breeder	78	1.42%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**5478**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	963	10.68%
Translational and applied research	1177	13.06%
Regulatory use and Routine production	6757	74.95%
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	118	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**9015**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	125	12.98%
Cardiovascular Blood and Lymphatic System	68	7.06%
Nervous System		
Respiratory System		
Gastrointestinal System including Liver	15	1.56%
Musculoskeletal System	35	3.63%
Immune System	174	18.07%
Urogenital/Reproductive System	74	7.68%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	472	49.01%
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research		
Total	**963**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1002	85.13%
Human Infectious Disorders		
Human Cardiovascular Disorders		
Human Nervous and Mental Disorders	24	2.04%
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	112	9.52%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	39	3.31%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1177**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	6717	99.41%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	40	0.59%
Total	**6757**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	175	2.61%
Pyrogenicity testing	111	1.65%
Batch potency testing	6431	95.74%
Other quality controls		
Total	**6717**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Kinetics	40	100%
Total	**40**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	6757	100%
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	**6757**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6757	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**6757**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	5478	60.77%
Yes	3537	39.23%
Total	**9015**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	105	1.16%
Mild [up to and including]	8559	94.94%
Moderate	351	3.89%
Severe		
Total	**9015**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	9015	100%
Yes		
Total	**9015**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	8538	94.71%
Genetically altered without a harmful phenotype	419	4.65%
Genetically altered with a harmful phenotype	58	0.64%
Total	**9015**	**100.00%**

Slovenia: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

Number of animals used for scientific purposes in 2016 has dropped significantly in comparison with numbers reported in 2015. In 2015, approximately 9.000 animals were used and in 2016, the number of animals used for scientific purposes is around 6.800. The highest drop in the number of used animals was in regulatory use and routine production.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As every year, more than 95% of all used animals are rodents and rabbits. Mice is the most commonly used species (95%), following rats (1, 36 %) and rabbits (less than 1%).
66 animals (rodents) were reported as GA animals, all without a harmful phenotype (50 mice and 16 rats). Those animals were used in basic research (oncology and cardiovascular blood and lymphatic system). No cats, dogs and non-human primates were used for scientific purposes in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Almost 86 % off all animals were used for the purpose of regulatory use and routine production. Out of this percentage, around 26 % of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.
1,54 % of all uses were classified as non – recovery (animals used for the purpose of translational and applied research and higher education). Almost 91% of all uses were mild, 4,5 % moderate and 3 % were classified as severe, where all uses were for the purpose of basic research (mice used for immune system research).

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No information submitted.

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No information submitted.

Slovenia: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	6542	97.28%
Rats	93	1.38%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	45	0.67%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds		
Pigs	32	0.48%
Goats		
Sheep	3	0.04%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	10	0.15%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish		
Cephalopods		
Total	**6725**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4920	99.8%
Animals born in the EU but not at a registered breeder	10	0.2%
Animals born in rest of Europe		
Animals born in rest of world		
Total	**4930**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	419	6.23%
Translational and applied research	1762	26.2%
Regulatory use and Routine production	4491	66.78%
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	53	0.79%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**6725**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	50	11.93%
Cardiovascular Blood and Lymphatic System	16	3.82%
Nervous System		
Respiratory System		
Gastrointestinal System including Liver	24	5.73%
Musculoskeletal System	32	7.64%
Immune System	224	53.46%
Urogenital/Reproductive System	49	11.69%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism		
Multisystemic		
Ethology / Animal Behaviour /Animal Biology		
Other basic research	24	5.73%
Total	**419**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1603	90.98%
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	17	0.96%
Human Urogenital/Reproductive Disorders	10	0.57%
Human Sensory Organ Disorders (skin, eyes and ears)		
Human Endocrine/Metabolism Disorders	122	6.92%
Other Human Disorders		
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	10	0.57%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1762**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4491	100%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology		
Total	**4491**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	70	1.56%
Pyrogenicity testing	40	0.89%
Batch potency testing	4381	97.55%
Other quality controls		
Total	**4491**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4491	100%

Testing by Legislation	Number of uses	Percentage
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	**4491**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4491	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**4491**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	4930	73.31%
Yes	1795	26.69%
Total	**6725**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	16	0.24%
Mild [up to and including]	6183	91.94%
Moderate	318	4.73%
Severe	208	3.09%
Total	**6725**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	6725	100%
Yes		
Total	**6725**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	6659	99.02%
Genetically altered without a harmful phenotype	66	0.98%
Genetically altered with a harmful phenotype		
Total	**6725**	**100.00%**

Slovenia: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

In 2017, the number of animals used for scientific purposes has been reduced in comparison with numbers reported in previous years. The number is around 5.000 animals. The highest drop in the number of used animals was in regulatory use and routine production, where almost 50% less animals were used compared to previous years. The reason is the replacement of in vivo methods, which follows the 3R principle of replacement. Further more, the reason can be found in the termination of certain projects for certain markets, which leads in reduction of use of animals for regulatory purposes. Not negligible is also the fact, that the principle of reduction is followed as much as possible and animals are being re-used.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

As every year, more than 95% of all used animals are rodents (mice and rats) and rabbits. Mice is the most commonly used species (88%), following rats (4, 40 %) and rabbits (less than 2,63%).
There is an increase of animals used in basic research where, in comparison with previous year almost 1.000 rodents (mice in rats) were used. The number was less than 400 rodents (mice and rats) in 2016. Animals were mainly used in research for the purpose of oncology, endocrine system, immune system and gastrointestinal system including liver. The highest number of rodents was used for the research of endocrine system.
A slight increase can be observed also in the use of GA animals. While there were 66 animals reported as GA in 2016, 351 GA animals were reported in 2017. This number represent 6,70 % of all used animals in Slovenia in 2017. Out of this 351 GA animals, 288 mice were reported as GA without a harmful phenotype and 63 mice with harmful phenotype. In 2016 no GA animal with harmful phenotype was reported.
Pyrogenicity testing is still used on rabbits for the purpose of quality control including batch safety and potency testing, but only when the alternative method (in vitro method) gives doubtful results.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Majority of procedures in Slovenia are still classified as mild (over 85%), around 12% are moderate and less than 2% severe, where all uses were for basic research for the purpose of immune system research.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory use - quality control, as prescribed and validated parameters were achieved with the re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

No cats, dogs and non-human primates were used in procedures in 2017.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

No information submitted.

6. Details on cases where the 'severe' classification is exceded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

No information submitted.

Slovenia: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	4563	88.74%
Rats	226	4.4%
Guinea-Pigs		
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	135	2.63%
Cats		
Dogs		
Ferrets		
Other carnivores		
Horses, donkeys and cross-breeds	2	0.04%
Pigs	80	1.56%
Goats		
Sheep	28	0.54%
Cattle		
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals		
Domestic fowl	10	0.19%
Other birds		
Reptiles		
Rana		
Xenopus		
Other Amphibians		
Zebra fish		
Other Fish	98	1.91%

Animal Species	Number of animals	Percentage
Cephalopods		
Total	**5142**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4569	100%
Animals born in the EU but not at a registered breeder		
Animals born in rest of Europe		
Animals born in rest of world		
Total	**4569**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total		

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater		
Self-sustaining colony		
Total		

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1035	20.13%
Translational and applied research	1786	34.73%
Regulatory use and Routine production	2183	42.45%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	16	0.31%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	122	2.37%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures		
Total	**5142**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	149	14.4%
Cardiovascular Blood and Lymphatic System		
Nervous System	70	6.76%
Respiratory System		
Gastrointestinal System including Liver	150	14.49%
Musculoskeletal System	34	3.29%
Immune System	102	9.86%
Urogenital/Reproductive System		
Sensory Organs (skin, eyes and ears)		
Endocrine System/Metabolism	375	36.23%
Multisystemic	59	5.7%
Ethology / Animal Behaviour /Animal Biology	48	4.64%
Other basic research	48	4.64%
Total	**1035**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	1552	86.9%
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	65	3.64%
Other Human Disorders	55	3.08%
Animal Diseases and Disorders		
Animal Welfare		
Diagnosis of diseases	114	6.38%
Plant diseases		
Non-regulatory toxicology and ecotoxicology		
Total	**1786**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2101	96.24%
Other efficacy and tolerance testing		
Routine production		
Toxicity and other safety testing including pharmacology	82	3.76%
Total	**2183**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	272	12.95%
Pyrogenicity testing	59	2.81%
Batch potency testing	1770	84.25%
Other quality controls		
Total	**2101**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Kinetics	82	100%
Total	**82**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2183	100%
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	**2183**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2183	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2183**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	4569	88.86%
Yes	573	11.14%
Total	**5142**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	44	0.86%
Mild [up to and including]	4372	85.03%
Moderate	637	12.39%
Severe	89	1.73%
Total	**5142**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	5087	98.93%
Yes	55	1.07%
Total	**5142**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	4791	93.17%
Genetically altered without a harmful phenotype	288	5.6%
Genetically altered with a harmful phenotype	63	1.23%
Total	**5142**	**100.00%**

Spain

Spain: Narrative 2015

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture, Fisheries, Food and the Environment (MAGRAMA) designed an IT application which was used for the first time this past year. Its purpose is to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The information is provided by the authorised centres, which input the reports from each centre in the system. The authorised centres are overseen by the competent authorities of the various Autonomous Communities which report to MAGRAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. It was therefore necessary to adapt both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This affects how the information about uses in 2014 compare with the same information in 2015. This problem should be resolved with the experience gained as future reports are created. This means that comparisons between years will be more reliable, and it will be possible to evaluate the trends which, for the moment, cannot be evaluated.

In 2015, there was a significant effort to improve the classification of uses under the corresponding headings and, as far as possible, to avoid using 'others'.

In addition, analysis of the data showed that the severity classification 'non-recovery' had at times been interpreted incorrectly. For this reason, there is a change in the proportions of the various severity classifications, which is largely due to better understanding of the meaning of each category. It is also partly due to the generally accepted practice of applying the precautionary principle. As a result, where there is uncertainty between two levels of severity, the higher level of actual severity is assigned to a use.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

In the report on uses in 2015, there were uses of new species not used in 2014. Nevertheless, this is not considered highly significant as such uses are associated with projects that use such species on an occasional basis (for example, frogs).

The proportion of 'other animal species' is high as there are several registered users that work with wildlife.

In 2015, several lines of research associated with zootechnics were developed. This can be seen in the use of 'production animals', although it is partially obscured by the reduction in the use of sheep.

In addition, a new user conducting research in the field of animal nutrition has been using relatively large groups of animals. This is because the user is working in commercial conditions, which significantly increases the figures reported.

The field of aquaculture, and the development of technologies to extend the practice, requires the use of 'non-habitual' species of fish, such as cephalopods, in significant numbers. The main species used are sea-bream, sea-bass, turbot and trout. The notable increase in the use of cephalopods has the same [...].

The increase in genetically altered mice is notable: this is a global trend on account of the wide range of options offered by the use of such animals.

Finally, with regard to the purposes for which animals are used, there is a notable decrease in uses in basic research in parallel with the increase in applied research. A reduction is apparent in the use of animals for regulatory purposes. This is partly due to better classification of the purposes for which animals are used. The significant increase in maintaining genetically altered lines is due to the increase in altered lines and, largely, to the fact that genotyping by invasive methods was considered a procedure. The emphasis placed on the need for thorough education and training in new surgical techniques was reflected in the increase in animals intended for training and teaching.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

In Spain, assignment of severity to the procedures is one of the most significant new features of the Directive. It was done for the first time following the application of the Directive.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced. In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific procedure.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - [and] by the assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose, along with the competent authorities themselves. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

The points on which the greatest effort is being made are: disseminating reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, cadavers etc., and finally with animals for which the severity of the procedures must not exceed the classification of 'mild'. However, this situation is not apparent in the statistics because of the increase in the number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

In the category 'other animals', the majority corresponds to 'other fishes', for two main reasons. The first is that the range of options for this group is limited to two options. This means that 'other fishes' in reality represents 'fishes other than zebrafish'. Secondly, in Spain there are several centres dedicated to researching the biology and needs of fish in aquaculture, for example trout, sea-bream, sea-bass, turbot etc. These represent a significant number of animals.

Furthermore, there are centres that work with wildlife, also for the purpose of thoroughly understanding their biology and behaviour.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This situation has not arisen in Spain.

Spain: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	483689	57.65%
Rats	57616	6.87%
Guinea-Pigs	7760	0.92%
Hamsters (Syrian)	665	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	193	0.02%
Rabbits	30408	3.62%
Cats	361	0.04%
Dogs	860	0.1%
Ferrets	94	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	210	0.03%
Pigs	9262	1.1%
Goats	389	0.05%

Animal Species	Number of animals	Percentage
Sheep	1980	0.24%
Cattle	519	0.06%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	289	0.03%
Rhesus monkey	4	0%
Vervets (Chlorocebus spp.)		
Baboons	18	0%
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	607	0.07%
Domestic fowl	98444	11.73%
Other birds	4585	0.55%
Reptiles	302	0.04%
Rana	14	0%
Xenopus	1304	0.16%
Other Amphibians	2267	0.27%
Zebra fish	44543	5.31%
Other Fish	76709	9.14%
Cephalopods	15848	1.89%
Total	**838940**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	744953	90.26%
Animals born in the EU but not at a registered breeder	76558	9.28%
Animals born in rest of Europe		
Animals born in rest of world	3802	0.46%
Total	**825313**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	21	8.61%
Animals born in rest of Europe		
Animals born in Asia	78	31.97%
Animals born in America		
Animals born in Africa	145	59.43%
Animals born elsewhere		
Total	**244**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	9	3.69%
F2 or greater	185	75.82%
Self-sustaining colony	50	20.49%
Total	**244**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	433171	51.63%
Translational and applied research	217468	25.92%
Regulatory use and Routine production	133876	15.96%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	17306	2.06%
Preservation of species	13	0%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	13922	1.66%
Forensic enquiries	1	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	23183	2.76%
Total	**838940**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	46399	10.71%
Cardiovascular Blood and Lymphatic System	35069	8.1%
Nervous System	83966	19.38%
Respiratory System	2755	0.64%
Gastrointestinal System including Liver	49205	11.36%
Musculoskeletal System	13259	3.06%
Immune System	24368	5.63%
Urogenital/Reproductive System	6680	1.54%
Sensory Organs (skin, eyes and ears)	7809	1.8%
Endocrine System/Metabolism	29287	6.76%
Multisystemic	41201	9.51%
Ethology / Animal Behaviour /Animal Biology	18301	4.22%
Other basic research	74872	17.28%
Total	**433171**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	62970	28.96%
Human Infectious Disorders	22693	10.44%
Human Cardiovascular Disorders	5317	2.44%
Human Nervous and Mental Disorders	17719	8.15%
Human Respiratory Disorders	5243	2.41%
Human Gastrointestinal Disorders including Liver	2286	1.05%
Human Musculoskeletal Disorders	3072	1.41%
Human Immune Disorders	3342	1.54%
Human Urogenital/Reproductive Disorders	1563	0.72%
Human Sensory Organ Disorders (skin, eyes and ears)	13873	6.38%
Human Endocrine/Metabolism Disorders	16953	7.8%
Other Human Disorders	1048	0.48%
Animal Diseases and Disorders	35315	16.24%
Animal Welfare	18539	8.52%
Diagnosis of diseases	5540	2.55%
Plant diseases	14	0.01%
Non-regulatory toxicology and ecotoxicology	1981	0.91%
Total	**217468**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	71438	53.36%
Other efficacy and tolerance testing	288	0.22%
Toxicity and other safety testing including pharmacology	59672	44.57%
Routine production	2478	1.85%
Total	**133876**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	16585	23.22%
Pyrogenicity testing	9960	13.94%
Batch potency testing	41617	58.26%
Other quality controls	3276	4.59%
Total	**71438**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16447	27.56%
Skin irritation/corrosion	103	0.17%
Skin sensitisation	630	1.06%
Eye irritation/corrosion	39	0.07%
Repeated dose toxicity	5172	8.67%
Carcinogenicity		
Phototoxicity		
Reproductive toxicity		
Genotoxicity	60	0.1%
Developmental toxicity	90	0.15%
Neurotoxicity	8400	14.08%
Kinetics	2069	3.47%
Pharmaco-dynamics (incl safety pharmacology)	3849	6.45%
Ecotoxicity	133	0.22%
Safety testing in food and feed area	19301	32.35%
Target animal safety	3331	5.58%
Other toxicity/safety testing	48	0.08%
Total	**59672**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	14047	85.41%
Other lethal methods	75	0.46%
Non lethal methods	2325	14.14%
Total	**16447**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3244	62.72%
29 - 90 days	1129	21.83%
> 90 days	799	15.45%
Total	**5172**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	57	42.86%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation	76	57.14%
Other ecotoxicity		
Total	**133**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	1759	70.98%
Monoclonal antibody by mouse ascites method	719	29.02%
Other product types		
Total	**2478**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	33313	24.88%
Legislation on medicinal products for veterinary use and their residues	65403	48.85%
Medical devices legislation	501	0.37%
Industrial chemicals legislation	510	0.38%
Plant protection product legislation	10	0.01%
Biocides legislation		
Food legislation including food contact material	21626	16.15%
Feed legislation including legislation for the safety of target animals, workers and environment	2368	1.77%
Cosmetics legislation		
Other legislation	10145	7.58%
Total	**133876**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	112896	84.33%
Legislation satisfying national requirements only [within EU]	3371	2.52%
Legislation satisfying Non-EU requirements only	17609	13.15%
Total	**133876**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	825557	98.4%
Yes	13383	1.6%
Total	**838940**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	72630	8.66%
Mild [up to and including]	382421	45.58%
Moderate	325697	38.82%
Severe	58192	6.94%
Total	**838940**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	814686	97.11%
Yes	24254	2.89%
Total	**838940**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	573795	68.4%
Genetically altered without a harmful phenotype	234380	27.94%
Genetically altered with a harmful phenotype	30765	3.67%
Total	**838940**	**100.00%**

Spain: Narrative 2016

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently throughout the reporting periods.

This can affect data patterns. We therefore believe that it is too early to draw conclusions regarding trends.

In 2016, efforts were maintained to improve the classification of uses under the corresponding headings, with the identification and correction of errors in the assignment of uses to the various categories available in the data collection form and, as far as possible, avoidance of using the heading 'others'.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The report on uses in 2016 includes species which are new, while others that appeared in previous reports have disappeared. Nevertheless, it is understood that these variations are not significant as they are associated with the implementation or completion of projects that use such species on an occasional basis.

The trend in increased use of genetically modified mice continues as the ability to design them to order makes them ideal experimental models for a multitude of studies.

The number of uses of fish continues to increase. This is due in part to the adaptation of the models that use zebrafish, which are being developed in an increasing number of fields, and in part to research concerning fish in aquaculture in Spain.

The proportion of 'other animal species' is high as there are several registered users that work with wildlife. Furthermore, as stated in the previous paragraph, the field of aquaculture, and the

development of technologies to extend the practice, requires the use of 'non-habitual' species of fish, such as cephalopods, in significant numbers. The main species used are sole, sea-bream, sea-bass, turbot and trout.

The increase in 'maintaining genetically modified lines' continues. This is due both to the greater presence of the genetically modified lines themselves, and to the fact that, as of this report, genotyping by invasive methods was considered a procedure.

The need for thorough education and training in new surgical techniques was reflected in an increase in animals intended for training and teaching, making it possible to refine post-research activity.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific use.

The apparent fall in the proportion of 'non-recovery' uses continues. However this variation can be attributed to correct information as a result of the concept of 'non-recovery use' being clarified rather than to any real variation in the type of procedures carried out.

Uses classified as severe, while increasing in absolute figures, remain unchanged (8% of uses) in comparison with last year when their relative importance is compared with the total uses.

The greatest severities can be seen to be associated with uses required by European Union legislation, in the category 'regulatory use', and to a lesser extent in studies on animal diseases.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - and by the

assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

Bearing in mind that the staff who work with the animals are one of the key aspects, more thorough and up-to-date training results not only in knowledge of more tools but also in greater motivation to use them.

The points on which the greatest effort is being made are: dissemination of reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

Improvements in training and in the instruments available enable progress in refining procedures.

However, this situation is obscured in the overall statistical figures by the significant increase of those... [text unclear] not apparent in the statistics because of the increased number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

5. Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.

In the 'other animals' section, a significant number of uses refer to 'other birds'. These are limited to centres working to gain detailed knowledge of the biology and behaviour of wildlife. Almost all of these uses (96%) have been classified as 'mild'.

However, the vast majority (95% of uses under 'other species') corresponds to fish other than zebrafish. In this case, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sole, trout, sea-bream, sea-bass and turbot.

A significant effort was made to avoid the classification of 'others' for the purposes of the uses of animals. As a result, the number fell dramatically.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

This situation has not arisen.

Spain: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	539959	61%
Rats	54910	6.2%
Guinea-Pigs	7223	0.82%
Hamsters (Syrian)	734	0.08%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	322	0.04%
Rabbits	28035	3.17%
Cats	358	0.04%
Dogs	1083	0.12%
Ferrets	74	0.01%
Other carnivores		
Horses, donkeys and cross-breeds	91	0.01%
Pigs	9434	1.07%
Goats	269	0.03%
Sheep	2695	0.3%
Cattle	888	0.1%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	272	0.03%
Rhesus monkey	2	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	383	0.04%
Domestic fowl	89795	10.14%
Other birds	2400	0.27%
Reptiles	684	0.08%
Rana	30	0%
Xenopus	1091	0.12%
Other Amphibians	110	0.01%
Zebra fish	68562	7.75%
Other Fish	67324	7.61%
Cephalopods	8444	0.95%
Total	**885172**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	840339	95.88%
Animals born in the EU but not at a registered breeder	34299	3.91%
Animals born in rest of Europe		
Animals born in rest of world	1804	0.21%
Total	**876442**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	115	66.47%
Animals born in America		
Animals born in Africa	58	33.53%
Animals born elsewhere		
Total	**173**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	1	0.58%
F2 or greater	172	99.42%
Self-sustaining colony		
Total	**173**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	442337	49.97%
Translational and applied research	256090	28.93%
Regulatory use and Routine production	132505	14.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8115	0.92%
Preservation of species	137	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	12261	1.39%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	33727	3.81%
Total	**885172**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	50747	11.47%
Cardiovascular Blood and Lymphatic System	52032	11.76%
Nervous System	82046	18.55%
Respiratory System	2184	0.49%
Gastrointestinal System including Liver	10033	2.27%
Musculoskeletal System	11870	2.68%
Immune System	28232	6.38%
Urogenital/Reproductive System	11156	2.52%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	9328	2.11%
Endocrine System/Metabolism	16138	3.65%
Multisystemic	86591	19.58%
Ethology / Animal Behaviour /Animal Biology	77993	17.63%
Other basic research	3987	0.9%
Total	**442337**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	98730	38.55%
Human Infectious Disorders	14506	5.66%
Human Cardiovascular Disorders	4516	1.76%
Human Nervous and Mental Disorders	23096	9.02%
Human Respiratory Disorders	3141	1.23%
Human Gastrointestinal Disorders including Liver	5094	1.99%
Human Musculoskeletal Disorders	3317	1.3%
Human Immune Disorders	4513	1.76%
Human Urogenital/Reproductive Disorders	3142	1.23%
Human Sensory Organ Disorders (skin, eyes and ears)	16927	6.61%
Human Endocrine/Metabolism Disorders	19038	7.43%
Other Human Disorders		
Animal Diseases and Disorders	39324	15.36%
Animal Welfare	11045	4.31%
Diagnosis of diseases	8568	3.35%
Plant diseases	10	0%
Non-regulatory toxicology and ecotoxicology	1123	0.44%
Total	**256090**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	74344	56.11%
Other efficacy and tolerance testing	7999	6.04%
Toxicity and other safety testing including pharmacology	49667	37.48%
Routine production	495	0.37%
Total	**132505**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	20368	27.4%
Pyrogenicity testing	9878	13.29%
Batch potency testing	39956	53.74%
Other quality controls	4142	5.57%
Total	**74344**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	12920	26.01%
Skin irritation/corrosion	99	0.2%
Skin sensitisation	794	1.6%
Eye irritation/corrosion	39	0.08%
Repeated dose toxicity	2032	4.09%
Carcinogenicity	146	0.29%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Genotoxicity	50	0.1%
Reproductive toxicity	530	1.07%
Developmental toxicity	166	0.33%
Neurotoxicity	2406	4.84%
Kinetics	2739	5.51%
Pharmaco-dynamics (incl safety pharmacology)	3679	7.41%
Phototoxicity		
Ecotoxicity	104	0.21%
Safety testing in food and feed area	18437	37.12%
Target animal safety	5523	11.12%
Other toxicity/safety testing	3	0.01%
Total	**49667**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10946	84.72%
Other lethal methods	56	0.43%
Non lethal methods	1918	14.85%
Total	**12920**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	791	38.93%
29 - 90 days	437	21.51%
> 90 days	804	39.57%
Total	**2032**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	104	100%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**104**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	140	28.28%
Monoclonal antibody by mouse ascites method	309	62.42%
Other product types	46	9.29%
Total	**495**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	35421	26.73%
Legislation on medicinal products for veterinary use and their residues	67169	50.69%
Medical devices legislation	376	0.28%
Industrial chemicals legislation	3374	2.55%
Plant protection product legislation	1172	0.88%
Biocides legislation	264	0.2%
Food legislation including food contact material	20105	15.17%
Feed legislation including legislation for the safety of target animals, workers and environment	4599	3.47%
Cosmetics legislation		
Other legislation	25	0.02%
Total	**132505**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	111915	84.46%
Legislation satisfying national requirements only [within EU]	4092	3.09%
Legislation satisfying Non-EU requirements only	16498	12.45%
Total	**132505**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	876615	99.03%
Yes	8557	0.97%
Total	**885172**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	50237	5.68%
Mild [up to and including]	471092	53.22%
Moderate	300645	33.96%
Severe	63198	7.14%
Total	**885172**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	855372	96.63%
Yes	29800	3.37%
Total	**885172**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	520719	58.83%
Genetically altered without a harmful phenotype	319969	36.15%
Genetically altered with a harmful phenotype	44484	5.03%
Total	**885172**	**100.00%**

Spain: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period.

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission's IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently in the reports from different periods.

This can affect data patterns and make it difficult to interpret possible trends in animal use.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures for uses of animals.

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

In 2017, the number of uses of animals for scientific purposes fell among all species except rats, carnivores, goats and cattle, reptiles and 'other amphibians'.

In the case of rats, the greatest increase was in the area of applied research in relation to research on the gastro-intestinal system, the nervous system and the sensory organs.

Use of carnivores increased by around 45% in comparison with 2016, especially in diagnosis of diseases but also in regulatory use (mainly in kinetics and efficiency controls).

There was an increase in the use of species of farm animals for studies on diseases in such animals as target species for such diseases.

As in previous years, reptiles are mainly used in biology and ethology studies.

The common badger was used for the first time, in a study of animal diseases, as was the common spadefoot toad in studies of animal biology.

In assessing the figures on uses, it must be taken into account that there are users conducting research in the field of animal nutrition. They use relatively large groups of animals because they are working in conditions similar to commercial conditions. This significantly increases the figures reported, as can be seen in the studies carried out in the area of nutrition in chickens for fattening. This is also the reason

for the significant reduction in the use of cephalopods given that, in 2017, this type of study was no longer being conducted.

The overall use of mice fell significantly, however their use increased in applied research in cancer, respiratory diseases and diseases of the nervous system.

The number of uses of fish fell by almost 40%. Nevertheless, there was a significant increase in the number of uses of genetically modified fish with a harmful phenotype, also partly due to a better understanding of the behaviour and biology of the fish, making it possible to identify the signs of the aforementioned harmful phenotype.

The proportion of 'other animal species' remains high as there are several registered users that work with wildlife, in particular mammals and birds. Furthermore, the field of aquaculture, and the development of technologies to extend the practice, requires the use of 'non-habitual' species of fish in significant numbers. The main species used are sea-bream, sea-bass, turbot, salmon and trout.

In 2017, an increase was apparent in the reuse of animals although it is difficult to evaluate the actual trend as the concept of 'reuse' has not always been interpreted consistently by reporters. The increase is especially clear in the reuse of dogs, cats and primates.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In 2017, as in previous years, the apparent fall in the proportion of 'non-recovery' uses continues. However this variation can be attributed to an improvement in the quality of the information as a result of the concept of 'non-recovery' use being clarified rather than to changes in the characteristics of the studies.

In 2017, an increase is apparent in the severity observed, especially in the procedures carried out with fish. This is due not only to the characteristics of the projects, but also to more training in identifying welfare indicators in this group of animals.

Nevertheless, the relative increase continues in uses with 'mild' severity with a corresponding decrease in 'moderate'. This is presumably due to the application of measures to refine procedures.

As in previous years, the greatest severities are associated with regulatory uses of animals required by European Union legislation. To a lesser extent, to studies on animal diseases [...]

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

It is understood that promoting the principles of the three 'Rs' must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as 'ethics committees for animal experimentation' - and by the assessment bodies, which in Spain are termed 'empowered bodies' authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

The consultative committees established by some competent authorities conduct a supplementary assessment of 'sensitive' projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that undergo this level of suffering.

Staff training involves both initial skills training in order to be able to work with animals and ongoing training. It is a basic tool for correctly applying the alternative strategies to the use of live animals in research and teaching. Proper training confers not only knowledge of the techniques, approaches and tools that can be useful, but also greater motivation for using them.

The user centres are working to optimise the sharing of animal models, and of the animals themselves, especially their cadavers in order to avoid the unnecessary killing of animals.

In order to reduce the number of animals and adapt the project designs, pilot studies are being carried out to enable research to be directed to much more specific procedures.

One of the areas in which the greatest effort is being made is in dissemination of reference tools and databases, along with access to articles, publications and guides related to the application of the three 'Rs', using emails to centres and sector organisations.

As in previous years, efforts continue in the field of teaching with increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

The inclusion of statistical experts in the teams represents an improvement in the design of procedures, making it possible to reduce the number of animals used.

Furthermore in their applications for project authorisation, project managers are required to provide increasingly detailed information with regard to strategies for applying the three 'Rs'.

In tissue sampling, this involves improving or substituting certain techniques, for example avoiding genotyping by tail-docking.

5. **Further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category.**

As in previous years, the number of uses of 'other species' is very high, totalling almost 50,000 uses.

The vast majority (90% of uses under 'other species') corresponds to fish other than zebrafish. As in previous years, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sea-bream, sea-bass, turbot, salmon and trout.

Of these 'other animals', 5% are birds used in the study of biology, behaviour and pathologies in wild birds.

In the case of 'other purposes', in basic research the majority are concerned with the field of animal nutrition, and of aquaculture, and in toxicology other quality controls, especially in conducting checks for absence of external viruses, duration of immunity and categorisation of active principles.

6. **Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.**

This situation has not arisen in Spain.

Spain: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	523467	65.19%
Rats	56036	6.98%
Guinea-Pigs	6747	0.84%
Hamsters (Syrian)	599	0.07%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	141	0.02%
Rabbits	25931	3.23%
Cats	531	0.07%
Dogs	1476	0.18%
Ferrets	164	0.02%
Other carnivores	25	0%
Horses, donkeys and cross-breeds	61	0.01%
Pigs	8656	1.08%
Goats	369	0.05%
Sheep	1953	0.24%
Cattle	1700	0.21%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	451	0.06%
Rhesus monkey		
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		

Animal Species	Number of animals	Percentage
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	99	0.01%
Domestic fowl	82107	10.23%
Other birds	2535	0.32%
Reptiles	1003	0.12%
Rana	18	0%
Xenopus	1204	0.15%
Other Amphibians	1996	0.25%
Zebra fish	41020	5.11%
Other Fish	44667	5.56%
Cephalopods	20	0%
Total	**802976**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	745928	94.13%
Animals born in the EU but not at a registered breeder	45911	5.79%
Animals born in rest of Europe	33	0%
Animals born in rest of world	606	0.08%
Total	**792478**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	104	42.28%
Animals born in America		
Animals born in Africa	142	57.72%
Animals born elsewhere		
Total	**246**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	2	0.81%
F2 or greater	244	99.19%
Self-sustaining colony		
Total	**246**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	329508	41.04%
Translational and applied research	281870	35.1%
Regulatory use and Routine production	120192	14.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6048	0.75%
Preservation of species	371	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	11785	1.47%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	53202	6.63%
Total	**802976**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	28417	8.62%
Cardiovascular Blood and Lymphatic System	26264	7.97%
Nervous System	78970	23.97%
Respiratory System	2457	0.75%
Gastrointestinal System including Liver	8885	2.7%
Musculoskeletal System	6997	2.12%
Immune System	24659	7.48%
Urogenital/Reproductive System	6548	1.99%
Sensory Organs (skin, eyes and ears)	10283	3.12%
Endocrine System/Metabolism	22634	6.87%
Multisystemic	37812	11.48%
Ethology / Animal Behaviour /Animal Biology	73215	22.22%
Other basic research	2367	0.72%
Total	**329508**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	116597	41.37%
Human Infectious Disorders	13579	4.82%
Human Cardiovascular Disorders	6440	2.28%
Human Nervous and Mental Disorders	21394	7.59%
Human Respiratory Disorders	2713	0.96%
Human Gastrointestinal Disorders including Liver	8755	3.11%
Human Musculoskeletal Disorders	2052	0.73%
Human Immune Disorders	5093	1.81%
Human Urogenital/Reproductive Disorders	1160	0.41%
Human Sensory Organ Disorders (skin, eyes and ears)	15801	5.61%
Human Endocrine/Metabolism Disorders	15652	5.55%
Other Human Disorders	1651	0.59%
Animal Diseases and Disorders	50632	17.96%
Animal Welfare	8413	2.98%
Diagnosis of diseases	9848	3.49%
Plant diseases	10	0%
Non-regulatory toxicology and ecotoxicology	2080	0.74%
Total	**281870**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	68653	57.12%
Other efficacy and tolerance testing	2121	1.76%
Toxicity and other safety testing including pharmacology	48164	40.07%
Routine production	1254	1.04%
Total	**120192**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	23330	33.98%
Pyrogenicity testing	9472	13.8%
Batch potency testing	31416	45.76%
Other quality controls	4435	6.46%
Total	**68653**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	11069	22.98%
Skin irritation/corrosion	43	0.09%
Skin sensitisation	616	1.28%
Eye irritation/corrosion	11	0.02%
Repeated dose toxicity	6225	12.92%
Carcinogenicity	56	0.12%
Genotoxicity	22	0.05%
Phototoxicity		
Reproductive toxicity		
Developmental toxicity	759	1.58%
Neurotoxicity	2017	4.19%
Kinetics	3364	6.98%
Pharmaco-dynamics (incl safety pharmacology)	1476	3.06%
Ecotoxicity	156	0.32%
Safety testing in food and feed area	21778	45.22%
Target animal safety	486	1.01%
Other toxicity/safety testing	86	0.18%
Total	**48164**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10180	91.97%
Other lethal methods		
Non lethal methods	889	8.03%
Total	**11069**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1906	30.62%
29 - 90 days	3714	59.66%
> 90 days	605	9.72%
Total	**6225**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	124	79.49%
Chronic toxicity		
Reproductive ecotoxicity	32	20.51%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**156**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	54	4.31%
Monoclonal antibody by mouse ascites method	55	4.39%
Other product types	1145	91.31%
Total	**1254**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	32566	27.09%
Legislation on medicinal products for veterinary use and their residues	62289	51.82%
Medical devices legislation	138	0.11%
Industrial chemicals legislation	3194	2.66%
Plant protection product legislation	28	0.02%
Biocides legislation	56	0.05%
Food legislation including food contact material	21850	18.18%
Feed legislation including legislation for the safety of target animals, workers and environment	68	0.06%
Cosmetics legislation		
Other legislation	3	0%
Total	**120192**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	107209	89.2%
Legislation satisfying national requirements only [within EU]	4112	3.42%
Legislation satisfying Non-EU requirements only	8871	7.38%
Total	**120192**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	792724	98.72%
Yes	10252	1.28%
Total	**802976**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	41203	5.13%
Mild [up to and including]	415094	51.69%
Moderate	280781	34.97%
Severe	65898	8.21%
Total	**802976**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	779035	97.02%
Yes	23941	2.98%
Total	**802976**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	512735	63.85%
Genetically altered without a harmful phenotype	243856	30.37%
Genetically altered with a harmful phenotype	46385	5.78%
Total	**802976**	**100.00%**

Sweden

Sweden: Narrative 2015

Adjustments in 2018

The European Commission noticed some irregularities in the Swedish statistic for 2015. After being in contact with four users, we have adjusted their reports. In total for 2015 (after the adjustments), 254,789 animal uses were reported, of which 235,961 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

1. General information on any changes in trends observed since the previous reporting period.

1.1 Number of animals

In 2015 SE 224,979 animals are reported in first time use, compared to 278,885 in 2014. The total figure encompassing reuse is 258,403 for 2015 and 284,170 for 2014.

The most used animal species are mice, followed by fish (mainly zebra fish) and rats. These categories topped the usage also in 2014. The figure for mice is lower compared to 2014, as is the figure for rats and other fish, while the use of zebra fish has increased.

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %).

1.2 More detailed data through the new statistics

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable '*Other'* group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of '*Other…*' for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as '*others*'. This is repeated in the 2015 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

i. Basic Research (first use and re-use); number of uses 200,580

Oncology 7 %
Cardiovascular Blood and Lymphatic System 14 %
Nervous System 22 %
Respiratory System 1 %
Gastrointestinal System including Liver 2 %
Musculoskeletal System 2 %

Immune System 15 %
Urogenital/Reproductive System 1 %
Sensory Organs (skin, eyes and ears) 2 %
Endocrine System/Metabolism 9 %
Multisystemic 9 %
Ethology / Animal Behaviour /Animal Biology 10 %
Other 6 %

Thus, for 2015, 51 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* is 6 % in 2015 compared to 8 % in 2014.

ii. Translational and applied research (first use and re-use); number of uses 43,441

Human Cancer 27 %
Human Infectious Disorders 2%
Human Cardiovascular Disorders 17 %
Human Nervous and Mental Disorders 6 %
Human Respiratory Disorders 15 %
Human Gastrointestinal Disorders including Liver 1 %
Human Musculoskeletal Disorders 1 %
Human Immune Disorders 5 %
Human Urogenital/Reproductive Disorders <1 %
Human Sensory Organ Disorders (skin, eyes and ears) <1 %
Human Endocrine/Metabolism Disorders 7 %
Other Human Disorders 4 %
Animal Diseases and Disorders 10 %
Animal Welfare < 1%
Diagnosis of diseases 1 %
Plant diseases 0%
Non-regulatory toxicology and ecotoxicology 5 %

Thus, for 2015, only 4 % of the translational and applied research was specified into more detailed human disorders instead of ending up in *Other human disorders*, compared to 20 % in 2014. These have been identified as pharmacokinetic studies, pharmacological analysis of new formulations of already approved pharmaceuticals, pharmacological studies of candidate drugs, research on hemorrhagic chock, skin and transplantation research, hematology, skeleton and cartilage diseases, development of models for sepsis and treatment of severe infections affecting organs and circulation, and development of pharmaceuticals against preeclampsia.

iii. Genetic status

Results show that most uses are animals that are genetically altered without a harmful phenotype (49%), followed by not genetically altered (44 %), and finally genetically altered with a harmful phenotype (7 %). This is a slight shift from 2014, where the main use was not genetically altered (51 %), followed by genetically altered without a harmful phenotype (46%), and genetically altered with a harmful phenotype (3%).

iv. Creation of a genetically modified line

The amount of uses in the creation of genetically modified line has increased from 1 % in 2014 to 10 % in 2015.

v. Regulatory use and routine production; number of uses 2,188

SE has a low figure in regulatory use during 2015, in line with previous reports. Most of the animals have been used in *toxicity and other safety testing including pharmacology* (93 %), mainly used in *ecotoxicity* (62 %) followed by *pharmaco-dynamics* (26 %), *kinetics* (7 %), *repeated dose toxicity* (4 %) and *other toxicity/safety testing* (1 %). The remaining 7% under regulatory use and routine production falls under *Other efficacy and tolerance testing*.

There is a drop in the figures from 2014; from 12,175 uses to 2,188 uses in 2015. This is due to an erroneous reporting in 2014 of regulatory use of roosters (9,664 uses), for more details see 2.ii. These uses were wrongly reported as EU statistics, when they should have been reported in the national statistics only. The error was detected in time for this report, and is thus not repeated for 2015.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

i. Total number of uses

There is a decrease in the total number of uses. There is, however, no clear reason for the decrease which can be due to normal fluctuations in research efforts and/or financing.

ii. Species

We see a slight decrease in the percentage of mice being used; 175,962 compared to 197,491 in 2014. During the last years the figure has been approximately the same although slightly decreasing compared to earlier years.

The use of rats decreased from 26,762 in 2014 to 21,907 in 2015. This is in line with the last years where the use has been decreasing.

The use of zebrafish more than doubled from 8,171 in 2014 to 20,519 in 2015. A major reason for this was a significant increase in the use of zebrafish in *Basic Research/Multisystemic* between the years, from 3,174 uses in 2014 to 16,233 uses in 2015.

The use of other fish has decreased by a third from 21,697 in 2014 to 14,355 in 2015. This is partly explained by a large feeding regime study constituting ca 25 % of the total uses in 2014, as well as one

user having a significant decrease in use in 2015. However, there are many users and many different projects, especially during 2014, and the analysis is complex.

The use of domestic fowl decreased from 10,899 in 2014 to 5,266 in 2015. However, what seems like a decrease is in fact an increase – in 2014, SE reported 9,664 domestic fowl, more specifically roosters, used for the production and harvesting of hyaluronic acid from their combs, as EU statistics. In 2015 roosters have been used for the same purpose, however, after due consideration this use has been categorized as non-EU purpose. The roosters used in 2014 were thus erroneously reported as EU statistics. The use in 2015 is now mostly derived from two major studies at one user; one on welfare indicators and one on ecologically produced chicken.

There was a rise in the use of cattle, from 129 in 2014 to 2,097 in 2015. The major part was under 2015 used in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* – but there was also a specific project on raw milk during the year causing the figures to increase.

Other rodents decreased slightly from 5,296 in 2014 to 3,323 in 2015. The decrease was almost in total due to a lower use by the same user and at least in part due a misreporting of insectivores under Other rodents, instead of reporting these under Other mammals. This was corrected in the 2015 report leading to a higher amount in this area; Other mammals doubled from 1,128 in 2014 to 2,104 in 2015.

Under 2015 57 uses of ferrets were reported whereas none was reported for 2014. The ferrets were used in a study under *Basic research/Nervous system*.

The use of horses, donkeys and cross-breads increased from 58 in 2014 to 275 in 2015. The increase is to the major part due to a large study on *Translational and applied research/Animal Diseases and Disorders.*

The use of pigs has increased from 585 in 2014 to 1,625 in 2015.This change is in part due to studies performed by users who did not use pigs in 2014, and also partly to an increase in the use of pigs for *Higher education or training for the acquisition, maintenance or improvement of vocational skills* by 420 uses.

The use of reptiles increased from 9 uses in 2014 to 50 in 2015. Both years the use took place in individual studies under *Basic Research/ Ethology/Animal Behaviour/Animal Biology*; one on European grass snake (*Natrix natrix*) (2014) and the other on the common European adder (*Vipera berus*) (2015).

Under 2015 600 uses of *Rana* were reported whereas none was reported for 2014. The *Rana* were used in a study for *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

The use of *Xenopus* decreased from 1,598 in 2014 to 574 in 2015. In 2014 more users performed studies on *Xenopus*, and there were also larger studies in *Translational and applied research/ Non-regulatory*

toxicology and ecotoxicology as well as studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other.*

The use of Other amphibians decreased from 2,857 uses in 2014 to 1,894 in 2015. In 2014 there was a large study of pH-changes in aquaria under *Basic Research/Ethology/Animal Behaviour /Animal Biology* with 2,080 uses, but the smaller decrease in 2015 does not reflect this entirely. A further explanation is that more animals were used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other* in 2015 compared to 2014.

iii. Use in specific areas

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2 %), *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (1 %), *Regulatory use and Routine production* (1 %), *Preservation of species* (<1 %), and finally *Maintenance of colonies of established genetically altered animals, not used in other procedures* (<1 %). This is in close correlation with figures from 2014, with the exception of *Preservation of species* which had decreased from 3 % to less than 1 % in 2015.The figures concerning *Regulatory use and Routine production* show a decrease from 4 % to 1 % in 2015, however, the 2014 figure is too high due to an erroneous report (for explanation see 1.2.v. and 2.ii.), therefore it is not a true decrease.

A comparison of specific areas under *Basic research* 2015 and 2014 shows many areas exhibit close correlation between the two years. There is a slight decrease in *Cardiovascular Blood and Lymphatic System* (14 % vs 19 %), Nervous System (22 % vs 30 %), *Urogenital/Reproductive System* (1 % vs 2 %) and *Other basic research* (6 % vs 8%). There is a slight increase in *Gastrointestinal System including Liver* (2 % vs 1 %), *Immune System* (15 % vs 12%), *Sensory Organs (skin, eyes and ears)* (2 % vs 1%) *Multisystemic* (9 % vs 7%), and *Ethology/Animal Behaviour/Animal Biology* (10 % vs 4 %). However, it is too early to tell if these changes are trends or simply normal fluctuations in research.

Furthermore, a comparison of specific areas under *Translational and applied research* 2015 and 2014 also shows close correlation between the two years. There is a slight decrease in *Human Nervous and Mental Disorders* (6 % vs 7 %), *Human Respiratory Disorders* (15 % vs 16 %), *Other Human Disorders* (4 % vs 20 %), *Animal Diseases and Disorders* (10 % vs 11 %), *Diagnosis of diseases* (1 % vs 2 %), and *Non-regulatory toxicology and ecotoxicology* (5 % vs 8 %). There is a slight increase in *Human Cancer* (27 % vs 19 %), *Human Infectious Disorders* (2 % vs 1 %), *Human Cardiovascular Disorders* (17 % vs 12 %), *Human Immune Disorders* (5 % vs 3 %), and *Human Endocrine/Metabolism Disorders* (7 % vs 0 %). As for *Basic research* it is too early to tell if these changes are trends or simply normal fluctuations in research.

iv. Reuse

Reuse is 13 % in 2015 compared to 2 % in 2014. The higher figure could indeed to some extent be due to a higher reuse, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of reuse with some users, leading to animals erroneously being recorded as reuse when

they should not have been. Where it has been possible to correct the figures this has been done, but this was not possible in all cases. Information work has been initiated to clear this misunderstanding in future reporting.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The results for 2015 show that (51 %) procedures are moderate followed by mild [up to and including] (36 %), non-recovery (6 %) and finally severe (7 %). It follows rather closely the figures from 2014, where (56 %) procedures were moderate followed by mild [up to and including] (28 %), non-recovery (9 %) and finally severe (7 %). No conclusions can be drawn from the material at this stage.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Swedish Board of Agriculture is since 2015 building a competence centre for the 3Rs. The Swedish National Committee will act as the steering group for the centre, which will be in place late 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2016, the Swedish National Committee for the protection of animals used for scientific purposes held two courses for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

5.1 Other animals

i. Fish

41 % of the reported fish constitutes of *Other fish*. Many different species are used, e.g. three-spined stickleback (*Gasterosteus aculeatus*), perch (*Perca fluviatilis*), eel (*Anguilla anguilla*), brown trout (*Salmo trutta*), rainbow trout (*Oncorhynchus mykiss*), *Cyclostomata*, salmon (*Salmo salar*), pike (*Esox lucius*) and burbot (*Lota lota*).

These were used mainly for *Basic research/Ethology/Animal behaviour/animal biology*, but also in f e *Protection of the natural environment in the interests of the health or welfare of human beings or*

animals and Preservation of species. In translational and applied research fish were used in *Non-regulatory toxicology and ecotoxicology*.

ii. Amphibians

More than half, 62 %, of the amphibians are registered as *Other amphibians*. These are Iberian ribbed newt (*Pleurodeles waltl*), eastern newt (*Notophthalmus viridescens*), European green toad (*Bufotes viridis*) and natterjack toad (*Epidalea calamita*).

Iberian ribbed newt and eastern newt have been used in *Other basic research*, more specifically studies of the ability of the nervous system and the locomotion to heal themselves and gene function. European green toad and natterjack toad have been used in *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

iii. Birds

A large percentage, 55 %, among the birds constitutes of *Other birds.* These are Old World flycatchers (*Muscicapidae*), collared flycatcher (*Ficedula albicollis*), Eurasian blue tit (*Cyanistes caeruleus*), great tit (*Parus major*), mallard (*Anas platyrhyncos*), northern wheatear (*Oenanthe oenanthe*), Eurasian teal (*Anas crecca*), bean goose (*Anser fabalis),* willow warbler (*Phylloscopus trochilus*), golden eagle (*Aquila chrysaetos*), Eurasian wryneck (*Jynx torquilla*), Eurasian skylark (*Alauda arvensis*), carrion crow (*Corvus [corone] corone*), hooded crow (*Corvus [corone] cornix)*, common crane (*Grus grus*), Eurasian wigeon (*Anas penelope*), tufted duck (*Aythya fuligula*), common pochard (*Aythya ferina*), and northern pintail (*Anas acuta*).

Approximately half of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses and prevalence of malaria, infections in wild animals, or behavioural studies without restraining equipment. The remaining half has been used in *Basic Research/ Ethology / Animal Behaviour /Animal Biology*.

iv. Carnivores

Among the carnivores SE had a large percentage (38 %) of *Other carnivores*. These are raccoon dog (*Nyctereutes procyonoides*), fox (*Vulpes vulpes*), American mink (*Neovison vison*), Eurasian lynx (*Lynx lynx*), wolf (*Canis lupus*) and wolverine (*Gulo gulo*).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the racoon dogs, which have been used in *Translational and applied research/Animal Welfare.*

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Sweden: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	175904	69.04%
Rats	21907	8.6%
Guinea-Pigs	482	0.19%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents		
Rabbits	446	0.18%
Cats	23	0.01%
Dogs	115	0.05%
Ferrets	57	0.02%
Other carnivores	118	0.05%
Horses, donkeys and cross-breeds	275	0.11%
Pigs	1625	0.64%
Goats		
Sheep	52	0.02%
Cattle	2097	0.82%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	7	0%
Rhesus monkey	1	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	1871	0.73%
Domestic fowl	5266	2.07%
Other birds	6551	2.57%
Reptiles	50	0.02%
Rana	600	0.24%
Xenopus	574	0.23%
Other Amphibians	1894	0.74%
Zebra fish	20519	8.05%
Other Fish	14355	5.63%
Cephalopods		
Total	**254789**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	190472	80.72%
Animals born in the EU but not at a registered breeder	39960	16.94%
Animals born in rest of Europe	249	0.11%
Animals born in rest of world	5277	2.24%
Total	**235958**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	3	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**3**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	3	100%
Self-sustaining colony		
Total	**3**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	202450	79.46%
Translational and applied research	39885	15.65%
Regulatory use and Routine production	2188	0.86%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6280	2.46%
Preservation of species	500	0.2%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3331	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	155	0.06%
Total	**254789**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	13825	6.83%
Cardiovascular Blood and Lymphatic System	28833	14.24%
Nervous System	44616	22.04%
Respiratory System	1652	0.82%
Gastrointestinal System including Liver	3971	1.96%
Musculoskeletal System	4597	2.27%
Immune System	29358	14.5%
Urogenital/Reproductive System	2892	1.43%
Sensory Organs (skin, eyes and ears)	3495	1.73%
Endocrine System/Metabolism	18578	9.18%
Multisystemic	18073	8.93%
Ethology / Animal Behaviour /Animal Biology	19510	9.64%
Other basic research	13050	6.45%
Total	**202450**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	11929	29.91%
Human Infectious Disorders	883	2.21%
Human Cardiovascular Disorders	7234	18.14%
Human Nervous and Mental Disorders	2777	6.96%
Human Respiratory Disorders	6436	16.14%
Human Gastrointestinal Disorders including Liver	386	0.97%
Human Musculoskeletal Disorders	263	0.66%
Human Immune Disorders	2053	5.15%
Human Urogenital/Reproductive Disorders	117	0.29%
Human Sensory Organ Disorders (skin, eyes and ears)	109	0.27%
Human Endocrine/Metabolism Disorders	2914	7.31%
Other Human Disorders	1636	4.1%
Animal Diseases and Disorders	728	1.83%
Animal Welfare	18	0.05%
Diagnosis of diseases	239	0.6%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	2163	5.42%
Total	**39885**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)		
Routine production		
Other efficacy and tolerance testing	144	6.58%
Toxicity and other safety testing including pharmacology	2044	93.42%
Total	**2188**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch potency testing		
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Repeated dose toxicity	80	3.91%
Kinetics	145	7.09%

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	535	26.17%
Ecotoxicity	1260	61.64%
Other toxicity/safety testing	24	1.17%
Total	**2044**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days	80	100%
Total	**80**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity	1260	100%
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total	**1260**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	928	42.41%
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	1260	57.59%
Cosmetics legislation		
Other legislation		
Total	**2188**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	928	42.41%
Legislation satisfying national requirements only [within EU]	1260	57.59%
Legislation satisfying Non-EU requirements only		
Total	**2188**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	235961	92.61%
Yes	18828	7.39%
Total	**254789**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	11034	4.33%
Mild [up to and including]	92991	36.5%
Moderate	132628	52.05%
Severe	18136	7.12%
Total	**254789**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	228629	89.73%
Yes	26160	10.27%
Total	**254789**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	109855	43.12%
Genetically altered without a harmful phenotype	126664	49.71%
Genetically altered with a harmful phenotype	18270	7.17%
Total	**254789**	**100.00%**

Sweden: Narrative 2016

Adjustments in 2018

The European Commission noticed some irregularities in the Swedish statistic for 2016. After being in contact with four users, we have adjusted their reports. In total for 2016 (after the adjustments), 345,433 animal uses were reported, of which 339,299 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

1. General information on any changes in trends observed since the previous reporting period

1.1 Number of animals

For 2016, 344,255 uses were reported as first time use, compared to 224,979 in 2015. The total figure encompassing re-use was 258,403 for 2015 and 350,664 for 2016. The large part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

Re-Use	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
No	*224,979*	*87*	*344,255*	*98*
Yes	*33,424*	*13*	*6,409*	*2*
Totally	***258,403***	***100***	***350,664***	***100***

The most used animal species were mice, followed by zebra fish, rats and other fish. These four categories topped the usage also in 2015. The uses of mice, zebra fish and other fish increased numerically compared to 2015 (mice: 175,962 vs 261,847, zebrafish: 20,519 vs 24,607, and other fish: 14,355 vs 18,024). The use of rats was similar in 2015 and 2016 (21,907 vs 21,218). For the first time more uses of zebra fish than rats were reported (24,607 compared to 21,218). The major part of animals are used within *Basic Research* (81 %), followed by *Translational and applied research* (14 %).

1.2 More detailed data through the new statistics

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable '*Other'* group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of '*Other…*' for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as '*others*'. This pattern is repeated in the 2015 as well as the 2016 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

vi. Basic Research (first use and re-use)

Basic research	2015		2016	
	Number of	*%*	*Number of*	*%*
Oncology	13,825	*7*	28,930	*10*
Cardiovascular Blood and Lymphatic System	28,833	*14*	39,229	*14*
Nervous System	44,616	*22*	51,837	*18*
Respiratory System	1,652	*1*	2,732	*1*
Gastrointestinal System including Liver	3,971	*2*	6,256	*2*
Musculoskeletal System	4,597	*2*	7,120	*3*
Immune System	29,358	*15*	42,537	*15*
Urogenital/Reproductive System	2,892	*1*	2,658	*1*
Sensory Organs (skin, eyes and ears)	3,495	*2*	4,523	*2*
Endocrine System/Metabolism	18,578	*9*	25,651	*9*
Multisystemic	18,073	*9*	31,111	*11*
Ethology / Animal Behaviour /Animal Biology	19,510	*10*	16,487	*6*
Other basic research	13,050	*6*	24,836	*9*
Totally	***202,450***	***100***	***283,907***	***100***

Thus, for 2016, 49 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* was 9 % in 2016 compared to 6 % in 2015.

vii. Translational and applied research (first use and re-use)

Translational and applied research	2015		2016	
	Number of	*%*	*Number of*	*%*
Human Cancer	11,929	*27*	14,014	*28*
Human Infectious Disorders	883	*2*	973	*2*
Human Cardiovascular Disorders	7,234	*17*	5,606	*11*
Human Nervous and Mental Disorders	2,777	*6*	4,523	*9*
Human Respiratory Disorders	6,436	*15*	5,806	*11*
Human Gastrointestinal Disorders including Liver	386	*1*	279	*1*
Human Musculoskeletal Disorders	263	*1*	246	*<1*
Human Immune Disorders	2,053	*5*	1,441	*3*
Human Urogenital/Reproductive Disorders	117	*<1*	75	*<1*
Human Sensory Organ Disorders (skin, eyes and ears)	109	*<1*	292	*1*
Human Endocrine/Metabolism Disorders	2,914	*7*	3,288	*7*
Other Human Disorders	1,636	*4*	3,802	*8*
Animal Diseases and Disorders	4,284	*10*	1,160	*2*
Animal Welfare	18	*<1*	6,578	*13*
Diagnosis of diseases	239	*1*	530	*1*
Plant diseases	0	*0*	0	*0*
Non-regulatory toxicology and ecotoxicology	2,163	*5*	1,955	*4*
Totally	***43, 441***	***100***	***50,568***	***100***

For 2016, 38 % of the translational and applied research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. For 2016, 8% were classified as *Other human disorders*, compared to 4% in 2015.

These have been identified among others as the following: Studies on anti-bacterial therapies against wound infections, research and development of products or devices in human medicine, understanding of growth mechanisms to treat children with growth abnormalities, creation of cartilage and skin in animal models, skeleton and cartilage diseases, studies on pharmaceuticals for patients with disturbed skin barriers e.g. psoriasis and eczema, research on haematology, recreation of human organs using tissue therapy for transplantation, creating individually designed blood vessels using tissue therapy for transplantation, test of substances to prevent rejection of transplanted organs, and pharmacokinetic studies of new formulations of registered pharmaceuticals.

viii. Genetic status

For 2016 most uses were of animals that were genetically altered without a harmful phenotype (52%), followed by not genetically altered (42 %), and finally genetically altered with a harmful phenotype (6 %). The figures are similar to the distribution in 2015.

Genetic Status	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Not genetically altered	113,411	*44*	146,110	*42*
Genetically altered without a harmful phenotype	126,722	*49*	182,261	*52*
Genetically altered with a harmful phenotype	18,270	*7*	22,293	*6*
Totally	**258,403**	***100***	**350,664**	***100***

ix. Creation of a genetically modified line

The amount of uses for the creation of genetically modified lines were 7 % for 2016 compared to 10 % in 2015.

x. Regulatory use and routine production

SE had a low figure in regulatory use during 2016 as in 2015. Most of the animals have been used in *Toxicity and other safety testing including pharmacology* (55 %), and *Quality control (incl batch safety and potency testing)* (40 %).

Regulatory use and routine production	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Quality control (incl batch safety and potency testing)	0	*0*	1,048	*40*
Other efficacy and tolerance testing	144	*7*	120	*5*
Toxicity and other safety testing including pharmacology	2,044	*93*	1,426	*55*
Routine production	0	*0*	5	*<1*
Totally	**2,188**	***100***	**2,599**	***100***

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

i. Total number of uses

There is an increase in the total number of uses reported, 350,664 uses in 2016 compared to 258,403

uses in 2015. The absolutely largest part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

ii. Species

There are increases as well as decreases in the number of uses in many of the species, however some of the species remain on the same level as the previous year. It is, however, difficult in most cases to determine the reasons behind the changes and also too early into the new reporting in accordance with Commission decision 2012/707/EU to tell if either increases or decreases are true significant differences that will prevail over time. We present data from 2014 to 2016 to illustrate the fluctuations over the past three year.

As discussed above, there was a large increase in number of mice uses being reported for 2016 (261,847 uses, 75 %) compared to 2015 (175,962 uses, 68 %). Much of this increase is due to a few users reporting considerably higher numbers for 2016 compared to 2015. In one case there is an increase of approximately 30,000 uses, and in another around 25,000 uses. The reason for this is unknown, but could be due to increased research funding, but also a mere consequence of the continuously rising use of mice in research that has been observed for the last decades.

Other rodents decreased from 3,323 uses in 2015 to 63 in 2016. All uses in 2016 were reported as *Basic Research* while all uses in 2015 was reported from one single user as *Translational and Applied Research*, more specifically as *Animal Diseases and Disorders*.

Cats increased from 23 uses in 2015 (all in *Basic Research/Musculoskeletal System*) to 94 uses in 2016 (54 uses in *Basic Research/Musculoskeletal System* and 40 uses in *Translational and applied research/Animal Diseases and Disorders*).

Dogs increased from 115 uses in 2015 to 204 uses in 2016. For both years most uses were reported as *Translational and applied research*. More specifically, in 2015, *Human Endocrine/ Metabolism Disorders* (83 uses), *Human Respiratory Disorders* (7 uses), *Non-regulatory toxicology and ecotoxicology* (14 uses), *Human Cardiovascular Disorders* (5 uses), and *Diagnosis of diseases* (2 uses). More specifically, in 2016,*Animal Diseases and Disorders* (128 uses), *Diagnosis of diseases* (21 uses), *Human Infectious Disorders* (6 uses), *Human Cardiovascular Disorders* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). The remaining uses in 2015 were reported in *Basic Research/Cardiovascular Blood and Lymphatic System* (5 uses), and in 2016 in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (24 uses), *Basic Research/Other* (12 uses), and *Regulatory use and Routine production/Toxicity and other safety testing including pharmacology/Kinetics* (4 uses). The wide distribution between many different categories makes it difficult to find clear reasons for the increase.

Other mammals decreased from 2,104 uses in 2015 to 427 uses in 2016. The main difference depends on the 1,500 uses of reindeer in 2015, and none in 2016. *Ethology/Animal Behaviour/Animal Biology* was the most common purpose in both years; 1,871 uses in 2015 and 416 uses in 2016.

Rabbits increased from 446 uses in 2015 to 1,447 uses in 2016. Most uses of rabbits in 2016 concerned *Basic Research* (1,391 uses), more specifically *Other basic research* (885 uses) and *Respiratory System* (409 uses).

Horses/donkeys increased from 275 uses in 2015 to 824 uses in 2016. Most uses of horses/donkeys 2016 was reported as *Translational and Applied Research* (741 uses), more specifically as *Animal Diseases and Disorders*.

Domestic fowls decreased from 5,266 in 2015 to 971 in 2016. In 2016 most uses were reported in *Translational and applied research* (586 uses), whereas 385 uses were reported in *Basic research*. The more specific areas were diverse. Under *Basic research*; *Sensory Organs (skin, eyes and ears)* (144 uses), *Ethology / Animal Behaviour /Animal Biology* (105 uses), *Cardiovascular Blood and Lymphatic System* (84 uses), *Other basic research* (polyclonal antibodies) (37 uses), and *Endocrine System/ Metabolism* (15 uses). Under *Translational*: *Human Gastrointestinal Disorders including Liver* (240 uses), *Non-regulatory toxicology and ecotoxicology* (105 uses), *Human Respiratory Disorders* (90 uses), *Animal Diseases and Disorders* (90 uses) and *Diagnosis of diseases* (61 uses). In 2015 most uses were reported under *Basic research*, more specifically *Ethology / Animal Behaviour /Animal Biology* (4,140 uses, of which 3,240 uses are reported in a study on welfare indicators and 600 uses on ecologically produced chicken) and *Nervous System* (120 uses). Remaining uses were reported under *Translational and applied research*; *Animal Diseases and Disorders* (475 uses), *Non-regulatory toxicology and ecotoxicology* (351 uses) and *Diagnosis of diseases* (180 uses).

Other birds increased from 6,551 in 2015 to 11,583 in 2016. Almost all uses were reported as *Basic research*. In 2015, 3,008 uses were reported in *Ethology/Animal Behaviour/Animal Biology,* and 3,543 uses in *Other Basic Research* (blood sampling for gene analyses and prevalence of malaria, 2,969 uses; infections on wild animals, 553 uses; behavioural studies, 21 uses). In 2016, 4,570 uses were reported in *Ethology/Animal Behaviour/Animal Biology.* The large increase for 2016 is found under *Other Basic Research* with 6,940 uses reported (blood sampling for genetical analyses, 3,486; blood sampling, 3,072 uses; infections on wild animals, 365 uses; and behavioural studies, 17 uses). Remaining uses were reported under *Musculoskeletal System* (8 uses), *Sensory organs* (4 uses) and *Translational and applied research, Animal Diseases and Disorders* (61 uses).

Reptiles increased from 50 in 2015 to 380 in 2016. All were used in *Basic research*, more specifically, in 2015 in *Ethology / Animal Behaviour /Animal Biology*, and in 2016 in the *Other* category; 300 uses in evolutionary biology and 80 uses for blood sampling and marking.

The use of Other amphibians increased from 1,894 in 2015 to 3,923 in 2016. All were reported under Basic research. In 2015, 1,236 uses were reported for studies of the ability of the nervous system and the locomotion to heal themselves and gene function compared to 1,624 in 2016. In 2016, 1,320 uses of moor frog (*Rana arvalis*) were reported in *Basic Research/Ethology/Animal Behaviour/Animal Biology*, and another study in 2016 reported 553 uses for how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. Remaining uses were reported in the *Other* category for 2016 (426 uses, 130 of these for marking) and in *Ethology/Animal Behaviour/Animal Biology* for 2015 (658 uses).

Animal group	**Animal species**	**2014**	**2015**	**2016**
Rodents	Mice	197,491	175,962	261,847
	Rats	26,762	21,907	21,218

	Guinea-Pigs	663	482	422
	Hamsters (Syrian)	0	0	0
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	5,296	3,323	63
Lagomorphs	Rabbits	571	446	1,447
Carnivores	Cats	28	23	94
	Dogs	111	115	204
	Ferrets	0	57	0
	Other carnivores	91	118	167
Ungulates	Horses, donkeys and cross-breeds	58	275	824
	Pigs	585	1,625	1,840
	Goats	0	0	58
	Sheep	51	52	27
	Cattle	129	2,097	1,436
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	3	7	10
	Rhesus monkey	0	1	28
	Vervets (Chlorocebus spp.)	0	0	0
	Baboons	0	0	0
	Squirrel monkey	0	0	0
	Other species of New World Monkeys (Ceboidea)	0	0	0
	Other species of Old World Monkeys (Cercopithecoidea)	0	0	0
	Other species of non-human primates	0	0	0

	Apes	0	0	0
Other mammals	Other mammals	1,128	2,104	427
Birds	Domestic fowl	10,899	5,266	971
	Other birds	5,972	6,551	11,583
Reptiles	Reptiles	9	50	380
Amphibians	Rana	0	600	623
	Xenopus	1,598	574	441
	Other amphibians	2,857	1,894	3,923
Fish	Zebra fish	8,171	20,519	24,607
	Other fish	21,697	14,355	18,024
Cephalopods	Cephalopods	0	0	0
	Total uses	**284,170**	**258,403**	**350,664**

iii. Use in specific areas

The uses in overall, in percentages, were similar in 2015 and 2016, but the percentages of two of the less frequent reported categories have changed between 2015 and 2016. The category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has dropped from 2.4 % (6,280 uses) to 0.7 % (2,759 uses). *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased from 0.1 % (213 uses) to 1.6 % (5,676 uses).

The percentages for the specific areas under both *Basic research* and *Translational and applied research* 2015 and 2016 are similar. The most notable differences are for *Animal Diseases and Disorders* which were reported for 10 % (4,284 uses) in 2015 and 2 % (1,160 uses) in 2016 and *Animal Welfare* which increased from <1 % (18 uses) in 2015 to 13 % (6,578 uses) in 2016.

It is too early to tell if these changes are trends or simply normal fluctuations in research.

iv. Re-use

Re-use were reported for 2 % of the uses in 2016. For 2015, that number was 13 %; that higher figure could indeed to some extent be due to a higher re-use, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of re-use with some users, leading to animals erroneously being recorded as re-used when they should not have been. Figures were corrected where it was possible, which was unfortunately not always the case. In order to improve the future quality of the reporting, information efforts were initiated, that are believed to have led to a more accurate reporting on re-use in the 2016 statistics.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The proportion of moderate severity has increased from 51 % in 2015 to 58 % in 2016, while the proportions of *Mild* and *Non-recovery* have decreased. No conclusions can be drawn from the material at this stage.

Severity	**2015**		**2016**	
	Number of	***%***	***Number of***	***%***
Non-recovery	14,648	*6*	6,427	*2*
Mild (up to and including)	92,991	*36*	112,034	*32*
Moderate	132,628	*51*	202,626	*58*
Severe	18,136	*7*	29,577	*8*
Totally	**258,403**	***100***	**350,664**	***100***

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The Swedish parliament decided in late 2016 to finance a competence centre for the 3Rs, placed at the Swedish Board of Agriculture. The Swedish National Committee will act as the steering group for the centre. The centre will have its official opening on the 21th of November 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2017, the Swedish National Committee for the protection of animals used for scientific purposes held one course for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

5.1 Other animals

i. Fish

42 % of the reported fish constitutes of *Other fish*. Of the 18,024 uses of *Other fish* most are reported as three-spined stickleback (*Gasterosteus aculeatus*, 4,339 uses), brown trout (*Salmo trutta,* 3,983 uses), salmon (*Salmo salar,* 3,417 uses), perch (*Perca fluviatilis,* 1,443 uses) and common roach (*Rutilus rutilus*, 1,358 uses).

The fish in this category were used mainly for *Basic research/Ethology/Animal behaviour/animal biology (8,303 uses)* and in *Translational and applied research/Animal Welfare* (6,566 uses), but also in *Protection of the natural environment in the interests of the health or welfare of human beings or*

animals (2,159 uses). Remaining uses are reported in *Basic research* (*Gastrointestinal System including Liver,* 294 uses*; Nervous system,* 66 uses*;* and *Cardiovascular Blood and Lymphatic System*, 29 uses); *Translational and applied research (Diagnosis of disease,* 154 uses; and *Non-regulatory toxicology and ecotoxicology*, 70 uses) and *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (13 uses).

ii. Amphibians

79 %, of the amphibians are registered as *Other amphibians*. The category (3,923 uses) consists mostly of moor frog (*Rana arvalis*, 1,614 uses), Iberian ribbed newt (*Pleurodeles waltl,* 1,570 uses), but also common toad (*Bufo bufo*, 500 uses), natterjack toad (*Epidalea calamita,* 143 uses), eastern newt (*Notophthalmus viridescens*, 54 uses), European green toad (*Bufotes virides*, 36 uses) and edible frog (*Pelophylax kl esculentus*, 6 uses).

Most other amphibians have been used in *Other basic research*. Iberian ribbed newt and eastern newt have been used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function. Furthermore, the common toad, moor frog, European green toad, natterjack toad and edible frog have been used to understand how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. 1,320 uses of moor frog were categorised as *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

iii. Birds

A large percentage, 92 %, among the birds constitutes of *Other birds.* These (11,583 uses) consist mostly of Old World flycatchers (*Muscicapidae,* 3,486 uses), followed by collared flycatcher (*Ficedula albicollis*, 1,750 uses), Eurasian blue tit (*Cyanistes caeruleus*, 1,962 uses), European pied flycatcher (*Ficedula hypoleuca*, 766 uses) and marsh tit (*Poecile palustris*, 641 uses).

60 % of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses, infections in wild animals, or behavioural studies without restraining equipment. The remaining birds have been used in *Basic Research: Ethology / Animal Behaviour /Animal Biology* (4,570 uses), *Musculoskeletal System* (8 uses) and *Sensory Organs* (4 uses); and in *Translational and applied research/Animal Diseases and Disorders* (61 uses).

iv. Carnivores

Among the carnivores SE had a large percentage (36 %) of *Other carnivores*. These (167 uses) are mainly brown bear (*Ursus arctos*, 68 uses) and raccoon dog (*Nyctereutes procyonoides*, 60 uses), but also fox (*Vulpes vulpes*, 17 uses), American mink (*Neovison vison*, 12 uses), wolf (*Canis lupus,* 6 uses), and wolverine (*Gulo gulo*, 4 uses).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the American mink, used in *Translational and applied research/Animal Welfare.*

5.2 Other legislation

14 % of the uses in *Testing by legislation* are reported under *Other legislation*. These constitute 320 uses of rainbow trout (*Oncorhyncus mykiss*) and 50 uses of three-spined stickleback (*Gasterosteus aculeatus*) in *Regulatory use and Routine production /Toxicity and other safety testing including pharmacology/Acute and sub-acute/Non lethal methods, Legislation satisfying EU requirements.* The user has identified this legislation as concerning biotoxicity.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Sweden: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	255949	74.24%
Rats	21218	6.15%
Guinea-Pigs	422	0.12%
Hamsters (Syrian)		
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	63	0.02%
Rabbits	1447	0.42%
Cats	94	0.03%
Dogs	204	0.06%
Ferrets		
Other carnivores	167	0.05%
Horses, donkeys and cross-breeds	824	0.24%
Pigs	1840	0.53%
Goats	58	0.02%
Sheep	27	0.01%
Cattle	1436	0.42%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	10	0%
Rhesus monkey	28	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	427	0.12%
Domestic fowl	971	0.28%
Other birds	11583	3.36%
Reptiles	380	0.11%
Rana	623	0.18%
Xenopus	441	0.13%
Other Amphibians	3923	1.14%
Zebra fish	24607	7.14%
Other Fish	18024	5.23%
Cephalopods		
Total	**344766**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	261665	77.28%
Animals born in the EU but not at a registered breeder	67459	19.92%
Animals born in rest of Europe	5884	1.74%
Animals born in rest of world	3586	1.06%
Total	**338594**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	38	100%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total	**38**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	38	100%
Self-sustaining colony		
Total	**38**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	283240	82.15%
Translational and applied research	50568	14.67%
Regulatory use and Routine production	2599	0.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2759	0.8%
Preservation of species		
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5155	1.5%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	445	0.13%
Total	**344766**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	28930	10.21%
Cardiovascular Blood and Lymphatic System	39229	13.85%
Nervous System	51837	18.3%
Respiratory System	2732	0.96%
Gastrointestinal System including Liver	6256	2.21%
Musculoskeletal System	7120	2.51%
Immune System	41870	14.78%
Urogenital/Reproductive System	2658	0.94%

Basic Research	Number of uses	Percentage
Sensory Organs (skin, eyes and ears)	4523	1.6%
Endocrine System/Metabolism	25651	9.06%
Multisystemic	31111	10.98%
Ethology / Animal Behaviour /Animal Biology	16487	5.82%
Other basic research	24836	8.77%
Total	**283240**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	14014	27.71%
Human Infectious Disorders	973	1.92%
Human Cardiovascular Disorders	5606	11.09%
Human Nervous and Mental Disorders	4523	8.94%
Human Respiratory Disorders	5806	11.48%
Human Gastrointestinal Disorders including Liver	279	0.55%
Human Musculoskeletal Disorders	246	0.49%
Human Immune Disorders	1441	2.85%
Human Urogenital/Reproductive Disorders	75	0.15%
Human Sensory Organ Disorders (skin, eyes and ears)	292	0.58%
Human Endocrine/Metabolism Disorders	3288	6.5%
Other Human Disorders	3802	7.52%
Animal Diseases and Disorders	1160	2.29%
Animal Welfare	6578	13.01%
Diagnosis of diseases	530	1.05%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1955	3.87%
Total	**50568**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1048	40.32%
Other efficacy and tolerance testing	120	4.62%
Toxicity and other safety testing including pharmacology	1426	54.87%
Routine production	5	0.19%
Total	**2599**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	36	3.44%
Other quality controls		
Pyrogenicity testing		
Batch potency testing	1012	96.56%
Total	**1048**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	370	25.95%
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Repeated dose toxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		
Target animal safety		
Neurotoxicity	119	8.35%
Kinetics	937	65.71%
Total	**1426**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods	370	100%
Total	**370**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days		
29 - 90 days		
> 90 days		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products	5	100%
Monoclonal antibody by mouse ascites method		
Other product types		
Total	**5**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1093	42.05%
Legislation on medicinal products for veterinary use and their residues	1136	43.71%
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	370	14.24%
Total	**2599**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2594	99.81%
Legislation satisfying national requirements only [within EU]	5	0.19%
Legislation satisfying Non-EU requirements only		
Total	**2599**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	338632	98.22%
Yes	6134	1.78%
Total	**344766**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	6427	1.86%
Mild [up to and including]	111460	32.33%
Moderate	197302	57.23%
Severe	29577	8.58%
Total	**344766**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	318807	92.47%
Yes	25959	7.53%
Total	**344766**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	145476	42.2%
Genetically altered without a harmful phenotype	176997	51.34%
Genetically altered with a harmful phenotype	22293	6.47%
Total	**344766**	**100.00%**

Sweden: Narrative 2017

1. General information on any changes in trends observed since the previous reporting period

Total number of uses
There was a decrease in the total number of uses reported for 2017 (325,838 uses) compared to 2016 (345,433 uses), but more were used than in 2015 (254,789 uses).

Genetic status
The use of genetically altered animals with a harmful phenotype has gradually increased since 2015; with twice as many uses reported in 2017 (36,929 uses, 11%) compared to 2015 (18,270 uses, 7%).

Place of birth
A minority of the animal uses in 2017 were with animals born in rest of the world (2,714 uses, 1%), and the numbers have decreased compared to 2016 (3,586 uses, 1%) and 2015 (5,277 uses, 2%).

Non-human Primate Source
Most uses of non-human primates in 2017 (19 uses, 76%) were of primates born in America. This is in contrast to both 2016 and 2015 were all were born in Asia (2016: 38 uses, 2015: 3 uses).

Species
Hamsters (Syrian) increased to 34 uses in 2017, while none was reported for 2016 and 2015. Most (31 uses) of the uses in 2017 were reported as *Translational and Applied Research*, mainly *Human Endocrine/Metobolism Studies* (26 uses). Other rodents decreased to 5 uses in 2017 compared to 63 uses in 2016; none was reported for 2015. All uses in 2017 of other rodents were reported as *Preservation of species.*

Dogs had 386 uses in 2017, which is an increase compared to 2016 (204 uses) and 2015 (115 uses). For all three years, most uses were reported as *Translational and applied research* (for 2017 it was 330 uses, 85%). More specifically in 2017: *Animal Diseases and Disorders* (251 uses), *Human Cardiovascular Disorders* (45 uses), *Human Respiratory Disorders* (15 uses), *Diagnosis of diseases* (10 uses), *Human Endocrine/Metobolism Studies* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). Also for 2016 *Animal Diseases and Disorders* were the most reported category in *Translational and applied research* (785 in 2016, 765 in 2017).

Horses, donkeys and cross-breeds had 41 uses in 2017 which is a large decrease compared to 2016 (824 uses) and 2015 (275 uses). The uses in 2017 was reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (26 uses) and *Basic research* (15 uses, of which 8 were for *Other basic research* and 7 for *Respiratory System*). A main difference from 2016 is that one user in 2016 reported 741 uses (90%) as *Translational and Applied Research* (more specifically as *Animal Diseases and Disorders*).

Goats had 30 uses in 2017, which is about half as many as in 2016 (58 uses); none was reported for 2015. In 2017 most uses were reported in *Translational and applied research,* more precisely *Diagnosis of diseases* (20 uses), whereas 10 uses were reported in *Basic research*. The uses was similar in 2016 except that 24 uses were reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* in 2016.

Domestic fowls had 1,452 uses in 2017, which is an increase compared to 2016 (971 uses), but a decrease compared to 2015 (5,266 uses). In 2017 most uses were reported in *Translational and applied research* (1,125 uses), more specifically *Non-regulatory toxicology and ecotoxicology* (653 uses), followed by *Animal Diseases and Disorders* (130 uses), *Human Infectious Disorders* (128 uses), and *Human Respiratory Disorders* (118 uses). Of the reported domestic fowls 327 uses were reported in *Basic research*, mainly in *Cardiovascular Blood and Lymphatic System* (200 uses) and *Oncology* (76 uses). Also in 2016 most fowl uses were reported as *Translational and applied research* (586 uses), followed by *Basic research* (385 uses). The more specific areas were diverse in 2016 as well.

No reptiles was reported for 2017, which is a decrease compared to 2016 (380 uses) and 2015 (50 uses). In 2016 all uses were reported as *Other basic research*, more specifically: evolutionary biology (300 uses) and blood sampling and marking (80 uses).

Rana (a genus of frogs) had 308 uses in 2017, which is about half as many compared to 2016 (623 uses) and 2015 (600 uses). In 2017, the uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (200 uses), and *Translational and applied research,* more specifically *Non-regulatory toxicology and ecotoxicology* (108 uses). For 2015 and 2016 all or almost all (100% respectively 96%) uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

Xenopus (a genus of frogs) had 261 uses in 2017, and has had a gradual decrease from 2015 to 2017 (2016: 441 uses and 2015: 574 uses). For 2017 the uses were reported as *Basic research* (145 uses, all under *Nervous System*) and *Translational and applied research* (116 uses, all under *Non-regulatory toxicology and ecotoxicology*). Both these categories had uses reported in 2015 and 2016 as well.

Other amphibians had 2,694 uses in 2017, which is a decrease compared to 2016 (3,923 uses), but an increase compared to 2015 (1,894 uses). For 2017 most uses were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses; all to study how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians). For 2017 an additional 60 uses were reported as *Preservation of species* and 60 uses as *Translational and applied research*, more specifically *Non-regulatory toxicology and ecotoxicology*. For both 2015 and 2016 all uses were reported under Basic research (*Ethology/Animal Behaviour/Animal Biology* and *Other basic research*).

Zebra fish has gradually increased since 2015. For 2017 was 29,158 uses reported, compared to 24,607 uses in 2016 and 20,519 uses in 2015. The uses in 2017 were reported as *Basic Research* (19,057 uses, mainly *Cardiovascular Blood and Lymphatic System* [7,282 uses] and *Multisystemic* [7,399 uses]) and *Translational and applied research* (10,101 uses, mainly
Human Nervous and Mental Disorders [7,000 uses] and *Human Endocrine/Metabolism Disorders* [300 uses]).

Other fish has gradually increased since 2015. For 2017 was 33,940 uses reported, compared to 18,024 uses in 2016 and 14,355 uses in 2015. For 2017 most uses was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in the category *Ethology/Animal Behaviour/Animal Biology*).

2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The uses in overall are similar 2015-2017. A change is that the category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has increased to 27,916 in 2017 compared to 2,759 uses in 2016 and 6,280 uses in 2015. In 2017, 98% of these uses were other fish. Another change is that *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased to 1,679 uses in 2017 compared to 445 uses in 2016 and 155 uses in 2015. In 2017, 99% of these uses were mice and all were classified as mild severity.

The number of uses for many of the categories under *Basic research* are either similar to 2016 or to 2015. A change is that *Respiratory System* increased to 7,362 uses in 2017 compared to 2,732 uses in 2016 and 1,652 uses in 2015. *Gastrointestinal System including Liver* has decreased to 1,531 uses from 6,256 uses in 2016 and 3,971 uses in 2015. In addition, the *Immune System* has decreased; 23,611 uses in 2017 compared to 42,537 uses in 2016.

The number of uses for many of the categories under *Translational and applied research* are either similar to 2016 or to 2015. A change is that *Human Nervous and Mental Disorders* increased to 9,737 uses in 2017 compared to 4,523 uses in 2016 and 2,777 uses in 2015. In addition, *Human Immune Disorders* increased to 9,271 uses in 2017 compared to 1,441 uses in 2016 and 2,053 uses in 2015; and *Human Endocrine/Metabolism Disorders* increased to 5,687 uses in 2017 compared to 3,288 uses in 2016 and 2,914 uses in 2015.

It is unclear what the changes depends on.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

The uses with severe severity has gradually increased since 2015, reaching 41,475 uses (13%) in 2017, which is more than twice as many as in 2015 (18,136 uses, 7%). Most uses classified as severe in 2017 were reported as *Basic research* (79%). Of those, *Oncology*, *Nervous system*, *Respiratory system* and *Musculoskeletal System* are purpose categories that has increased 2015-2017. *Oncology* increased from 516 uses in 2015 to 4,854 uses in 2017, *Nervous system* from 8,375 uses in 2015 to 12,466 uses in 2017, *Respiratory system* from 0 uses in 2015 to 979 uses in 2017, and *Musculoskeletal System* from 732 uses in 2015 to 1,895 uses in 2017.

Of the uses classified as severe in 2017 under *Translational and applied research* (21%), *Human Immune disorders* increased most (2015: 50 uses; 2017: 7,191 uses) and *Human Cancer* decreased most (2015: 853 uses; 2017: 33 uses).

25% of the uses reported as severe in 2017 comes from two purposes in two user reports. One of the report has 6,869 uses within *Human Immune disorders* and the other has 3,316 uses within *Nervous System* (*Basic research*).

It is unclear what the changes depends on.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

Sweden established a 3Rs center for the promotion of the 3Rs. The Swedish 3Rs Center had its official opening on the 21st of November 2017. The 3Rs Center is the executive body of the Swedish National Committee for the Protection of Animals Used for Scientific Purposes. As such, the 3Rs Center assists the Committee in carrying out its tasks by e.g. developing advice on alternative methods, disseminating information on the 3Rs, and supporting the local animal welfare bodies, the regional ethics committees and authorities concerned with animal experiments.

During 2017, two working groups were appointed by the National Committee to develop advice for marking and tagging of fish, and group housing of male mice. While the fish project is entirely based on existing literature, the mice project also includes workshops and a questionnaire targeting animal technicians and researchers.

On 14 June 2017, the Swedish 3Rs Center together with the Users' Committee and the Ethics and Education Committee held a meeting with Sweden's animal welfare bodies.
The purpose of the meeting was to establish contact and develop efficient cooperation methods between the animal welfare bodies and the 3Rs Center as the committee's executive body. The meeting provided an opportunity for the participants to make new contacts, gather new knowledge and acquire new tools to carry out their assignments effectively.

On 17–19 October 2017, the Committee on ethics and education of the National Committee together with the Swedish Centre for Animal Welfare (SCAW) arranged the annual education in ethical evaluation for members of the regional ethics committees. The Swedish 3Rs Center participated with a lecture.

In November 2017, the 3Rs Centre used a quantitative questionnaire to learn more about researchers´ thoughts and implementation of the 3Rs, but also to increase their awareness of the 3Rs and the Swedish 3Rs Centre. The results from the survey shall serve as base for the development of further strategies to promote the 3Rs. The results were presented at the scientific conference Scand-LAS in 2018, and will be published in a report.

The Swedish Government has suggested that the Swedish 3Rs Center support six authorities in their 3Rs work by, for example, compiling and reviewing the authorities' 3R-related activities and the establishing of 3R-strategies. During 2017, the centre begun working on compiling and analysing these authorities' 3R-strategies.

The Swedish 3Rs Center created a website during 2017. This is an important channel for disseminating information on the 3Rs. It is accessible via the Swedish Board of Agriculture's website with its home page: www.jordbruksverket.se/3R. During the development of the website, the focus was on putting together pages with information on what the 3Rs are and why it is important to work with the 3Rs. The website also contains information on the centre's history, vision, mission and objectives as well as the National Committees and 3Rs centers organisational structure. During 2017 the 3Rs Center started also working on developing more specialised pages with information on, for example, animal welfare bodies, how to apply for research funding for projects linked to the 3Rs as well as links to other organisations

that work with animal welfare and 3R-related issues. Those pages were published early in 2018. The 3Rs Center also publishes news and information on its website regarding courses and conferences related to the 3Rs.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Other fish
54% of the reported fish constitutes of other fish. Of the 33,940 uses of other fish most are reported as goldsinny wrasse (*Ctenolabrus rupestris*, 8,518 uses), corkwing wrasse (S*ymphodus melops*, 6,127 uses), and Atlantic cod (*Gadus morhua,* 5,224 uses). As mentioned above (section 1), most uses of other fish was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in *Ethology/Animal Behaviour/Animal Biology*).

Other amphibians
83% of the amphibians are registered as other amphibians. This category (2,787 uses) consists mostly of moor frog (*Rana arvalis*, 1,132 uses), Iberian ribbed newt (*Pleurodeles waltl,* 956 uses) and common toad (*Bufo bufo*, 388 uses). As mentioned above (section 1), most uses of other amphibians were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses).

Other birds
89% of the birds are reported as other birds. These 11,269 uses consist mostly of European pied flycatcher (*Ficedula hypoleuca,* 3,511 uses), followed by Eurasian blue tit (*Cyanistes caeruleus*, 1,882 uses), collared flycatcher (*Ficedula albicollis*, 1,800 uses), great tit (*Parus major*, 978 uses), mallard (*anas platyrhynchos*, 663 uses), and marsh tit (*Poecile palustris*, 558 uses). Most uses of other birds was reported as *Basic research* (10,744 uses, of which 10,072 was specified as *Ethology/Animal Behaviour/Animal Biology*).

Other carnivores
22% of the carnivores was recorded as other carnivores. These 140 uses consist of *Arctic fox* (*Vulpes lagopus*, 66 uses), raccoon dog (*Nyctereutes procyonoides*, 39 uses), red fox (*Vulpes vulpes*, 22 uses), wolverine (*Gulo gulo*, 7 uses) and wolf (*Canis lupus,* 6 uses). The uses of other carnivores was reported as *Preservation of species* (73 uses), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (369 uses), and *Basic research* (28 uses).

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

There has been no such case in SE up to this date.

Appendix

The European Commission noticed some irregularities in the Swedish statistic for 2015 and 2016. After being in contact with those users, we have adjusted their reports. We have used the updated numbers for 2015 and 2016 in the present narrative.

Animal group	Animal species	2015	2016	2017
Rodents	Mice	175,904	256,616	221,232
	Rats	21,907	21,218	19,437
	Guinea-Pigs	482	422	409
	Hamsters (Syrian)	0	0	34
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	0	63	5
Lagomorphs	Rabbits	446	1,447	1,574
Carnivores	Cats	23	94	104
	Dogs	115	204	386
	Ferrets	57	0	0
	Other carnivores	118	167	140
Ungulates	Horses, donkeys and cross-breeds	275	824	41
	Pigs	1,625	1,840	1,557
	Goats	0	58	30
	Sheep	52	27	35
	Cattle	2,097	1,436	1,420
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	7	10	2
	Rhesus monkey	1	28	23
	Vervets (Chlorocebus spp.)	0	0	0
	Baboons	0	0	0
	Squirrel monkey	0	0	0
	Other species of New World Monkeys (Ceboidea)	0	0	0
	Other species of Old World Monkeys (Cercopithecoidea)	0	0	0
	Other species of non-human primates	0	0	0
	Apes	0	0	0
Other mammals	Other mammals	1,871	427	327
Birds	Domestic fowl	5,266	971	1,452
	Other birds	6,551	11,583	11,269

Reptiles	Reptiles	50	380	0
Amphibians	Rana	600	623	308
	Xenopus	574	441	261
	Other amphibians	1,894	3,923	2,694
Fish	Zebra fish	20,519	24,607	29,158
	Other fish	14,355	18,024	33,940
Cephalopods	Cephalopods	0	0	0
	Total uses	**254,789**	**345,433**	**325,838**

Severity	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Non-recovery	11,034	*4*	6,427	*2*	*9,324*	*3*
Mild (up to and including)	92,991	*37*	112,034	*32*	*109,950*	*34*
Moderate	132,628	*52*	197,395	*57*	*165,089*	*51*
Severe	18,136	*7*	29,577	*9*	*41,475*	*13*
Totally	**258,345**	***100***	**345,433**	***100***	***325,838***	***100***

Genetic Status	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Not genetically altered	109,855	*43*	146,110	*42*	*150,383*	*46*
Genetically altered without a harmful phenotype	126,664	*50*	177,030	*51*	*138,526*	*43*
Genetically altered with a harmful phenotype	18,270	*7*	22,293	*6*	*36,929*	*11*
Totally	**254,789**	***100***	**345,433**	***100***	***325,838***	***100***

Regulatory use and routine production	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Quality control (incl batch safety and potency testing)	0	*0*	1,048	*40*	*773*	*32*
Other efficacy and tolerance testing	144	*7*	120	*5*	*235*	*10*
Toxicity and other safety testing including pharmacology	2,044	*93*	1,426	*55*	*1,416*	*58*
Routine production	0	*0*	5	*<1*	*0*	*0*
Totally	**2,188**	***100***	**2,599**	***100***	***2,424***	***100***

Re-use	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
No	235,961	*93*	339,299	*98*	319,236	*98*
Yes	18,828	*7*	6,134	*2*	6,602	*2*
Totally	**254,789**	***100***	**345,433**	***100***	**325,838**	***100***

Basic research (first use and re-use)	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Oncology	13,825	*7*	28,930	*10*	*22,557*	*10*
Cardiovascular Blood and Lymphatic System	28,833	*14*	39,229	*14*	*44,731*	*19*
Nervous System	44,616	*22*	51,837	*18*	*53,838*	*23*
Respiratory System	1,652	*1*	2,732	*1*	*7,362*	*3*
Gastrointestinal System including Liver	3,971	*2*	6,256	*2*	*1,531*	*1*
Musculoskeletal System	4,597	*2*	7,120	*3*	*4,220*	*2*
Immune System	29,358	*15*	42,537	*15*	*23,611*	*10*
Urogenital/Reproductive System	2,892	*1*	2,658	*1*	*6,543*	*3*
Sensory Organs (skin, eyes and ears)	3,495	*2*	4,523	*2*	*3,150*	*1*
Endocrine System/Metabolism	18,578	*9*	25,651	*9*	*28,055*	*12*
Multisystemic	18,073	*9*	31,111	*11*	*10,201*	*4*
Ethology / Animal Behaviour /Animal Biology	19,510	*10*	16,487	*6*	*16,914*	*7*
Other basic research	13,050	*6*	24,836	*9*	*10,528*	*5*
Totally	***202,450***	***100***	***283,907***	***100***	***233,241***	***100***

Translational and applied research (first use and re-use)	**2015**		**2016**		**2017**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Human Cancer	11,929	*30*	14,014	*28*	10,841	*19*
Human Infectious Disorders	883	*2*	973	*2*	1,328	*2*
Human Cardiovascular Disorders	7,234	*18*	5,606	*11*	6,483	*12*
Human Nervous and Mental Disorders	2,777	*7*	4,523	*9*	9,737	*17*
Human Respiratory Disorders	6,436	*16*	5,806	*11*	5,077	*9*
Human Gastrointestinal Disorders including Liver	386	*1*	279	*1*	0	*0*
Human Musculoskeletal Disorders	263	*1*	246	*<1*	862	*2*
Human Immune Disorders	2,053	*5*	1,441	*3*	9,271	*17*
Human Urogenital/Reproductive Disorders	117	*<1*	75	*<1*	255	*<1*
Human Sensory Organ Disorders (skin, eyes and ears)	109	*<1*	292	*1*	500	*1*
Human Endocrine/Metabolism Disorders	2,914	*7*	3,288	*7*	5,687	*10*
Other Human Disorders	1,636	*4*	3,802	*8*	2,323	*4*
Animal Diseases and Disorders	728	*2*	1,160	*2*	704	*1*
Animal Welfare	18	*<1*	6,578	*13*	105	*<1*
Diagnosis of diseases	239	*1*	530	*1*	542	*1*
Plant diseases	0	*0*	0	*0*	0	*0*
Non-regulatory toxicology and ecotoxicology	2,163	*5*	1,955	*4*	1,998	*4*
Totally	***39,885***	***100***	***50,568***	***100***	***55,713***	***100***

Sweden: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	220281	67.83%
Rats	19321	5.95%
Guinea-Pigs	409	0.13%
Hamsters (Syrian)	34	0.01%
Hamsters (Chinese)		
Mongolian gerbil		
Other Rodents	5	0%
Rabbits	1574	0.48%
Cats	104	0.03%
Dogs	386	0.12%
Ferrets		
Other carnivores	140	0.04%
Horses, donkeys and cross-breeds	41	0.01%
Pigs	1557	0.48%
Goats	30	0.01%
Sheep	35	0.01%
Cattle	1420	0.44%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	2	0%
Rhesus monkey	23	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	327	0.1%
Domestic fowl	1452	0.45%
Other birds	11269	3.47%
Reptiles		
Rana	308	0.09%
Xenopus	261	0.08%
Other Amphibians	2694	0.83%
Zebra fish	29158	8.98%
Other Fish	33940	10.45%
Cephalopods		
Total	**324771**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	249147	78.31%
Animals born in the EU but not at a registered breeder	64675	20.33%
Animals born in rest of Europe	1608	0.51%
Animals born in rest of world	2714	0.85%
Total	**318144**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU		
Animals born in rest of Europe		
Animals born in Asia	6	24%
Animals born in America	19	76%
Animals born in Africa		
Animals born elsewhere		
Total	**25**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	25	100%
Self-sustaining colony		
Total	**25**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	232174	71.49%
Translational and applied research	55713	17.15%
Regulatory use and Routine production	2424	0.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	27916	8.6%
Preservation of species	617	0.19%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4248	1.31%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	1679	0.52%
Total	**324771**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	22549	9.71%
Cardiovascular Blood and Lymphatic System	44502	19.17%
Nervous System	53425	23.01%
Respiratory System	7362	3.17%
Gastrointestinal System including Liver	1531	0.66%
Musculoskeletal System	4220	1.82%
Immune System	23194	9.99%
Urogenital/Reproductive System	6543	2.82%
Sensory Organs (skin, eyes and ears)	3150	1.36%
Endocrine System/Metabolism	28055	12.08%
Multisystemic	10201	4.39%
Ethology / Animal Behaviour /Animal Biology	16914	7.29%
Other basic research	10528	4.53%
Total	**232174**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	10841	19.46%
Human Infectious Disorders	1328	2.38%
Human Cardiovascular Disorders	6483	11.64%
Human Nervous and Mental Disorders	9737	17.48%
Human Respiratory Disorders	5077	9.11%
Human Gastrointestinal Disorders including Liver		
Human Musculoskeletal Disorders	862	1.55%
Human Immune Disorders	9271	16.64%
Human Urogenital/Reproductive Disorders	255	0.46%
Human Sensory Organ Disorders (skin, eyes and ears)	500	0.9%
Human Endocrine/Metabolism Disorders	5687	10.21%
Other Human Disorders	2323	4.17%
Animal Diseases and Disorders	704	1.26%
Animal Welfare	105	0.19%
Diagnosis of diseases	542	0.97%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	1998	3.59%
Total	**55713**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	773	31.89%
Other efficacy and tolerance testing	235	9.69%
Toxicity and other safety testing including pharmacology	1416	58.42%
Routine production		
Total	**2424**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing		
Other quality controls		
Pyrogenicity testing		
Batch potency testing	773	100%
Total	**773**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute		
Carcinogenicity		
Developmental toxicity		
Ecotoxicity		
Eye irritation/corrosion		
Genotoxicity		
Neurotoxicity		
Other toxicity/safety testing		
Pharmaco-dynamics (incl safety pharmacology)		
Phototoxicity		
Reproductive toxicity		
Safety testing in food and feed area		
Skin irritation/corrosion		
Skin sensitisation		

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety		
Repeated dose toxicity	113	7.98%
Kinetics	1303	92.02%
Total	**1416**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50		
Other lethal methods		
Non lethal methods		
Total		

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	113	100%
29 - 90 days		
> 90 days		
Total	**113**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity		
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total		

Routine production

Routine production	Number of uses	Percentage
Blood based products		
Monoclonal antibody by mouse ascites method		
Other product types		
Total		

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1651	68.11%
Legislation on medicinal products for veterinary use and their residues	773	31.89%
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		

Testing by Legislation	Number of uses	Percentage
Cosmetics legislation		
Other legislation		
Total	**2424**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2424	100%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only		
Total	**2424**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	318169	97.97%
Yes	6602	2.03%
Total	**324771**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9324	2.87%
Mild [up to and including]	109850	33.82%
Moderate	164539	50.66%
Severe	41058	12.64%
Total	**324771**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	291525	89.76%
Yes	33246	10.24%
Total	**324771**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	149970	46.18%
Genetically altered without a harmful phenotype	137872	42.45%
Genetically altered with a harmful phenotype	36929	11.37%
Total	**324771**	**100.00%**

United Kingdom

United Kingdom: Narrative 2015

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2015 data for Great Britain on the 20 July 2016 and the statistical release can be accessed online here:

https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2015.

The Northern Ireland Department for Health data is available here:
https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the Department for Health. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures' whereas this information is not provided to the EU. The UK releases additionally include, for all other purposes of procedure, procedures assessed as having sub-threshold or mild severity but such procedures are submitted to the EU in the "Mild [up to and including]" category. Additional breakdowns are also collected for the source of animals (distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (birds, dogs). These breakdowns are aggregated to form the EU categories prior to submission to the EU.

Comparison between the 2015 and 2014 data should be exercised with caution due to some under-reporting and misclassification in 2014. See introductory section, data quality section (page 7) of 'Annual Statistics of Scientific Procedures on Living Animals Great Britain 2015' for further information. The report can be accessed online at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/537708/scientific-procedures-living-animals-2015.pdf.

1. General information on any changes in trends observed since the previous reporting period.

In 2015, a total of 3.17 million procedures were completed. This represents an increase of 3% (92 thousand) compared with the 3.08 million procedures completed in 2014.

Of the 3.17 million procedures, 2.10 million (66%) were experimental procedures and 1.07 million (34%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2014, experimental procedures have increased by 8% (155 thousand) and creation/breeding procedures have decreased by 6% (63 thousand).

There were 3.10 million animals used for the first time in completed procedures in 2015, representing an increase of 3% (89 thousand) compared with 2014.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 2.10 million experimental procedures completed in 2015, the majority involved the use of mice (61%), fish (14%), and rats (12%). Comparing with 2014, there were notable changes[2] to the number of procedures involving:

- mice, which increased by 107 thousand (9%) to 1.28 million procedures in 2015;
- fish[3], which increased by 29 thousand (11%) to 294 thousand procedures in 2015;
- rats, which increased by 24 thousand (10%) to 258 thousand procedures in 2015;
- pigs, which increased by 1,900 (45%) to 6,100 procedures in 2015;
- hamsters[4], which decreased by 1,300 (-46%) to 1,500 procedures in 2015;
- goats, which decreased by 240 (-69%) to 110 procedures in 2015.

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (87%), fish (12%), and amphibians (0.7%). Comparing with 2014, there were notable changes[5] to the number of procedures involving:

- fish[6], which increased by 47 thousand (61%) to 124 thousand procedures in 2015;
- amphibians[7], which increased by 6,000 thousand (414%) to 7,400 procedures in 2015;
- mice, which decreased by 105 thousand (-10%) to 932 thousand procedures in 2015;
- rats, which decreased by 11 thousand (-60%) to 6,900 procedures in 2015;
- sheep, which decreased by 80 (-71%) to 30 procedures in 2015.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 2.10 million experimental procedures completed in 2015:

- 6% (123 thousand) were assessed as non-recovery (compared with 7% in 2014);
- 64% (1.34 million) were assessed as (up to and including) mild (compared with 60% in 2014);
- 24% (509 thousand) were assessed as moderate (compared with 25% in 2014);
- 6% (124 thousand) were assessed as severe (compared with 8% in 2014).

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.2% (2,100) were assessed as non-recovery (compared with 0.2% in 2014);
- 88% (940 thousand) were assessed as (up to and including) mild (compared with 90% in 2014);
- 6% (67 thousand) were assessed as moderate (compared with 7% in 2014);
- 6% (62 thousand) were assessed as severe (compared with 3% in 2014).

The changes in severity from 2014 to 2015 are compared as proportions only due to the suspected under-reporting of procedures that occurred in 2014. Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather

[2] Covers the three largest numeric and the three largest percentage changes between 2014 and 2015.
[3] Specifically, Zebrafish and other fish species.
[4] Specifically, Syrian Hamsters.
[5] Covers the three largest numeric and the three largest percentage changes between 2014 and 2015. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed.
[6] Specifically, Zebrafish and other fish species.
[7] Specifically, Xenopus (Laevis and Tropicalis).

than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death. Further guidance is required in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other member states, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals and work is ongoing to improve guidance for users on this matter.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research through the project licence evaluation process, advice given by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research “other category” included:

- Embryology and molecular biology;
- Parasitology;
- Some probable erroneous entries caused by confusion, e.g. research on renal system which could have been returned under urogenital/reproduction. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation.

Applied research “other” category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial disease;
- Haematology.

Regulatory use, routine production “other”:

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);
- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose "other":

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity "other":

- Effects on non-target (i.e. ASPA non-Schedule 2) species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2015

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	2208377	69.7%
Rats	264697	8.35%
Guinea-Pigs	21831	0.69%
Hamsters (Syrian)	1500	0.05%
Hamsters (Chinese)		
Mongolian gerbil	278	0.01%
Other Rodents	1763	0.06%
Rabbits	14224	0.45%
Cats	322	0.01%
Dogs	4753	0.15%
Ferrets	626	0.02%
Other carnivores	496	0.02%
Horses, donkeys and cross-breeds	8356	0.26%
Pigs	6350	0.2%
Goats	105	0%
Sheep	47237	1.49%
Cattle	4629	0.15%
Prosimians		
Marmoset and tamarins	131	0%
Cynomolgus monkey	3333	0.11%
Rhesus monkey	148	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	720	0.02%
Domestic fowl	128718	4.06%
Other birds	14061	0.44%
Reptiles		

Animal Species	Number of animals	Percentage
Rana	378	0.01%
Xenopus	15577	0.49%
Other Amphibians	1840	0.06%
Zebra fish	271773	8.58%
Other Fish	146257	4.62%
Cephalopods		
Total	**3168480**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2830494	91.43%
Animals born in the EU but not at a registered breeder	239430	7.73%
Animals born in rest of Europe	8705	0.28%
Animals born in rest of world	17316	0.56%
Total	**3095945**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	221	9.89%
Animals born in rest of Europe		
Animals born in Asia	596	26.68%
Animals born in America		
Animals born in Africa	1417	63.43%
Animals born elsewhere		
Total	**2234**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	598	26.77%
Self-sustaining colony	1636	73.23%
Total	**2234**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1408901	44.47%
Translational and applied research	417992	13.19%
Regulatory use and Routine production	556113	17.55%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	18200	0.57%
Preservation of species	757	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1845	0.06%
Forensic enquiries	121	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	764551	24.13%
Total	**3168480**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	161953	11.49%
Cardiovascular Blood and Lymphatic System	95627	6.79%
Nervous System	256944	18.24%
Respiratory System	30767	2.18%
Gastrointestinal System including Liver	27312	1.94%
Musculoskeletal System	31016	2.2%
Immune System	247072	17.54%
Urogenital/Reproductive System	50092	3.56%
Sensory Organs (skin, eyes and ears)	29681	2.11%
Endocrine System/Metabolism	34373	2.44%
Multisystemic	274443	19.48%
Ethology / Animal Behaviour /Animal Biology	90950	6.46%
Other basic research	78671	5.58%
Total	**1408901**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	84909	20.31%
Human Infectious Disorders	62048	14.84%
Human Cardiovascular Disorders	8285	1.98%
Human Nervous and Mental Disorders	55650	13.31%
Human Respiratory Disorders	9648	2.31%
Human Gastrointestinal Disorders including Liver	6115	1.46%
Human Musculoskeletal Disorders	2637	0.63%
Human Immune Disorders	19467	4.66%
Human Urogenital/Reproductive Disorders	3666	0.88%
Human Sensory Organ Disorders (skin, eyes and ears)	11059	2.65%
Human Endocrine/Metabolism Disorders	5416	1.3%
Other Human Disorders	84111	20.12%
Animal Diseases and Disorders	28285	6.77%
Animal Welfare	5283	1.26%
Diagnosis of diseases	3182	0.76%
Plant diseases	9	0%
Non-regulatory toxicology and ecotoxicology	28222	6.75%
Total	**417992**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	185742	33.4%
Other efficacy and tolerance testing	18374	3.3%
Toxicity and other safety testing including pharmacology	211600	38.05%
Routine production	140397	25.25%
Total	**556113**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	16803	9.05%
Pyrogenicity testing	2609	1.4%
Batch potency testing	154450	83.15%
Other quality controls	11880	6.4%
Total	**185742**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16115	7.62%
Skin irritation/corrosion	340	0.16%
Skin sensitisation	5304	2.51%
Eye irritation/corrosion	173	0.08%
Repeated dose toxicity	44153	20.87%
Carcinogenicity	15365	7.26%
Genotoxicity	5335	2.52%
Reproductive toxicity	26842	12.69%
Developmental toxicity	64814	30.63%
Neurotoxicity	395	0.19%
Kinetics	4792	2.26%
Pharmaco-dynamics (incl safety pharmacology)	4240	2%
Phototoxicity		
Ecotoxicity	12433	5.88%
Safety testing in food and feed area	681	0.32%
Target animal safety	7004	3.31%
Other toxicity/safety testing	3614	1.71%
Total	**211600**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	8898	55.22%
Other lethal methods	285	1.77%
Non lethal methods	6932	43.02%
Total	**16115**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	24189	54.78%
29 - 90 days	12736	28.85%
> 90 days	7228	16.37%
Total	**44153**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	4152	33.39%
Chronic toxicity	6816	54.82%
Reproductive ecotoxicity		
Endocrine activity	932	7.5%

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Bioaccumulation	265	2.13%
Other ecotoxicity	268	2.16%
Total	**12433**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	48690	34.68%
Monoclonal antibody by mouse ascites method		
Other product types	91707	65.32%
Total	**140397**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	269750	48.51%
Legislation on medicinal products for veterinary use and their residues	128586	23.12%
Medical devices legislation	8308	1.49%
Industrial chemicals legislation	75640	13.6%
Plant protection product legislation	22056	3.97%
Biocides legislation	1550	0.28%
Food legislation including food contact material	1934	0.35%
Feed legislation including legislation for the safety of target animals, workers and environment	5971	1.07%
Cosmetics legislation		
Other legislation	42318	7.61%
Total	**556113**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	536912	96.55%
Legislation satisfying national requirements only [within EU]	161	0.03%
Legislation satisfying Non-EU requirements only	19040	3.42%
Total	**556113**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	3098179	97.78%
Yes	70301	2.22%
Total	**3168480**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	125003	3.95%
Mild [up to and including]	2281252	72%
Moderate	576163	18.18%
Severe	186062	5.87%
Total	**3168480**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2861245	90.3%
Yes	307235	9.7%
Total	**3168480**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1485634	46.89%
Genetically altered without a harmful phenotype	1220639	38.52%
Genetically altered with a harmful phenotype	462207	14.59%
Total	**3168480**	**100.00%**

United Kingdom: Narrative 2016

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2016 data for Great Britain on the 13 July 2017 and the statistical release can be accessed online here: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2016.

The Northern Ireland Department for Health data is available here: https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures', whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold or mild severity, whereas all such procedures are combined into the "Mild [up to and including]" category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

1. General information on any changes in trends observed since the previous reporting period.

In 2016, a total of 2.79 million procedures were completed. This represents a decrease of 12% (378,000) compared with the 3.17 million procedures completed in 2015.

Of the 2.79 million procedures, 2.04 million (73%) were experimental procedures and 751,000 (27%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2015, experimental procedures have decreased by 3% (57,000) and creation/breeding procedures have decreased by 30% (321,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to occur because licensees are more accurately recording actual severity, rather than returning procedures according to the prospective severity category. As such, in 2016, a substantially greater proportion of breeding procedures prospectively accorded mild severity were returned as sub-threshold and therefore not included in this dataset.

There were 2.72 million animals used for the first time in completed procedures in 2016, representing a decrease of 12% (378,000) compared with 2015. This difference from the previous year may be explained, at least in part, by an improvement in the accuracy of recording the procedural severity. Licensees are increasingly correctly returning the actual severity suffered by the animal rather than the prospective severity of the procedure as described in their licence, as explained above. Other reasons why the number of animals has dropped sharply may also include an actual reduction in the number in experimental animals required and the reported improved efficiencies in the creation of new strains, in particular by the use of CRISPR/Cas9 technology.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 2.04 million experimental procedures completed in 2016, the majority involved the use of mice (60%), fish (14%), and rats (12%). Comparing with 2015, there were notable changes[8] to the number of procedures involving:

- mice, which decreased by 47,000 (-4%) to 1.23 million procedures in 2016;
- rats, which decreased by 19,000 (-7%) to 239,000 procedures in 2016;
- birds[9], which increased by 8,100 (6%) to 150,000 procedures in 2016;
- guinea pigs, which increased by 4,400 (20%) to 26,000 procedures in 2016;
- ferrets, which decreased by 150 (-24%) to 480 procedures in 2016;
- goats, which increased by 110 (104%) to 210 procedures in 2016.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (83%), fish (16%), and rats (1%). Comparing with 2015, there were notable changes[10] to the number of procedures involving:

- mice, which decreased by 309,000 (-33%) to 623,000 procedures in 2016;
- amphibians[11], which decreased by 6,200 (-83%) to 1,300 procedures in 2016;
- fish[12], which decreased by 5,300 (-4%) to 119,000 procedures in 2016;
- birds[13], which increased by 500 (83%) to 1,100 procedures in 2016;
- sheep, which increased by 160 (516%) to 190 procedures in 2016.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 2.04 million experimental procedures completed in 2016:

- 8% (155,000) were assessed as non-recovery, compared with 6% (123,000) in 2015;
- 58% (1.18 million) were assessed as (up to and including) mild, compared with 64% (1.34 million) in 2015;
- 29% (589,000) were assessed as moderate, compared with 24% (509,000) in 2015;
- 6% (115,000) were assessed as severe, compared with 6% (124,000) in 2015.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.2% (1,500) were assessed as non-recovery, compared with 0.2% (2,100) in 2015;
- 88% (659,000) were assessed as (up to and including) mild, compared with 88% (940,000) in 2015;
- 7% (51,000) were assessed as moderate, compared with 6% (67,000) in 2015;
- 5% (40,000) were assessed as severe, compared with 6% (62,000) in 2015).

---

[8] Covers the three largest numeric and the three largest percentage changes between 2015 and 2016.
[9] Specifically, domestic fowl and other bird species.
[10] Covers the three largest numeric and the three largest percentage changes between 2015 and 2016. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed.
[11] Specifically, Xenopus (Laevis and Tropicalis).
[12] Specifically, Zebrafish and other fish species.
[13] Specifically domestic fowl.

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as 'severe'. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2016 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research "other category" included:

- Embryology and molecular biology;
- Parasitology;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation.
- Some probable erroneous entries caused by confusion. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;

Applied research "other" category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial diseases;
- Haematology.

Regulatory use, routine production "other":

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);

- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose “other”:

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2016

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1852305	66.38%
Rats	244904	8.78%
Guinea-Pigs	26192	0.94%
Hamsters (Syrian)	1239	0.04%
Hamsters (Chinese)	230	0.01%
Mongolian gerbil	236	0.01%
Other Rodents	1521	0.05%
Rabbits	15568	0.56%
Cats	345	0.01%
Dogs	5005	0.18%
Ferrets	476	0.02%
Other carnivores	236	0.01%
Horses, donkeys and cross-breeds	8948	0.32%
Pigs	6361	0.23%
Goats	214	0.01%
Sheep	48596	1.74%
Cattle	4996	0.18%
Prosimians		
Marmoset and tamarins	197	0.01%
Cynomolgus monkey	3240	0.12%
Rhesus monkey	132	0%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	860	0.03%
Domestic fowl	139789	5.01%
Other birds	11543	0.41%
Reptiles		

Animal Species	Number of animals	Percentage
Rana	225	0.01%
Xenopus	10123	0.36%
Other Amphibians	893	0.03%
Zebra fish	308108	11.04%
Other Fish	97910	3.51%
Cephalopods		
Total	**2790392**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2593408	95.42%
Animals born in the EU but not at a registered breeder	108530	3.99%
Animals born in rest of Europe	4803	0.18%
Animals born in rest of world	11057	0.41%
Total	**2717798**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	263	10.78%
Animals born in rest of Europe		
Animals born in Asia	652	26.72%
Animals born in America		
Animals born in Africa	1525	62.5%
Animals born elsewhere		
Total	**2440**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1		
F2 or greater	701	28.73%
Self-sustaining colony	1739	71.27%
Total	**2440**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1350177	48.39%
Translational and applied research	354145	12.69%
Regulatory use and Routine production	539454	19.33%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	18800	0.67%
Preservation of species	1789	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1675	0.06%
Forensic enquiries	92	0%
Maintenance of colonies of established genetically altered animals, not used in other procedures	524260	18.79%
Total	**2790392**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	173650	12.86%
Cardiovascular Blood and Lymphatic System	89072	6.6%
Nervous System	271513	20.11%
Respiratory System	16937	1.25%
Gastrointestinal System including Liver	28417	2.1%
Musculoskeletal System	23767	1.76%
Immune System	243534	18.04%
Urogenital/Reproductive System	41652	3.08%
Sensory Organs (skin, eyes and ears)	31810	2.36%
Endocrine System/Metabolism	32237	2.39%
Multisystemic	181829	13.47%
Ethology / Animal Behaviour /Animal Biology	55479	4.11%
Other basic research	160280	11.87%
Total	**1350177**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	86416	24.4%
Human Infectious Disorders	86702	24.48%
Human Cardiovascular Disorders	6491	1.83%
Human Nervous and Mental Disorders	37303	10.53%
Human Respiratory Disorders	15171	4.28%
Human Gastrointestinal Disorders including Liver	6347	1.79%
Human Musculoskeletal Disorders	5447	1.54%
Human Immune Disorders	10463	2.95%
Human Urogenital/Reproductive Disorders	2464	0.7%
Human Sensory Organ Disorders (skin, eyes and ears)	9052	2.56%
Human Endocrine/Metabolism Disorders	6651	1.88%
Other Human Disorders	8292	2.34%
Animal Diseases and Disorders	29218	8.25%
Animal Welfare	2908	0.82%
Diagnosis of diseases	1434	0.4%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	39786	11.23%
Total	**354145**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	181199	33.59%
Other efficacy and tolerance testing	26707	4.95%
Toxicity and other safety testing including pharmacology	189460	35.12%
Routine production	142088	26.34%
Total	**539454**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	7239	4%
Pyrogenicity testing	2472	1.36%
Batch potency testing	145190	80.13%
Other quality controls	26298	14.51%
Total	**181199**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	18993	10.02%
Skin irritation/corrosion	266	0.14%
Skin sensitisation	4586	2.42%
Eye irritation/corrosion	128	0.07%
Repeated dose toxicity	43054	22.72%
Carcinogenicity	3742	1.98%
Genotoxicity	3746	1.98%
Reproductive toxicity	39078	20.63%
Developmental toxicity	44812	23.65%
Neurotoxicity	280	0.15%
Kinetics	4197	2.22%
Pharmaco-dynamics (incl safety pharmacology)	4472	2.36%
Phototoxicity		
Ecotoxicity	15038	7.94%
Safety testing in food and feed area	346	0.18%
Target animal safety	2265	1.2%
Other toxicity/safety testing	4457	2.35%
Total	**189460**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	11204	58.99%
Other lethal methods	326	1.72%
Non lethal methods	7463	39.29%
Total	**18993**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	20143	46.79%
29 - 90 days	14889	34.58%
> 90 days	8022	18.63%
Total	**43054**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3786	25.18%
Chronic toxicity	8066	53.64%
Reproductive ecotoxicity	2370	15.76%
Endocrine activity	389	2.59%
Bioaccumulation	427	2.84%
Other ecotoxicity		
Total	**15038**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	52732	37.11%
Monoclonal antibody by mouse ascites method		
Other product types	89356	62.89%
Total	**142088**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	250469	46.43%
Legislation on medicinal products for veterinary use and their residues	127249	23.59%
Medical devices legislation	9641	1.79%
Industrial chemicals legislation	71086	13.18%
Plant protection product legislation	17480	3.24%
Biocides legislation	3149	0.58%
Food legislation including food contact material	1904	0.35%
Feed legislation including legislation for the safety of target animals, workers and environment	12988	2.41%
Cosmetics legislation		
Other legislation	45488	8.43%
Total	**539454**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	517132	95.86%
Legislation satisfying national requirements only [within EU]	96	0.02%
Legislation satisfying Non-EU requirements only	22226	4.12%
Total	**539454**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2720238	97.49%
Yes	70154	2.51%
Total	**2790392**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	156086	5.59%
Mild [up to and including]	1839922	65.94%
Moderate	640064	22.94%
Severe	154320	5.53%
Total	**2790392**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2564079	91.89%
Yes	226313	8.11%
Total	**2790392**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1380447	49.47%
Genetically altered without a harmful phenotype	1041325	37.32%
Genetically altered with a harmful phenotype	368620	13.21%
Total	**2790392**	**100.00%**

United Kingdom: Narrative 2017

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2017 data for Great Britain on the 19 July 2018 and the statistical release can be accessed online here:
https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2017.

The Northern Ireland Department for Health (NIDH) published their 2017 data here:
https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure '[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures', whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold from those of mild severity, whereas all such procedures (i.e. all procedures other than PG43) are combined into the "Mild [up to and including]" category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

1. General information on any changes in trends observed since the previous reporting period.

In 2017, a total of 2.57 million procedures were completed. This represents a decrease of 8% (216,000) compared with the 2.79 million procedures completed in 2016.

Of the 2.57 million procedures, 1.91 million (74%) were experimental procedures and 669,000 (26%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2016, experimental procedures have decreased by 7% (134,000) and creation/breeding procedures have decreased by 11% (82,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to be due largely for two reasons: i) a decrease in the number of zebra fish bred but not used compared to 2016 and ii) more accurate recording of actual severity (a greater proportion of animals reported to be subthreshold instead of mild and hence omitted from the UK return).

There were 2.51 million animals used for the first time in completed procedures in 2017, representing a decrease of 8% (214,000) compared with 2016. The reason for this is not clear but appears to reflect a reduction in research activity across several sectors and is not confined to any particular purpose.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

Of the 1.91 million experimental procedures completed in 2017, the majority involved the use of mice (58%), fish (16%) and rats (12%). Comparing with 2016, there were notable changes[14] to the number of procedures involving:

- mice, which decreased by 124,000 (-10%) to 1.10 million procedures in 2017;
- birds[15], which decreased by 19,000 (-13%) to 131,000 procedures in 2017;
- Rana, which decreased by 120 (-52%) to 110 procedures in 2017.
- other rodents, which increased by 810 (+53%) to 2,300 procedures in 2017;
- cattle, which increased by 4,100 (+82%) to 9,100 procedures in 2017;
- fish[16], which increased by 22,000(+8%) to 309,000 procedures in 2017;

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (84%), fish (15%), and rats (0.5%). Comparing with 2016, there were notable changes[17] to the number of procedures involving:

- mice, which decreased by 63,000 (-10%) to 560,000 procedures in 2017;
- fish[18], which decreased by 16,000 (-13%) to 104,000 procedures in 2017;
- rats, which decreased by 2,400 (-45%) to 3,100 procedures in 2017;
- sheep, which decreased by 170 (-91%) to 20 procedures in 2017;
- pigs, which decreased by 120 (-49%) to 120 procedures in 2017;
- amphibians[19], which decreased by 620 (-49%) to 640 procedures in 2017;

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

Of the 1.91 million experimental procedures completed in 2017:

- 7% (135,000) were assessed as non-recovery, compared with 8% (155,000) in 2016;
- 61% (1.17 million) were assessed as (up to and including) mild, compared with 58% (1.18 million) in 2016;
- 26% (504,000) were assessed as moderate, compared with 29% (589,000) in 2016;
- 5% (95,000) were assessed as severe, compared with 6% (115,000) in 2016.

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures:

- 0.07% (470) were assessed as non-recovery, compared with 0.2% (1,500) in 2016;
- 85% (570,000) were assessed as (up to and including) mild, compared with 88% (658,000) in 2016;
- 8% (55,000) were assessed as moderate, compared with 7% (51,000) in 2016;
- 6% (43,000) were assessed as severe, compared with 5% (40,000) in 2016.

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

[14] Covers the three largest numeric and the three largest percentage changes between 2016 and 2017.
[15] Specifically, domestic fowl and other bird species.
[16] Specifically, Zebrafish and other fish species.
[17] Covers the three largest numeric and the three largest percentage changes between 2016 and 2017.
[18] Specifically, Zebrafish and other fish species.
[19] Specifically, Xenopus (Laevis and Tropicalis).

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as 'severe'. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2017 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

Basic research "other category" included:

- Embryology, cell and molecular biology;
- Genetics;
- Parasitology;
- Studies of infectious agents where it was the agent, rather than the disease, under investigation;
- Some probable erroneous entries eg. renal disease, caused by confusion as to which category to use. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future.

Applied research "other" category included:

- Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
- Mitochondrial diseases;
- Haematology;
- Wound healing;
- Pain disorders;
- Sleep.

Regulatory use, routine production "other":

- Antigens, infectious agents including parasites, oocytes, etc;
- Antibodies (but not by ascites method);

- Urine.

Regulatory use, quality control “other”:

- Method development, agent standardisation;
- Vaccine stability and testing of seed materials.
- Rodenticide evaluation (not field trials).

Regulatory use, legislative purpose “other”:

- Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, toxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species;
- Metabolism.

Regulatory Use: Other legislative requirements

- Mainly production to meet industry specifications.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

Not applicable.

United Kingdom: Statistical Data 2017

All uses of animals by species

Animal Species	Number of animals	Percentage
Mice	1665386	64.68%
Rats	237831	9.24%
Guinea-Pigs	22560	0.88%
Hamsters (Syrian)	1126	0.04%
Hamsters (Chinese)		
Mongolian gerbil	311	0.01%
Other Rodents	2327	0.09%
Rabbits	10444	0.41%
Cats	288	0.01%
Dogs	3949	0.15%
Ferrets	405	0.02%
Other carnivores	244	0.01%
Horses, donkeys and cross-breeds	10600	0.41%
Pigs	4742	0.18%
Goats	304	0.01%
Sheep	47946	1.86%
Cattle	9085	0.35%
Prosimians		
Marmoset and tamarins	166	0.01%
Cynomolgus monkey	2662	0.1%
Rhesus monkey	132	0.01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of non-human primates		
Other species of Old World Monkeys (Cercopithecoidea)		

Animal Species	Number of animals	Percentage
Other species of New World Monkeys (Ceboidea)		
Apes		
Other Mammals	804	0.03%
Domestic fowl	125670	4.88%
Other birds	6729	0.26%
Reptiles	92	0%
Rana	108	0%
Xenopus	8095	0.31%
Other Amphibians	533	0.02%
Zebra fish	320146	12.43%
Other Fish	92190	3.58%
Cephalopods		
Total	**2574875**	**100.00%**

Place of birth of animals other than non-human primates as registered at first use

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	2377256	94.92%
Animals born in the EU but not at a registered breeder	112655	4.5%
Animals born in rest of Europe	3240	0.13%
Animals born in rest of world	11315	0.45%
Total	**2504466**	**100.00%**

Source of non-human primates as registered at first use

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	253	11.42%
Animals born in rest of Europe		
Animals born in Asia	616	27.81%
Animals born in America		
Animals born in Africa	1346	60.77%
Animals born elsewhere		
Total	**2215**	**100.00%**

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F0		
F1	1	0.05%
F2 or greater	587	26.5%
Self-sustaining colony	1627	73.45%
Total	**2215**	**100.00%**

Purposes for which animals are used

Purpose Category	Number of uses	Percentage
Basic Research	1314541	51.05%
Translational and applied research	335968	13.05%
Regulatory use and Routine production	505504	19.63%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	11901	0.46%
Preservation of species	1925	0.07%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1235	0.05%
Forensic enquiries	88	0%

Purpose Category	Number of uses	Percentage
Maintenance of colonies of established genetically altered animals, not used in other procedures	403713	15.68%
Total	**2574875**	**100.00%**

Basic Research

Basic Research	Number of uses	Percentage
Oncology	176024	13.39%
Cardiovascular Blood and Lymphatic System	78397	5.96%
Nervous System	273172	20.78%
Respiratory System	11654	0.89%
Gastrointestinal System including Liver	26197	1.99%
Musculoskeletal System	28423	2.16%
Immune System	246232	18.73%
Urogenital/Reproductive System	34838	2.65%
Sensory Organs (skin, eyes and ears)	23477	1.79%
Endocrine System/Metabolism	29411	2.24%
Multisystemic	173366	13.19%
Ethology / Animal Behaviour /Animal Biology	67223	5.11%
Other basic research	146127	11.12%
Total	**1314541**	**100.00%**

Translational and applied research

Translational and applied research	Number of uses	Percentage
Human Cancer	90879	27.05%
Human Infectious Disorders	70203	20.9%
Human Cardiovascular Disorders	4374	1.3%
Human Nervous and Mental Disorders	42354	12.61%
Human Respiratory Disorders	12633	3.76%
Human Gastrointestinal Disorders including Liver	3943	1.17%
Human Musculoskeletal Disorders	6113	1.82%
Human Immune Disorders	7354	2.19%
Human Urogenital/Reproductive Disorders	3541	1.05%
Human Sensory Organ Disorders (skin, eyes and ears)	10854	3.23%
Human Endocrine/Metabolism Disorders	7815	2.33%
Other Human Disorders	10850	3.23%
Animal Diseases and Disorders	23507	7%
Animal Welfare	2843	0.85%
Diagnosis of diseases	3476	1.03%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	35229	10.49%
Total	**335968**	**100.00%**

Regulatory use and Routine production

Regulatory use and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	145113	28.71%
Other efficacy and tolerance testing	24606	4.87%
Toxicity and other safety testing including pharmacology	196061	38.79%
Routine production	139724	27.64%
Total	**505504**	**100.00%**

Regulatory use - Quality control (including batch safety and potency testing)

Regulatory use - Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	18401	12.68%
Pyrogenicity testing	1125	0.78%
Batch potency testing	114151	78.66%
Other quality controls	11436	7.88%
Total	**145113**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology

Regulatory use - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	16580	8.46%
Skin irritation/corrosion	112	0.06%
Skin sensitisation	2942	1.5%
Eye irritation/corrosion	63	0.03%
Repeated dose toxicity	40429	20.62%
Carcinogenicity	8067	4.11%
Genotoxicity	5314	2.71%
Reproductive toxicity	61241	31.24%
Developmental toxicity	34779	17.74%
Neurotoxicity	314	0.16%
Kinetics	3124	1.59%
Pharmaco-dynamics (incl safety pharmacology)	5309	2.71%
Phototoxicity		
Ecotoxicity	11444	5.84%
Safety testing in food and feed area	183	0.09%
Target animal safety	1360	0.69%
Other toxicity/safety testing	4800	2.45%
Total	**196061**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10622	64.07%
Other lethal methods	98	0.59%
Non lethal methods	5860	35.34%
Total	**16580**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	21572	53.36%
29 - 90 days	11727	29.01%
> 90 days	7130	17.64%
Total	**40429**	**100.00%**

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	3653	31.92%
Chronic toxicity	6320	55.23%
Reproductive ecotoxicity	514	4.49%
Endocrine activity	84	0.73%
Bioaccumulation	873	7.63%
Other ecotoxicity		
Total	**11444**	**100.00%**

Routine production

Routine production	Number of uses	Percentage
Blood based products	55197	39.5%
Monoclonal antibody by mouse ascites method		
Other product types	84527	60.5%
Total	**139724**	**100.00%**

Uses of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	208938	41.33%
Legislation on medicinal products for veterinary use and their residues	118458	23.43%
Medical devices legislation	7285	1.44%
Industrial chemicals legislation	86337	17.08%
Plant protection product legislation	18417	3.64%
Biocides legislation	292	0.06%
Food legislation including food contact material	1688	0.33%
Feed legislation including legislation for the safety of target animals, workers and environment	14831	2.93%
Cosmetics legislation		
Other legislation	49258	9.74%
Total	**505504**	**100.00%**

Legislative requirements

Legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	478397	94.64%
Legislation satisfying national requirements only [within EU]	1670	0.33%
Legislation satisfying Non-EU requirements only	25437	5.03%
Total	**505504**	**100.00%**

First uses and re-uses

Re-use	Number of uses	Percentage
No	2506681	97.35%
Yes	68194	2.65%
Total	**2574875**	**100.00%**

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	135780	5.27%
Mild [up to and including]	1741624	67.64%
Moderate	559401	21.73%
Severe	138070	5.36%
Total	**2574875**	**100.00%**

Use in creation of a new genetic line

Creation of new GL	Number of uses	Percentage
No	2309701	89.7%
Yes	265174	10.3%
Total	**2574875**	**100.00%**

Uses by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	1263597	49.07%
Genetically altered without a harmful phenotype	1102809	42.83%
Genetically altered with a harmful phenotype	208469	8.1%
Total	**2574875**	**100.00%**