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PART 2/2

COMMISSION STAFF WORKING DOCUMENT

Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2018

PART C:

MEMBER STATE DATA 2018

MEMBER STATE COMPARATIVE TABLES FOR 2018

MEMBER STATE DATA 2018

VI Member State narratives and data submissions 2018

VI.1. Introduction

Member States submitted 2018 statistical data to the Commission using the categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU. In addition, each Member State has provided a narrative for their data of 2018.

The submissions include data from all 28 Member States of the Union in 2018, and Norway.

The Member State data tables in the following pages are presented respecting the same three-way division as the Union report.

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

In some cases, the numbers referred to in the Member State narratives may differ from those shown in the respective Member State data tables. This is due to the fact that some Member States when having compiled the narratives, have not distinguished animals used directly in research and testing from those used for the creation and maintenance of genetically altered animals but instead used the combined total numbers.

In addition, it is important to know that some Member States may require additional data to be reported at national level; for example, statistics on the number of animals killed for organs and/or tissue. Therefore, national statistical publications sometimes differ from the data reported to the Commission. To ensure that the data is harmonised and comparable at Union level, only the data required by Commission Implementing Decision 2020/569/EU are submitted for publication in the Union report.

VI.2. Member State narratives and data submissions for 2018

Austria

Austria: Narrative 2018

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 2018 is 237.727 (2017: 264.071), which is a decrease of approx. 10 % or in absolute numbers 26.344 animals. In comparison with the previous two years an increase was observed in 2017, while in 2018 the number of animals used for scientific purpose declined almost to the level of 2016 (236.459 animals).

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 2018 is 28.441 (2017: 20.927). Zebra fish were mainly used for the purposes "Basic Research, Other" in particular cell and developmental biology and "Basic Research, Endocrine system/metabolism" and "Translational and applied research, Human Musculoskeletal Disorders". Other fish were mainly used for the purposes "Basic Research, Ethology/Animal Behaviour/ Animal Biology" and "Protection of the natural environment in the interests of the health or welfare of human beings or animals".

With regard to the categories of purposes, a decrease is observed in "Basic research, Nervous System" (from 16.591 to 11.678 animals used in 2018), "Regulatory use and routine production type, Quality control (incl batch safety and potency testing), Pyrogenicity testing" (from 9.125 to 1.923 rabbits in 2018) and "Maintenance of colonies of established genetically altered animals, not used in procedures" (from 29.361 to 12.045 animals in 2018). An increase is observed for "Basic research, Oncology" (from 25.406 to 28.696 animals in 2018) and „Translational and applied research, Human Cancer" (from 14.506 to 17.094 animals in 2018).

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 the common vole; "Other mammals" include i.a. wild boar and red deer, "Other birds" i.a. Columbidae, Anser anser, Corvus corax and Passer domesticus; "Other fish" include i.a. Alburnus alburnus, Chondrostoma nasus and Rutilus rutilus; "Other amphibian" include Ambystoma mexicanum and Staurois parvus.

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	161338	81.72%
Rats	3805	1.93%
Guinea-Pigs	484	0.25%
Hamsters (Syrian)	162	0.08%
Other rodents	842	0.43%
Rabbits	3111	1.58%
Cats	6	0%
Dogs	77	0.04%
Horses, donkeys and cross-breeds	13	0.01%
Pigs	1546	0.78%
Goats	42	0.02%
Sheep	42	0.02%
Cattle	467	0.24%
Other mammals	80	0.04%
Domestic fowl	2302	1.17%
Other birds	323	0.16%
Xenopus	448	0.23%
Other amphibians	1085	0.55%
Zebra fish	7370	3.73%
Other fish	13881	7.03%
Total	197424	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	146854	74.39%
Animals born in the EU but not at a registered breeder	17397	8.81%
Animals born in rest of Europe	30926	15.66%
Animals born in rest of world	2247	1.14%
Total	197424	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	161338	365	161703
Rats	3805		3805
Guinea-Pigs	484		484
Hamsters (Syrian)	162	16	178
Other rodents	842		842
Rabbits	3111	18	3129
Cats	6		6
Dogs	77	36	113
Horses, donkeys and cross-breeds	13	55	68
Pigs	1546	2	1548
Goats	42		42
Sheep	42	8	50
Cattle	467	28	495
Other mammals	80		80
Domestic fowl	2302		2302
Other birds	323		323
Xenopus	448	1	449
Other amphibians	1085		1085
Zebra fish	7370		7370
Other fish	13881		13881
Total	197424	529	197953

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	90949	45.94%
Translational and applied research	77341	39.07%
Regulatory use and Routine production	20787	10.5%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5925	2.99%
Preservation of species	62	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2889	1.46%
Total	197953	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	17556	19.3%
Cardiovascular Blood and Lymphatic System	6458	7.1%
Nervous System	11407	12.54%
Respiratory System	151	0.17%
Gastrointestinal System including Liver	2328	2.56%
Musculoskeletal System	4235	4.66%
Immune System	23307	25.63%
Urogenital/Reproductive System	719	0.79%
Sensory Organs (skin, eyes and ears)	1025	1.13%

Endocrine System/Metabolism	5515	6.06%
Multisystemic	4153	4.57%
Ethology / Animal Behaviour /Animal Biology	7489	8.23%
Other basic research	6606	7.26%
Total	90949	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	17094	22.1%
Human Infectious Disorders	42382	54.8%
Human Cardiovascular Disorders	2907	3.76%
Human Nervous and Mental Disorders	4550	5.88%
Human Respiratory Disorders	309	0.4%
Human Gastrointestinal Disorders including Liver	645	0.83%
Human Musculoskeletal Disorders	2059	2.66%
Human Immune Disorders	669	0.87%
Human Urogenital/Reproductive Disorders	18	0.02%
Human Sensory Organ Disorders (skin, eyes and ears)	280	0.36%
Human Endocrine/Metabolism Disorders	809	1.05%
Other Human Disorders	1696	2.19%
Animal Diseases and Disorders	3226	4.17%
Diagnosis of diseases	629	0.81%
Non-regulatory toxicology and ecotoxicology	68	0.09%
Total	77341	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	19712	94.83%
Toxicity and other safety testing including pharmacology	965	4.64%
Routine production	110	0.53%
Total	20787	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1074	5.45%
Pyrogenicity testing	1923	9.76%
Batch potency testing	16116	81.76%
Other quality controls	599	3.04%
Total	19712	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	87	9.02%
Neurotoxicity	36	3.73%
Target animal safety	842	87.25%
Total	965	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	45	51.72%
29 - 90 days	42	48.28%
Total	87	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19799	95.75%
Plant protection product legislation	842	4.07%
Other legislation	36	0.17%
Total	20677	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	17396	84.13%
Legislation satisfying Non-EU requirements only	3281	15.87%
Total	20677	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	110	100%
Total	110	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	197424	99.73%
Yes	529	0.27%
Total	197953	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	5082	2.57%
Mild [up to and including]	113870	57.52%
Moderate	61224	30.93%
Severe	17777	8.98%
Total	197953	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	132129	66.75%
Genetically altered without a harmful phenotype	50057	25.29%
Genetically altered with a harmful phenotype	15767	7.97%
Total	197953	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	20525		20525
Rabbits	14		14
Zebra fish	7064		7064
Other fish	126		126
Total	27729		27729

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	26032	93.88%
Moderate	1633	5.89%
Severe	64	0.23%
Total	27729	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	5587	20.15%
Genetically altered without a harmful phenotype	14383	51.87%
Genetically altered with a harmful phenotype	7759	27.98%
Total	27729	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	11140	40.17%
Cardiovascular Blood and Lymphatic System	1097	3.96%
Nervous System	271	0.98%
Gastrointestinal System including Liver	463	1.67%
Immune System	2397	8.64%
Endocrine System/Metabolism	1061	3.83%
Multisystemic	6533	23.56%
Other basic research	4767	17.19%
Total	27729	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	12045		12045
Total	12045		12045

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	11603	96.33%
Moderate	442	3.67%
Total	12045	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1472	12.22%
Genetically altered without a harmful phenotype	7815	64.88%
Genetically altered with a harmful phenotype	2758	22.9%
Total	12045	100.00%

Belgium

Belgium: Narrative 2018

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

Compared to 2017 (543,074 animals used), there is an increase of 2.43% in the number of animals used for scientific purposes in 2018 (556,271 animals used). The increase in 2018 is the result of an increased use of mice in maintenance of colonies of established genetically altered animals (not used in other procedures) and an increased use of other fish in preservation of species (mainly research on the impact of axial flow pumps on different species).

In 2018 it was noted by the European Commission that the percentage of Maintenance in Belgium was lower than the European average of 6%. This raised the question of whether this concept was understood correctly. Therefore, active contact was made with the institutions to explain the concept. Consequently, we see that this category shows a significant increase in 2018. 5.15% of the animal use now falls under Maintenance, which is more in line with the European average.

Number of use in 2016	Number of use in 2017	Number of use in 2018
534854	543074	556271

Since 2015, the numbers of re-used animals continues to decline. Compared to 2017 there is a decrease of 7.17% and even a decrease of 42.57% compared to the numbers of 2016.

Re-Use	Number of use in 2016	Number of use in 2017	Number of use in 2018
No	526723	538043	551601
Yes	8131	5031	4670
Total uses	**534854**	**543074**	**556271**

On the species grouping level, there are no significant changes.

Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
Mammals	441476	442398	454576
	30734	46812	45412

Birds			
Fish	62221	52462	54843
Amphibians	1226	1241	1116
Reptiles	172	181	324
Cephalopods	0	0	0
Total uses	**535829**	**543094**	**556271**

Within the mammals category we notice that the use of mice is slightly increasing throughout the years (increase of 3.84% compared to 2016 and 4.64% compared to 2017). The use of rabbits increased more rapidly with an increase of 28.18% compared to 2016 and an increase of 6.37% compared to 2017. The use of pigs is also rising with an increase of 49.56% since 2016 and an increase of 9.24% since 2017. The increase compared to the use in 2017 is the result of an increase in research in the domain of the Cardiovascular Blood and Lymphatic System. In recent decades, porcine (pig) models have become very popular for cardiovascular research. Their physiology, heart size, immune system and anatomy closely resemble that of humans and their coronaries have very little collateral circulation.

On the other hand a decrease was noted for rats and guinea-pigs. As you can see in the table below, the use of rats decreased by 34.06% since 2016 and by 16.04% since 2017. This change can be explained at least in part by a reduced use of rat studies (and increased use of mouse studies) in Alzheimer's research. The use of guinea-pigs decreased by 13.52% since 2016 and by 9.72% since 2017 due to a reduction of the use of this species in the Regulatory field.

Animal Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
Mice	336052	334054	348937
Rats	30337	23826	20003
Guinea-Pigs	16223	15541	14029
Rabbits	48036	57888	61575
Pigs	3630	4970	5429

In the birds category, there is an increase for domestic fowl compared to 2016 (49.46%) but a status quo compared to 2017. The other birds increased significantly compared to 2016 (37.86%) but decreased this year (13.01%).

Animal Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
	26230	39674	39203

Domestic fowl			
Other birds	4504	7138	6209

In the fish category, there is a decrease in the use of zebra fish compared to 2016 (30.47%) and compared to 2017 (8.9%). The decrease in the use of zebra fish compared to 2017 can partly be explained by the fact that a number of large projects requiring more laboratory animals ended in 2017.

The use of other fish however increased by 15.92% compared to 2016 (and by 20.45% compared to 2017). The increase in 2018 is, among other things, due to an increasing use of larvae of North Sea sole (research that was temporarily put on hold in 2017 and was restarted in 2018) and the use of fish in research on the impact of axial flow pumps.

Animal Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
Zebra fish	37256	28435	25904
Other Fish	24965	24027	28939

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

Between 2017 and 2018, basic research diminished by 7.73%. This was in particular due to decreases in the area of Immune System. Other important decreases were noted in the area of the Nervous System and other basic research. However, the research in the domain of the Cardiovascular Blood and Lymphatic System significantly increased (31.49%) between 2017 and 2018.

During the same time period Translational and applied research augmented by 3.74%. We noted a significant increase in the research on Human cancer (18,138 animal uses in 2018 compared to 12,720 in 2017) and in Animal Diseases and Disorders (22,693 animal uses in 2018 compared to 17,960 in 2017). A decrease was noted in Non-regulatory toxicology and ecotoxicology (10,308 animal uses in 2018 compared to 13,111 animals in 2017).

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

Within the actual severities classification we noted that the category "severe" decreased from 15.61% to 12.48%. The decrease in severity is mainly the result of a decrease in research in Oncology and Immune System. These types of research are more often classified as “severe” because of the induction of tumours leading to metastases, tumours that lead to cachexia, invasive bone tumours, ulcerating tumours, loss of immunity, etc.

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

No specific new initiatives in 2018. Continuation of the RE-Place project to create a database that brings together expertise on alternative methods for animal testing.

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

1. Other fish

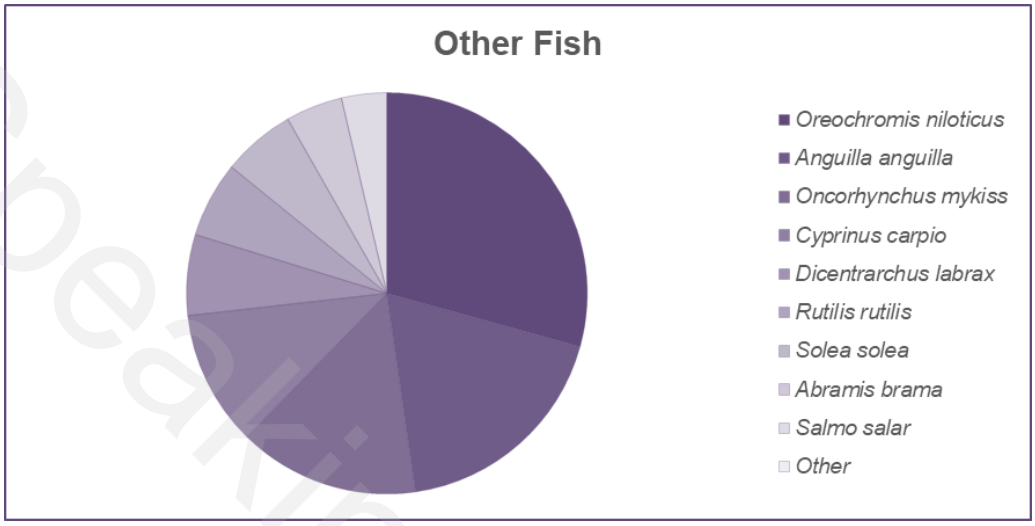
52,77% of the fishes are reported under the “other” category.

They are mostly Cichlidae (*Oreochromis niloticus* represents 26.46% of other fish), Anguillidae (*Anguilla anguilla* represents 16.62% of other fish), Salmonidae (*Salmo salar* and *Oncorhynchus mykiss* represent 16.50% of other fish), Cyprinidae (*Cyprinus carpio*, *Rutilis rutilis* and *Abramis brama* represent 19.54% of other fish), Moronidae (*Dicentrarchus labrax* represents 5.87% of other fish), Soleidae (*Solea solea* represents 5.34% of other fish).

Other Species	Number of uses
Oreochromis niloticus	7656
Anguilla anguilla	4811
Oncorhynchus mykiss	3820
Cyprinus carpio	2853
Dicentrarchus labrax	1700
Rutilis rutilis	1600
Solea solea	1544
Abramis brama	1200
Salmo salar	955
Nothobranchius furzeri	567
Gasterosteus aculeatus	547
Kryptolebias marmoratus	460
Poecilia reticulata	300
Lota lota	270
Pleuronectes platessa	131
Limanda limanda	104
Gadus morhua	65
Clarias gariepinus	50
Raja clavata	38
Ophthalmotilapia ventralis	28
Synodontis grandiops	26
Microsynodontis batesii	16
Pseudotropheus saulosi	14
Neogobius melanostomus	12
Ophthalmotilapia nasuta	11
Pygocentrus nattereri	9
Poecilia sphenops	8
Raja brachyura	8
Nimbochromis venustus	7

Parophidion vasali	7
Myleus schomburgkii	6
Synodontis eupterus	6
Alosa fallax	5
Carassius auratus	5
Catoprion mento	5
Metynnis hypsauchen	5
Piaractus brachypomus	5
Pygopristis denticulata	5
Gerochromis niloticus	4
Raja undulata	4
Synodontis njassae	4
Synodontis soloni	4
Botia morleti	3
Chromobotia macracanthus	3
Idotropheus sprengerae	3
Myloplus rubripinnis	3
Pantodon buchholzi	3
Pygocentrus cariba	3
Sahyadria denisonii	3
Serrasalmus maculatus	3
Serrasalmus spilopleura	3
Synodontis ilebrevis	3
Ancistrus dolichopterus	2
Botia modesta	2
Epalzeorhynchos bicolor	2
Helostoma temminkii	2
Iodotropheus sprengerae	2
Maylandia zebra	2
Pangasianodon hypophthalmus	2
Pangasius sp.	2
Pygocentrus piraya	2
Raja montagui	2
Serrasalmus elongatus	2
Synodontis sp.	2
Colossoma macropomum	1
Corydoras panda	1
Corydoras sp.	1
Hyphessobrycon sp.	1
Hypostomus plecostomus	1
Metynnis lippincottianus	1
Pterophyllum confer scalare	1
Puntigrus tetrazona	1
Serrasalmus manueli	1
Synodontis victoriae	1

Total uses:	**28939**

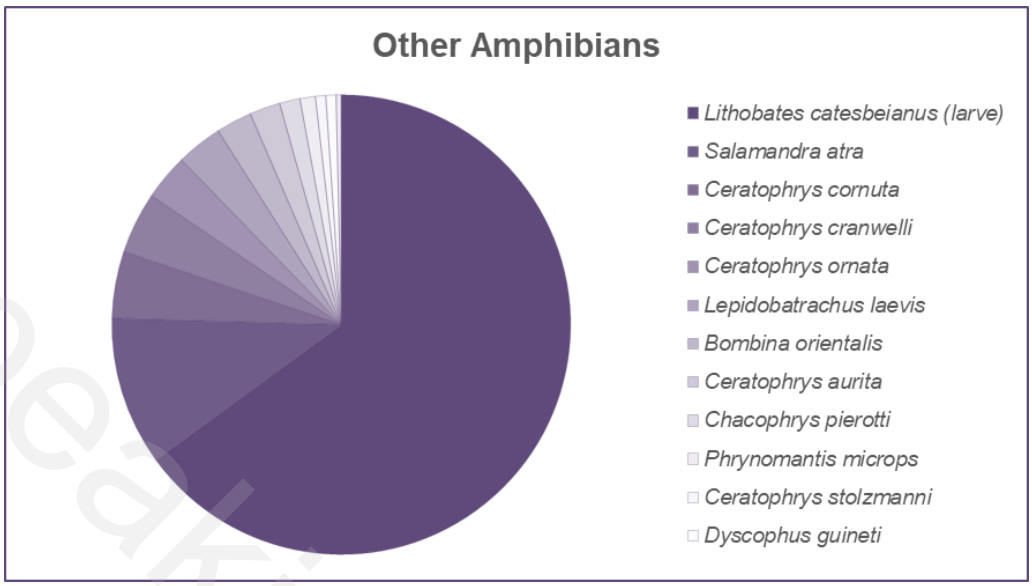


2. Other amphibians

24.82% of the amphibians are reported under the "other" category.

They are mostly Ranidae (*Lithobates catesbeianus larva*) (64.98% of other amphibians), Ceratophrydae (in order of importance: Ceratophrys cornuta, Ceratophrys cranwelli, Ceratophrys ornate, Lepidobatrachus laevis, Ceratophrys aurita and Ceratophrys stolzmanni) (18.41% of other amphibians) and Salamandridae (*Salamandra atra)* (10.47% of other amphibians).

Other Amphibians	Number of uses
Lithobates catesbeianus (larve)	180
Salamandra atra	29
Ceratophrys cornuta	13
Ceratophrys cranwelli	12
Ceratophrys ornata	9
Lepidobatrachus laevis	9
Bombina orientalis	7
Ceratophrys aurita	6
Chacophrys pierotti	4
Phrynomantis microps	3
Ceratophrys stolzmanni	2
Dyscophus guineti	2
Xenopus muelleri	1
Total uses:	**277**



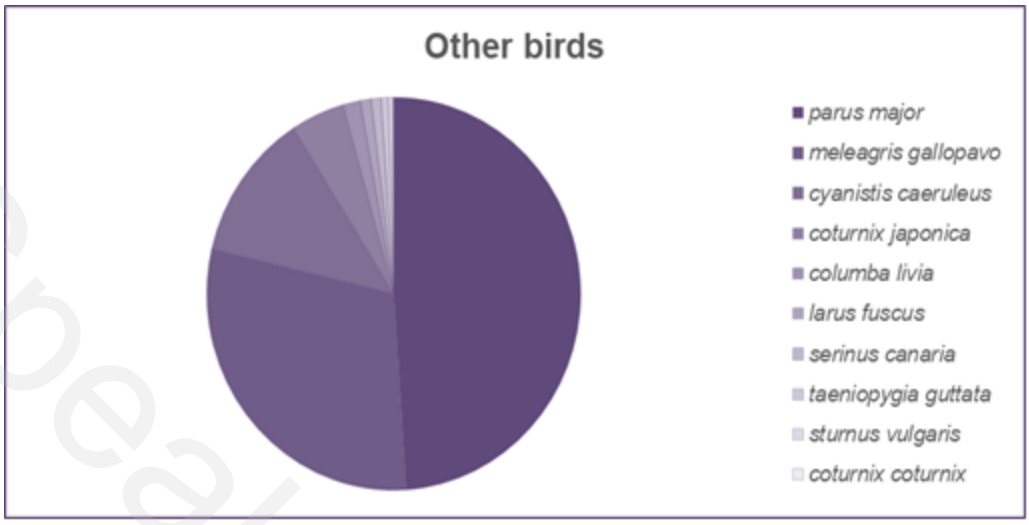
3. Other birds

13,67% of the birds are reported under the "other" category.

They are mostly Paridae (*Parus major and Cyanistis caeruleus*) (61,23% of other birds) and Phasianidae (*Meleagris gallopavo, Coturnix japonica, Coturnix coturnix*) (34.47% of other birds).

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

Other Birds	Number of uses
Parus major	3038
Meleagris gallopavo	1847
Cyanistis caeruleus	764
Coturnix japonica	287
Columba livia	94
Larus fuscus	58
Serinus canaria	53
Taeniopygia guttata	38
Sturnus vulgaris	24
Coturnix coturnix	6
Total uses:	**6209**



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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	290477	59.54%
Rats	18902	3.87%
Guinea-Pigs	14006	2.87%
Hamsters (Syrian)	772	0.16%
Mongolian gerbil	105	0.02%
Other rodents	55	0.01%
Rabbits	61504	12.61%
Cats	19	0%
Dogs	367	0.08%
Horses, donkeys and cross-breeds	233	0.05%
Pigs	5256	1.08%
Goats	58	0.01%
Sheep	520	0.11%
Cattle	680	0.14%
Cynomolgus monkey	2	0%
Rhesus monkey	5	0%
Other mammals	102	0.02%

Domestic fowl	39184	8.03%
Other birds	6163	1.26%
Reptiles	54	0.01%
Xenopus	810	0.17%
Other amphibians	12	0%
Zebra fish	20380	4.18%
Other fish	28177	5.78%
Total	487843	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	461068	94.51%
Animals born in the EU but not at a registered breeder	21797	4.47%
Animals born in rest of Europe	309	0.06%
Animals born in rest of world	4662	0.96%
Total	487836	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	5	71.43%
Animals born in Asia	2	28.57%
Total	7	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	7	100%
Total	7	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	290477	641	291118
Rats	18902	651	19553
Guinea-Pigs	14006	23	14029
Hamsters (Syrian)	772		772
Mongolian gerbil	105		105
Other rodents	55		55
Rabbits	61504	71	61575
Cats	19	15	34
Dogs	367	1317	1684
Horses, donkeys and cross-breeds	233	69	302
Pigs	5256	173	5429
Goats	58	1	59
Sheep	520	8	528
Cattle	680	170	850
Cynomolgus monkey	2		2
Rhesus monkey	5	36	41
Other mammals	102	69	171
Domestic fowl	39184	19	39203
Other birds	6163	46	6209
Reptiles	54	270	324
Xenopus	810	29	839
Other amphibians	12	265	277
Zebra fish	20380	1	20381
Other fish	28177	762	28939
Total	487843	4636	492479

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	216638	43.99%
Translational and applied research	121546	24.68%
Regulatory use and Routine production	140896	28.61%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	359	0.07%
Preservation of species	5598	1.14%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	7442	1.51%
Total	492479	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	48183	22.24%
Cardiovascular Blood and Lymphatic System	11858	5.47%
Nervous System	31995	14.77%
Respiratory System	4937	2.28%
Gastrointestinal System including Liver	16108	7.44%

Musculoskeletal System	7061	3.26%
Immune System	48884	22.56%
Urogenital/Reproductive System	4348	2.01%
Sensory Organs (skin, eyes and ears)	2719	1.26%
Endocrine System/Metabolism	9666	4.46%
Multisystemic	4518	2.09%
Ethology / Animal Behaviour /Animal Biology	14256	6.58%
Other basic research	12105	5.59%
Total	216638	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18138	14.92%
Human Infectious Disorders	15412	12.68%
Human Cardiovascular Disorders	1272	1.05%
Human Nervous and Mental Disorders	28971	23.84%
Human Respiratory Disorders	6783	5.58%
Human Gastrointestinal Disorders including Liver	1706	1.4%
Human Musculoskeletal Disorders	984	0.81%
Human Immune Disorders	2435	2%
Human Urogenital/Reproductive Disorders	815	0.67%
Human Sensory Organ Disorders (skin, eyes and ears)	5709	4.7%
Human Endocrine/Metabolism Disorders	1749	1.44%
Other Human Disorders	22	0.02%
Animal Diseases and Disorders	22678	18.66%
Animal Welfare	2323	1.91%
Diagnosis of diseases	5038	4.14%
Non-regulatory toxicology and ecotoxicology	7511	6.18%
Total	121546	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	61229	43.46%
Other efficacy and tolerance testing	18296	12.99%
Toxicity and other safety testing including pharmacology	4407	3.13%
Routine production	56964	40.43%
Total	140896	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	5225	8.53%
Batch potency testing	53362	87.15%
Other quality controls	2642	4.31%
Total	61229	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	821	18.63%
Repeated dose toxicity	850	19.29%
Genotoxicity	3	0.07%
Kinetics	486	11.03%
Ecotoxicity	1096	24.87%
Safety testing in food and feed area	971	22.03%

Target animal safety	180	4.08%
Total	4407	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	310	37.76%
Non lethal methods	511	62.24%
Total	821	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	730	85.88%
29 - 90 days	120	14.12%
Total	850	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1096	100%
Total	1096	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	55900	66.6%
Legislation on medicinal products for veterinary use and their residues	25087	29.89%
Medical devices legislation	1047	1.25%
Food legislation including food contact material	740	0.88%
Feed legislation including legislation for the safety of target animals, workers and environment	62	0.07%
Other legislation	1096	1.31%
Total	83932	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	69020	82.23%
Legislation satisfying national requirements only [within EU]	310	0.37%
Legislation satisfying Non-EU requirements only	14602	17.4%
Total	83932	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	56918	99.92%
Monoclonal antibody by mouse ascites method	11	0.02%
Other product types	35	0.06%
Total	56964	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	487843	99.06%

Yes	4636	0.94%
Total	492479	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	19391	3.94%
Mild [up to and including]	254533	51.68%
Moderate	149835	30.42%
Severe	68720	13.95%
Total	492479	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	387661	78.72%
Genetically altered without a harmful phenotype	89253	18.12%
Genetically altered with a harmful phenotype	15565	3.16%
Total	492479	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	29382	21	29403
Rats	239		239
Zebra fish	5523		5523
Total	35144	21	35165

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	1174	3.34%
Mild [up to and including]	28854	82.05%
Moderate	4485	12.75%
Severe	652	1.85%
Total	35165	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	5962	16.95%
Genetically altered without a harmful phenotype	24034	68.35%
Genetically altered with a harmful phenotype	5169	14.7%
Total	35165	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	7817	22.29%
Cardiovascular Blood and Lymphatic System	5843	16.66%
Nervous System	6648	18.96%
Gastrointestinal System including Liver	3718	10.6%
Musculoskeletal System	889	2.54%
Immune System	1902	5.42%
Urogenital/Reproductive System	882	2.52%
Sensory Organs (skin, eyes and ears)	377	1.08%
Endocrine System/Metabolism	5107	14.56%
Multisystemic	1838	5.24%
Other basic research	45	0.13%
Total	35066	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	60	60.61%
Human Urogenital/Reproductive Disorders	24	24.24%
Animal Diseases and Disorders	15	15.15%
Total	99	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	28403	13	28416
Rats	211		211
Total	28614	13	28627

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	28273	98.76%
Moderate	313	1.09%
Severe	41	0.14%
Total	28627	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	346	1.21%
Genetically altered without a harmful phenotype	26428	92.32%
Genetically altered with a harmful phenotype	1853	6.47%
Total	28627	100.00%

Bulgaria

Bulgaria: Narrative 2018

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

The total number of animals, used for 2018, compared to 2017 is reduced. The number of re-used animals is increased. The used animals are only animals born in the EU at register breeder. The number of used rodents is slightly increased, but the number of used rabbits and artiodactyla are reduced.

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 used for 2018 animals, compared to 2017 is reduced. In some cases, depending on the project type, the Ethic Commission made recommendations for reduction of the used animals. The project authorization is not given of projects, who do not consider with the recommendation. It was asked, some of the tests to be filmed.

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

The procedures with non-recovery severity are increased. The number of procedures with moderate or severe severity are decreased. The reason for minimizing the procedures with severe severity in 2018 is:

- a lot of procedures for the purpose of training students were filmed;
- existing scientific publications in connection with experiments conducted for the same purpose.

The reason for increasing the procedures with non-recovery severity is the following: Often, in one authorization project are combined several diagnostic procedures, related to diagnostic purposes or testing new pharmaceutical products for which there is no literature available regarding the subsequent impact on treated animals.

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

The number of re-used animals is increased. Often, the Ethic Commission made recommendations for reduction of the used animals.

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

No.

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.

Bulgaria : Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1176	16.78%
Rats	1861	26.55%
Guinea-Pigs	1800	25.68%
Rabbits	293	4.18%
Dogs	25	0.36%
Pigs	104	1.48%
Domestic fowl	60	0.86%
Rana	1420	20.26%
Other amphibians	270	3.85%
Total	7009	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	7009	100%
Total	7009	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1176		1176
Rats	1861	16	1877
Guinea-Pigs	1800	1	1801
Rabbits	293	132	425
Dogs	25		25
Pigs	104		104
Domestic fowl	60		60
Rana	1420		1420
Other amphibians	270		270
Total	7009	149	7158

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	2439	34.07%
Translational and applied research	97	1.36%
Regulatory use and Routine production	2955	41.28%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1667	23.29%
Total	7158	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	94	3.85%
Nervous System	1236	50.68%
Gastrointestinal System including Liver	9	0.37%
Musculoskeletal System	195	8%
Immune System	15	0.62%
Sensory Organs (skin, eyes and ears)	64	2.62%
Endocrine System/Metabolism	500	20.5%
Multisystemic	326	13.37%
Total	2439	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	30	30.93%
Human Respiratory Disorders	37	38.14%
Human Endocrine/Metabolism Disorders	30	30.93%
Total	97	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2782	94.15%
Toxicity and other safety testing including pharmacology	173	5.85%
Total	2955	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2650	95.26%
Pyrogenicity testing	132	4.74%
Total	2782	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin irritation/corrosion	30	17.34%
Repeated dose toxicity	60	34.68%
Pharmaco-dynamics (incl safety pharmacology)	73	42.2%
Ecotoxicity	10	5.78%
Total	173	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
> 90 days	60	100%
Total	60	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10	100%
Total	10	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2822	95.5%
Legislation on medicinal products for veterinary use and their residues	133	4.5%
Total	2955	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2955	100%
Total	2955	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	7009	97.92%
Yes	149	2.08%
Total	7158	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2881	40.25%
Mild [up to and including]	3849	53.77%
Moderate	428	5.98%
Total	7158	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	7158	100%
Total	7158	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Croatia

Croatia: Narrative 2018

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

Animal Species used for scientific procedures

Data for 2018, 2017 and 2016:

Animal Species	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Mice	18,295	70.87	19,806	69.41	14,976	68.38
Rats	6,885	26.67	7,700	26.99	5,762	26.31
Guinea Pigs	17	0.07	21	0.07	71	0.32
Rabbits	250	0.97	426	1,49	704	3.21
Horses, donkeys & cross-breeds	18	0.07	25	0.09	27	0.12
Pigs	20	0.08	2	0.01	2	0.01
Sheep	22	0.09	39	0.14	49	0.22
Cattle	-	-	30	0.11	50	0.23
Domestic fowl	275	1.07	255	0.89	260	1.19
Zebra fish	34	0.13	230	0.81	0	0
Summary	25,816	100	28,534	100	21,901	100

Compared to the data for 2016 and 2017, the data for 2018 shows:

- an overall decrease in the total number of animals used for scientific purposes and most in mice, rats, guinea pigs, rabbits, horses, sheep and zebra fish
- slightly increase in the number of domestic fowl and the increase of the number of pigs used for scientific purposes and
- totally decrease in the number of cattle used for scientific purposes.

Re-use vs first use

Data for 2018, 2017 and 2016:

Re-Use	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
No	25,769	99.82	28,431	99.64	21,790	99.49
Yes	47	0.18	103	0.36	111	0.51
Total uses	25,816	100	28,534	100	21,901	100

Compared to the data for 2016 and 2017, the data for 2018 shows there are no significant changes in the proportion of Re-use vs first use.

Genetically altered animals

Data for 2018, 2017 and 2016:

Genetic Status	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Not genetically altered	24,711	95.72	26,027	91.21	19,422	88.68
Genetically altered without a harmful phenotype	968	3.75	2,452	8.59	2,350	10.73
Genetically altered with a harmful phenotype	137	0.53	55	0.19	129	0.59
Summary	25,816	100	28,534	100	21,901	100

Compared to the data for 2016 and 2017, the data for 2018 shows:

- number of not genetically altered animals slightly decreased than in 2017
- there is overall decrease of the number of genetically altered animals without a harmful phenotype in the three years period
- number of genetically altered animals with a harmful phenotype is slightly higher than in 2016 and significantly higher than in 2017.

The proportion of animals used for scientific purposes within three types of genetically status did not change significantly during three years period.

Creation of New Genetically altered lines

Data for 2018, 2017 and 2016:

Creation of New GL	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
No	25,782	99.87	28,304	99.19	21,901	100
Yes	34	0.13	230	0.81	0	0
Summary	25,816	100	28,534	100	21,901	100

Compared to the data for 2017, the data for 2018 shows the decrease of number of animals used for creation of new genetically altered lines while in 2016 the new genetically altered lines was not reported.

Origins of animals

Data for 2018, 2017 and 2016:

Place of Birth	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Animals born in the	25,739	99.88	28,292	99.51	21,701	99.59

EU at a registered breeder						
Animals born in the EU but not at a registered breeder	30	0.12	60	0.21	89	0.41
Animals born in the rest of Europe	0	0	0	0	0	0
Animals born in the rest of world	0	0	79	0.28	0	0
Summary	25,769	100	28,431	100	21,790	100

Compared to the data for 2016 and 2017, the data for 2018 shows there are no significant changes regarding the place of birth of animals.

Legislative Requirement

Data for 2018, 2017 and 2016:

Legislative Requirement	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Legislation satisfying EU requirements	2,461	9.53	2,182	7.65	988	4.52
Legislation satisfying national requirements only (within EU)	0	0	0	0	0	0
Legislation satisfying Non-EU requirements only	0	0	0	0	0	0

Compared to the data for 2016 and 2017, the data for 2018 shows that there is a slightly increase of number of animals used for scientific purposes regarding the legislation satisfying EU requirements.

Primates have never been used for scientific purposes in Croatia.

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

Purpose Category

Data for 2018, 2017 and 2016:

Purpose Category	**2018**	**2017**	**2016**

	number	%	number	%	number	%
Basic Research	18,865	73.07	22,067	77.34	19,183	87.59
Translational and applied research	3,169	12.28	2,761	9.68	456	2.08
Regulatory use and Routine production	2,461	9.53	2,182	7.65	988	4.51
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,321	5.12	1,428	5.00	1,203	5.49
Maintenance of colonies of established genetically altered animals, not used in other procedures	0	0	96	0.34	71	0,32
Summary	25,816	100	28,534	100	21,901	100

Compared to the data for 2016 and 2017, the data for 2018 shows there is no significant changes regarding purpose category for which animals were used, except animals no more used for maintenance of colonies of established genetically altered animals, not used in other procedures.

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

Actual Severities

Data for 2018, 2017 and 2016:

Severity of procedures	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Non-recovery	1,250	4.84	3,005	10.53	3,220	14.70
Mild (up to and including)	7,693	29.80	8,338	29.22	6,857	31.31
Moderate	16,170	62.64	11,593	40.63	11,394	52.03
Severe	703	2.72	5,598	19.62	430	1.96
Total number	25,816	100	28,534	100	21,901	100

Compared to the data for 2016 and 2017, the data for 2018 shows an increase in number of animals used in moderate procedures and significant decrease in number of animals used in severe and non-recovery procedures.

There is a decrease in numbers of animals used in severe procedures because more attention during the planning and evaluation of the projects has been paid to the development and use of humane end points.

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

- 3rs CroLASA Congress: Laboratory Animals in Scientific Research, 25-26 October 2018, Zagreb, Croatia

- Workshop on the Severity Classification and Reporting under EU Directive 2010/63/EU, 26 October 2018, Zagreb, Croatia

- 3rs CroLASA Congress: Laboratory Animals in Scientific Research, Round table "Retrospective Assessment of the Project", 26 October 2018, Zagreb, Croatia

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

Purpose Category

Data for 2018, 2017 and 2016:

Purpose Category	**2018**		**2017**		**2016**	
	number	**%**	**number**	**%**	**number**	**%**
Regulatory use and routine production – Quality control (incl batch safety and potency testing) - Other quality controls	900	76.60	1,195	75.39	360	43.32

For regulatory use and routine production - Quality control (incl batch safety and potency testing) - Other quality controls in 2016, 2017 and 2018 tests performed have been required by EU Pharmacopeia and animals used in tests are mice.

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	18295	71.09%
Rats	6873	26.71%
Guinea-Pigs	12	0.05%
Rabbits	250	0.97%
Pigs	20	0.08%
Sheep	10	0.04%
Domestic fowl	275	1.07%
Total	25735	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	25705	99.88%
Animals born in the EU but not at a registered breeder	30	0.12%
Total	25735	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	18295		18295
Rats	6873	12	6885
Guinea-Pigs	12	5	17
Rabbits	250		250
Horses, donkeys and cross-breeds		18	18
Pigs	20		20
Sheep	10	12	22
Domestic fowl	275		275
Total	25735	47	25782

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	18865	73.17%
Translational and applied research	3135	12.16%
Regulatory use and Routine production	2461	9.55%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1321	5.12%
Total	25782	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	502	2.66%
Cardiovascular Blood and Lymphatic System	569	3.02%
Nervous System	1241	6.58%
Respiratory System	2975	15.77%
Gastrointestinal System including Liver	3512	18.62%
Musculoskeletal System	173	0.92%
Immune System	4740	25.13%
Urogenital/Reproductive System	568	3.01%
Sensory Organs (skin, eyes and ears)	946	5.01%
Endocrine System/Metabolism	636	3.37%
Multisystemic	2681	14.21%
Ethology / Animal Behaviour /Animal Biology	37	0.2%
Other basic research	285	1.51%
Total	18865	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	31	0.99%
Human Respiratory Disorders	2587	82.52%
Human Gastrointestinal Disorders including Liver	100	3.19%
Human Musculoskeletal Disorders	70	2.23%
Human Endocrine/Metabolism Disorders	220	7.02%
Other Human Disorders	120	3.83%
Diagnosis of diseases	7	0.22%

Total	3135	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1175	47.74%
Toxicity and other safety testing including pharmacology	1251	50.83%
Routine production	35	1.42%
Total	2461	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	275	23.4%
Other quality controls	900	76.6%
Total	1175	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	268	21.42%
Kinetics	983	78.58%
Total	1251	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	268	100%
Total	268	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2151	88.66%
Legislation on medicinal products for veterinary use and their residues	275	11.34%
Total	2426	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2426	100%
Total	2426	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	35	100%
Total	35	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	25735	99.82%
Yes	47	0.18%
Total	25782	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	1250	4.85%
Mild [up to and including]	7693	29.84%
Moderate	16136	62.59%
Severe	703	2.73%
Total	25782	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	24677	95.71%
Genetically altered without a harmful phenotype	968	3.75%
Genetically altered with a harmful phenotype	137	0.53%
Total	25782	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Zebra fish	34		34
Total	34		34

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Moderate	34	100%
Total	34	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	34	100%
Total	34	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Non-regulatory toxicology and ecotoxicology	34	100%
Total	34	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Cyprus

Cyprus: Narrative 2018

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

In 2018, the number of the projects and the animals used, increased. Specifically, in 2017, were running 8 projects and during 2018, 15 projects, that means an increase of 87.5%.

Also, in a project, 100 animals were classified in “severe” procedures, which means an increase of 5.32% in this category of procedures.

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

During 2018, there was a significant increase in the number of animals participating in several projects, due to the increase of the number of projects. Specifically, the number of animals used, increased by 35,58%.

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

100 animals were classified in “severe” procedures, due to the fact that in 2018, a project was authorized to involve severe procedures.

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

The National Committee for Welfare of Animals used for Scientific Purposes, ensures the 3Rs implementation at the Project evaluation during the procedure for licencing.

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

There were no significant proportion of animals used 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.

There were no such cases for the year 2018.

Cyprus: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1461	100%
Total	1461	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1461	100%
Total	1461	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1461	349	1810
Total	1461	349	1810

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1432	79.12%
Translational and applied research	378	20.88%
Total	1810	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	267	18.65%
Nervous System	435	30.38%
Musculoskeletal System	298	20.81%
Urogenital/Reproductive System	54	3.77%
Multisystemic	228	15.92%
Other basic research	150	10.47%
Total	1432	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	200	52.91%
Human Gastrointestinal Disorders including Liver	120	31.75%
Animal Diseases and Disorders	58	15.34%
Total	378	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1461	80.72%
Yes	349	19.28%
Total	1810	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	102	5.64%
Mild [up to and including]	1560	86.19%
Moderate	48	2.65%
Severe	100	5.52%
Total	1810	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	978	54.03%
Genetically altered without a harmful phenotype	805	44.48%
Genetically altered with a harmful phenotype	27	1.49%
Total	1810	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	68		68
Total	68		68

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	68	100%
Total	68	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	68	100%
Total	68	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Nervous System	68	100%
Total	68	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Czechia

Czechia: Narrative 2018

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. Also in year 2018 continue trend increasing number of animal used for preservation of species since 2015.
In 2018 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. We expect increase in use animals in few years, especially in regulatory testing, because of development of facilities.

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 2018 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 2018 statistical data.

Czechia: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	67527	31.19%
Rats	21270	9.82%
Guinea-Pigs	1188	0.55%
Hamsters (Syrian)	24	0.01%
Mongolian gerbil	49	0.02%
Other rodents	717	0.33%
Rabbits	2555	1.18%
Cats	78	0.04%
Dogs	425	0.2%
Ferrets	80	0.04%
Other carnivores	38	0.02%
Horses, donkeys and cross-breeds	201	0.09%
Pigs	1719	0.79%
Goats	24	0.01%
Sheep	499	0.23%
Cattle	1565	0.72%
Other mammals	130	0.06%
Domestic fowl	20333	9.39%
Other birds	1364	0.63%
Reptiles	263	0.12%
Xenopus	20	0.01%
Zebra fish	7215	3.33%
Other fish	89251	41.22%
Total	216535	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	202608	93.57%
Animals born in the EU but not at a registered breeder	13371	6.17%
Animals born in rest of Europe	148	0.07%
Animals born in rest of world	408	0.19%
Total	216535	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	67527	1461	68988
Rats	21270	206	21476
Guinea-Pigs	1188		1188
Hamsters (Syrian)	24		24
Mongolian gerbil	49		49
Other rodents	717		717
Rabbits	2555	59	2614
Cats	78		78
Dogs	425	325	750
Ferrets	80		80
Other carnivores	38		38
Horses, donkeys and cross-breeds	201	16	217
Pigs	1719	575	2294
Goats	24	4	28
Sheep	499	386	885
Cattle	1565	1321	2886
Other mammals	130	7	137
Domestic fowl	20333	57	20390
Other birds	1364	26	1390
Reptiles	263		263
Xenopus	20		20
Zebra fish	7215		7215
Other fish	89251	467	89718
Total	216535	4910	221445

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	71821	32.43%
Translational and applied research	22655	10.23%
Regulatory use and Routine production	56482	25.51%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	55110	24.89%
Preservation of species	7517	3.39%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	7860	3.55%
Total	221445	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6946	9.67%
Cardiovascular Blood and Lymphatic System	8926	12.43%
Nervous System	10908	15.19%
Respiratory System	322	0.45%
Gastrointestinal System including Liver	2326	3.24%
Musculoskeletal System	87	0.12%

Immune System	11389	15.86%
Urogenital/Reproductive System	7254	10.1%
Sensory Organs (skin, eyes and ears)	146	0.2%
Endocrine System/Metabolism	4137	5.76%
Multisystemic	2658	3.7%
Ethology / Animal Behaviour /Animal Biology	2827	3.94%
Other basic research	13895	19.35%
Total	71821	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	4877	21.53%
Human Infectious Disorders	2398	10.58%
Human Cardiovascular Disorders	2026	8.94%
Human Nervous and Mental Disorders	717	3.16%
Human Gastrointestinal Disorders including Liver	350	1.54%
Human Musculoskeletal Disorders	60	0.26%
Human Immune Disorders	97	0.43%
Human Urogenital/Reproductive Disorders	283	1.25%
Human Sensory Organ Disorders (skin, eyes and ears)	193	0.85%
Human Endocrine/Metabolism Disorders	1840	8.12%
Other Human Disorders	141	0.62%
Animal Diseases and Disorders	3404	15.03%
Animal Welfare	1285	5.67%
Diagnosis of diseases	4936	21.79%
Non-regulatory toxicology and ecotoxicology	48	0.21%
Total	22655	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	10551	18.68%
Other efficacy and tolerance testing	682	1.21%
Toxicity and other safety testing including pharmacology	28512	50.48%
Routine production	16737	29.63%
Total	56482	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	682	6.46%
Pyrogenicity testing	53	0.5%
Batch potency testing	9684	91.78%
Other quality controls	132	1.25%
Total	10551	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	2141	7.51%
Skin irritation/corrosion	8	0.03%
Skin sensitisation	444	1.56%
Eye irritation/corrosion	6	0.02%
Repeated dose toxicity	814	2.85%
Reproductive toxicity	52	0.18%
Developmental toxicity	458	1.61%

Kinetics	142	0.5%
Ecotoxicity	23990	84.14%
Safety testing in food and feed area	80	0.28%
Target animal safety	48	0.17%
Other toxicity/safety testing	329	1.15%
Total	28512	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	651	30.41%
Other lethal methods	44	2.06%
Non lethal methods	1446	67.54%
Total	2141	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	94	11.55%
29 - 90 days	332	40.79%
> 90 days	388	47.67%
Total	814	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	22440	93.54%
Other ecotoxicity	1550	6.46%
Total	23990	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	2443	6.15%
Legislation on medicinal products for veterinary use and their residues	11212	28.21%
Medical devices legislation	637	1.6%
Industrial chemicals legislation	982	2.47%
Feed legislation including legislation for the safety of target animals, workers and environment	64	0.16%
Other legislation	24407	61.41%
Total	39745	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	22767	57.28%
Legislation satisfying national requirements only [within EU]	16978	42.72%
Total	39745	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	775	4.63%
Monoclonal antibody by mouse ascites method	93	0.56%
Other product types	15869	94.81%

Total	16737	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	216535	97.78%
Yes	4910	2.22%
Total	221445	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	12214	5.52%
Mild [up to and including]	80680	36.43%
Moderate	105495	47.64%
Severe	23056	10.41%
Total	221445	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	190772	86.15%
Genetically altered without a harmful phenotype	26635	12.03%
Genetically altered with a harmful phenotype	4038	1.82%
Total	221445	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	9464		9464
Rats	141		141
Hamsters (Syrian)	89		89
Domestic fowl	100		100
Total	9794		9794

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	6418	65.53%
Mild [up to and including]	628	6.41%
Moderate	2748	28.06%
Total	9794	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	144	1.47%
Genetically altered without a harmful phenotype	9587	97.89%
Genetically altered with a harmful phenotype	63	0.64%
Total	9794	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	111	1.15%
Nervous System	641	6.65%
Immune System	2587	26.84%
Urogenital/Reproductive System	5932	61.54%
Other basic research	369	3.83%
Total	9640	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	100	64.94%
Animal Welfare	54	35.06%
Total	154	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	626		626
Total	626		626

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	626	100%
Total	626	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	626	100%
Total	626	100.00%

Denmark

Denmark: Narrative 2018

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

In 2018, the overall number of animals used for experimental procedures in Denmark was 249,747. The number is slightly higher than in 2017, where the total number of animals was 235,512 resulting in a 6 % increase. The increase can be explained by a rise in the use of mainly mice but also in mink and domestic fowl compared to 2017.

The majority of experimental procedures used mice (70 %), rats (15 %) and fish (6 %) and together these species were used in approx. 91 % of all experimental procedures in 2018. A high percentage of experimental procedures involving mice and rats are Oncology and Immune system (basic research purposes) and Human Endocrine / Metabolism Disorders and Human Nervous and Mental Disorders (translational and applied research purposes). Fish are mostly used for experimental procedures involving Ethology / Animal behavior / Animal biology (basic research purpose) and animal diseases and disorders (translational and applied research purpose).

The overall distribution in purposes of procedures for all animal species are 41 % Basic research, 46 % Translational and applied research and 10 % Regulatory testing for 2018.

The severity assessment for 2018 shows that 61 % of experimental procedures in animals were mild and 32 % were moderate. Only 1 % of the animals used for experimental procedures experienced severe suffering in 2018 and this confirms the trend from the previous years.

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

The number of mice and rats has remained stable for several years. In 2018 the number of mice is slightly higher (175.708 mice) compared to 2017 (163.281 mice) resulting in roughly 8 % increase, but there is no obvious reason. A rising use of GA animals could affect the number of mice, but the use of GA animals has not changed significantly from 2017 to 2018. The explanation could therefore be that in a small country like Denmark, a strengthened focus from a few research groups can have a large impact on the statistics.

The use of 3.077 mink in 2018 is remarkably high, as the number in 2017 was only 935 animals. This is due to two research groups, where one is new, both studying animal welfare and animal behavior in mink for farming. The research focus is especially on nutrition/metabolism and weaning of cups and the vast majority of these experiments are within mild severity.

Finally, there has been an increase in the use of domestic fowls from 402 animals in 2017 to 2.283 animals in 2018. A large public interest has caused an increased research effort on animal welfare for domestic fowls used in farming with special focus on combatting infectious diseases and pathology.

In recent years, Denmark is experiencing an increased public interest in animal welfare in farm animals. Therefore, the need for research within this area will probably continue the following years.

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

There has been an increase in the percentage of mild severity from 53 % in 2017 to 61 % in 2018 and a small drop in the percentage of moderate severity from 36 % in 2017 to 32 % in 2018. There is no apparent explanation for this change, but the Danish competent authority will follow the numbers closely in order to identify any lasting changes.

The number of animals experiencing severe severity has increased from 0.74 % in 2017 to 1.14 % in 2018. Compared to the number from 2016, which was 1.57%, the numbers are relatively stable and consistently low. As Denmark generally has few animals experiencing severe severity, a changed focus from just one or two research groups can affect the statistical outcome in one way or the other.

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

The Danish National Committee supports the animal welfare bodies by hosting a yearly meeting, providing platforms for charring best practice and dissemination of guidelines.

The National Committee has also initiated a survey to optimize the use of animals for the purpose of higher education and training in relation to the 3R's. In Denmark, 2 % of all animals used for scientific research purposes fall into this category.

The Danish 3R-center is still working hard to promote the 3R's and one way is by funding research. Another event is the 3R-centers annual symposium, which is open to all interested. In 2018, some of the key topics were improving reproducibility and translatability, animal free methods and unconscious bias in scientific research. Further information is available on www.3rcenter.dk.

The Danish Animal Experiments Inspectorate hosts three annual mini-seminars for both scientific staff and animal caretakers. The seminars are a good forum for discussing best practice and new models, as well as disseminating 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

On three cases the use of the category 'Other' is relatively high in Denmark – this concerns 'other carnivores', 'other fish' and 'other birds'.

Denmark has a large proportion of commercial aquaculture and fur production. Therefore, the distribution of carnivores and fish in the category 'other' is very high. The number of 'other fish' (82 %) is due to a large research focus on farming especially rainbow trout, seabass, cod and salmon. The number of 'other carnivores' (90 %) is due to a large research focus on improving animal welfare for farming mink.

Research involving “other birds” are primarily field studies on i.e. common eider, common redstart and willow warbler with focus on population research and spread of diseases studies.

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.

Denmark has no cases where the ‘severe’ classification was exceeded in 2018.

Denmark: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	172248	70.12%
Rats	36360	14.8%
Guinea-Pigs	2659	1.08%
Hamsters (Syrian)	292	0.12%
Other rodents	13	0.01%
Rabbits	3116	1.27%
Cats	3	0%
Dogs	357	0.15%
Other carnivores	3077	1.25%
Horses, donkeys and cross-breeds	178	0.07%
Pigs	6977	2.84%
Goats	13	0.01%
Sheep	75	0.03%
Cattle	1997	0.81%
Other mammals	28	0.01%
Domestic fowl	2283	0.93%
Other birds	559	0.23%
Reptiles	155	0.06%
Rana	809	0.33%
Xenopus	429	0.17%
Other amphibians	94	0.04%
Zebra fish	2028	0.83%
Other fish	11888	4.84%
Total	245638	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	212734	86.6%
Animals born in the EU but not at a registered breeder	23373	9.52%
Animals born in rest of Europe	2866	1.17%
Animals born in rest of world	6665	2.71%
Total	245638	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	172248	2263	174511
Rats	36360	920	37280
Guinea-Pigs	2659		2659
Hamsters (Syrian)	292		292
Other rodents	13		13
Rabbits	3116		3116
Cats	3		3
Dogs	357	13	370
Other carnivores	3077	270	3347
Horses, donkeys and cross-breeds	178	3	181
Pigs	6977	666	7643
Goats	13		13
Sheep	75	3	78
Cattle	1997	2	1999
Other mammals	28	1	29
Domestic fowl	2283		2283
Other birds	559		559
Reptiles	155		155
Rana	809		809
Xenopus	429	960	1389
Other amphibians	94		94
Zebra fish	2028		2028
Other fish	11888		11888
Total	245638	5101	250739

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	101815	40.61%
Translational and applied research	117026	46.67%
Regulatory use and Routine production	24225	9.66%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1598	0.64%
Preservation of species	943	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5132	2.05%
Total	250739	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	22009	21.62%
Cardiovascular Blood and Lymphatic System	5251	5.16%
Nervous System	15611	15.33%
Respiratory System	2608	2.56%
Gastrointestinal System including Liver	3676	3.61%
Musculoskeletal System	2935	2.88%

Immune System	25598	25.14%
Urogenital/Reproductive System	1119	1.1%
Sensory Organs (skin, eyes and ears)	401	0.39%
Endocrine System/Metabolism	11364	11.16%
Multisystemic	215	0.21%
Ethology / Animal Behaviour /Animal Biology	6370	6.26%
Other basic research	4658	4.57%
Total	101815	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	8285	7.08%
Human Infectious Disorders	7899	6.75%
Human Cardiovascular Disorders	4200	3.59%
Human Nervous and Mental Disorders	27344	23.37%
Human Respiratory Disorders	48	0.04%
Human Gastrointestinal Disorders including Liver	303	0.26%
Human Musculoskeletal Disorders	398	0.34%
Human Immune Disorders	2678	2.29%
Human Urogenital/Reproductive Disorders	904	0.77%
Human Sensory Organ Disorders (skin, eyes and ears)	126	0.11%
Human Endocrine/Metabolism Disorders	44717	38.21%
Other Human Disorders	6537	5.59%
Animal Diseases and Disorders	9314	7.96%
Animal Welfare	2516	2.15%
Diagnosis of diseases	1231	1.05%
Non-regulatory toxicology and ecotoxicology	526	0.45%
Total	117026	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	18545	76.55%
Other efficacy and tolerance testing	619	2.56%
Toxicity and other safety testing including pharmacology	4275	17.65%
Routine production	786	3.24%
Total	24225	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	3484	18.79%
Batch potency testing	15061	81.21%
Total	18545	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	160	3.74%
Skin irritation/corrosion	16	0.37%
Skin sensitisation	118	2.76%
Repeated dose toxicity	2292	53.61%
Reproductive toxicity	480	11.23%
Kinetics	361	8.44%
Pharmaco-dynamics (incl safety pharmacology)	687	16.07%
Ecotoxicity	154	3.6%

Other toxicity/safety testing	7	0.16%
Total	4275	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	160	100%
Total	160	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	1174	51.22%
29 - 90 days	895	39.05%
> 90 days	223	9.73%
Total	2292	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	154	100%
Total	154	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	22525	96.1%
Industrial chemicals legislation	634	2.7%
Other legislation	280	1.19%
Total	23439	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23439	100%
Total	23439	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	786	100%
Total	786	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	245638	97.97%
Yes	5101	2.03%
Total	250739	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	14016	5.59%
Mild [up to and including]	151794	60.54%
Moderate	82027	32.71%
Severe	2902	1.16%

Total	250739	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	212489	84.75%
Genetically altered without a harmful phenotype	28009	11.17%
Genetically altered with a harmful phenotype	10241	4.08%
Total	250739	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	3281		3281
Zebra fish	649		649
Total	3930		3930

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	109	2.77%
Mild [up to and including]	3787	96.36%
Moderate	31	0.79%
Severe	3	0.08%
Total	3930	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1947	49.54%
Genetically altered without a harmful phenotype	1982	50.43%
Genetically altered with a harmful phenotype	1	0.03%
Total	3930	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	1	0.03%
Nervous System	415	10.81%
Gastrointestinal System including Liver	6	0.16%
Urogenital/Reproductive System	119	3.1%
Endocrine System/Metabolism	150	3.91%
Multisystemic	358	9.32%
Other basic research	2791	72.68%
Total	3840	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Musculoskeletal Disorders	60	66.67%
Human Endocrine/Metabolism Disorders	30	33.33%
Total	90	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	179		179
Total	179		179

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	2	1.12%
Moderate	173	96.65%
Severe	4	2.23%
Total	179	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	179	100%
Total	179	100.00%

Estonia

Estonia: Narrative 2018

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

There were less project applications submitted and consequently authorisations granted in 2018 comparing to previous years. The number of animals used has been decreasing year after year with now a minor decline of 4,64% from 3146 animals used in 2017 to 3000 in 2018. Use of GA animals increased from 38% in 2017 to 48% in 2018. Of those animals 0.5% had a harmful phenotype (none in 2017). While for creation of new GL 2,8% of animals were used in 2017, no animals were used for that purpose in 2018. Mice were still the most commonly used species, however their use dropped 23,35% from 2578 animals in 2017 to 1976 animals in 2018. Also, use of rats declined by almost 1/5 in 2018. There was an increase in the use of cattle, fish and rabbits. In 2017 and 2018 all animals used were born in the EU. In 2017 94,28% of all animals used were born at a registered breeder and in 2018 it had dropped to 83,9%. No re-use occurred neither in 2017 nor 2018.

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

The most significant change in use of animals occurred in the maintenance of GA colonies, where uses increased from 12,5% in 2017 to 21,4% of all uses in 2018 since laboratories are using more GA lines. The most uses overall still occurred in basic research which accounted for 76% of all uses in 2017 and 72,1% in 2018 with numbers of animals 2392 and 2165 respectively. The numbers dropped slightly due to fewer active projects during the reporting year. In 2017 oncology was the area of basic research with the highest numbers of animals used (41% of animals used for basic research and ~1/3 of all uses) but in 2018 it was Ethology/Animal Behaviour/Animal Biology (22,3% of animals used in basic research and 16,1% of all uses). This change was due to more projects being authorised for research of wildlife populations. In 2017 3,56% of all uses were for regulatory use, none in 2018. The decrease in use of animals was insignificant, ranging from 1,6% to 0,1% in 2018 compared to 2017 in translational and applied research and education and training.

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

Of all uses in 2017 44,02% were classified as mild, 43,04% moderate, 8,74% severe and 4,2% non-recovery. In 2018 the proportions were 29,87% mild, 48,27% moderate, 5,83% severe and 16,03% non-recovery. The rise in non-recovery in 2018 was due to the increased use of animals in cardiovascular system research.

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 along with their compliance to the 3Rs. The members of our PAC include experts in mathematical statistics, pharmacology and welfare

of experimental animals who along with other members of the committee help make sure that use of 3Rs has been considered and applied.

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

The proportion of animals classified as “other” was 16,1% of all animals used in 2018. 72 birds were classified as “other” and accounted for 2,4% of all animals used. Of those 42 were great tits (*Parus major*) and 30 were common gulls (*Larus canus*). “Other” fish accounted for 13,7% of all animals used in 2018. All 411 fish categorised as “other” were northern pike (*Esox lucius*).

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 haven’t been any cases where severity has exceeded the “severe” classification. Also, no projects exceeding severe classification have been authorised.

Estonia: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1333	56.55%
Rats	295	12.52%
Rabbits	12	0.51%
Pigs	4	0.17%
Cattle	163	6.92%
Domestic fowl	67	2.84%
Other birds	72	3.05%
Other fish	411	17.44%
Total	2357	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1874	79.51%
Animals born in the EU but not at a registered breeder	483	20.49%
Total	2357	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1333		1333
Rats	295		295
Rabbits	12		12
Pigs	4		4
Cattle	163		163
Domestic fowl	67		67
Other birds	72		72
Other fish	411		411
Total	2357		2357

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	2165	91.85%
Translational and applied research	154	6.53%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	38	1.61%
Total	2357	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	373	17.23%
Cardiovascular Blood and Lymphatic System	359	16.58%
Nervous System	361	16.67%
Gastrointestinal System including Liver	36	1.66%
Musculoskeletal System	32	1.48%
Immune System	154	7.11%
Sensory Organs (skin, eyes and ears)	72	3.33%
Endocrine System/Metabolism	190	8.78%
Multisystemic	84	3.88%
Ethology / Animal Behaviour /Animal Biology	483	22.31%
Other basic research	21	0.97%
Total	2165	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	154	100%
Total	154	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	2357	100%
Total	2357	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	481	20.41%
Mild [up to and including]	896	38.01%
Moderate	805	34.15%
Severe	175	7.42%
Total	2357	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1554	65.93%
Genetically altered without a harmful phenotype	788	33.43%

Genetically altered with a harmful phenotype	15	0.64%
Total	2357	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	643		643
Total	643		643

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Moderate	643	100%
Total	643	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	643	100%
Total	643	100.00%

Finland

Finland: Narrative 2018

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

In year 2018, 110 723 procedures were done in Finland, which was 8 % more than in 2017 (102 575 procedures).

The overall picture was quite similar as in previous years, the most used species being mice, rats, zebra fish and other fish. The use of mice and zebra fish included regularly gene modification.

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

The changes seemed to be caused by changes in activities of single research groups. The severe procedures decreased from 13 % (year 2017) to 11 % of all procedures in mice and rats.

The greatest increases in the numbers of procedures occurred with Other fish, Dogs and Other rodents (8 971, 3 236 and 1 849 animals more, respectively).

Other fish (mainly salmon species) were used in Basic Research in areas of Immune system, Ethology/Animal Behaviour/Animal Biology and Urogenital/Reproductive System. The increases in numbers were due to increased research in these areas. The severity of procedures were mainly Mild.

Dogs used in procedures were mainly needed for purpose of Translational and Applied Research/Animal Diseases and Disorders, where 5981 pet dogs and 187 pet cats gave a blood sample for the studies of disease genes. Pets participated also in patient studies (31 procedures in cats and 159 in dogs). Dogs bred and used in laboratory included 157 procedures with 117 re-use. Severity of dog procedures were Mild (6 258 procedures) or Moderate (39 procedures).

Other rodents used were voles needed for studies in Basic Research, Ethology/Animal Behaviour/Animal Biology.

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

The severity of procedures were classified as 10 % Non-recovery, 52 % Mild, 32 % Moderate and 6 % Severe. The severe procedures involved 4857 mice (7 125 in 2017) and 1 940 rats (1 568 in 2017). As in previous years, the severe procedures were done mainly in the purpose of Human nervous and mental disorders in translational research (4802 procedures, 29 % decrease).

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

The National Committee for the Protection of Animals Used for Scientific and Educational Purposes in Finland promoted education and 3R information sharing in Finland via 3R working group. The group

organized four courses 2018-2019: *In vitro* models, Ethical principles in using laboratory animals, *In silico* -training, and Modern Methods in Life Science and Drug Research. The 3R group will arranged meetings with researchers using and developing replacement models and the responsible persons from institutions using animals to make further plans of a **3R Consortium in Finland**. The Consortium aims to act as a national focal point on 3Rs and promote the 3Rs on national level. It will organize education, share information and promote co-research projects. The coordinator of 3R-consortium is FICAM, The Finnish Centre for Alternative Methods, Tampere university. FICAM participated in 3R activities listed above.

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

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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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	47444	45.11%
Rats	10890	10.35%
Guinea-Pigs	1	0%
Hamsters (Syrian)	72	0.07%
Other rodents	2539	2.41%
Rabbits	186	0.18%
Cats	218	0.21%
Dogs	6180	5.88%
Other carnivores	35	0.03%
Horses, donkeys and cross-breeds	144	0.14%
Pigs	958	0.91%
Sheep	1348	1.28%
Cattle	165	0.16%
Other mammals	319	0.3%
Domestic fowl	5468	5.2%
Other birds	1063	1.01%
Reptiles	30	0.03%
Other amphibians	77	0.07%
Zebra fish	7339	6.98%
Other fish	20700	19.68%
Total	105176	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	75710	71.98%
Animals born in the EU but not at a registered breeder	25524	24.27%
Animals born in rest of Europe	14	0.01%
Animals born in rest of world	3928	3.73%
Total	105176	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	47444	55	47499
Rats	10890	61	10951
Guinea-Pigs	1		1
Hamsters (Syrian)	72		72
Other rodents	2539		2539
Rabbits	186		186
Cats	218		218
Dogs	6180	117	6297
Other carnivores	35		35
Horses, donkeys and cross-breeds	144	92	236
Pigs	958		958
Sheep	1348		1348
Cattle	165	25	190
Other mammals	319		319
Domestic fowl	5468		5468
Other birds	1063		1063
Reptiles	30		30
Other amphibians	77		77
Zebra fish	7339		7339
Other fish	20700		20700
Total	105176	350	105526

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	58571	55.5%
Translational and applied research	37275	35.32%
Regulatory use and Routine production	7481	7.09%
Preservation of species	46	0.04%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2153	2.04%
Total	105526	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	3499	5.97%
Cardiovascular Blood and Lymphatic System	3453	5.9%
Nervous System	8598	14.68%
Respiratory System	150	0.26%
Gastrointestinal System including Liver	419	0.72%
Musculoskeletal System	557	0.95%
Immune System	11553	19.72%
Urogenital/Reproductive System	4985	8.51%
Sensory Organs (skin, eyes and ears)	481	0.82%
Endocrine System/Metabolism	2268	3.87%
Multisystemic	8641	14.75%

Ethology / Animal Behaviour /Animal Biology	12417	21.2%
Other basic research	1550	2.65%
Total	58571	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	4177	11.21%
Human Infectious Disorders	2481	6.66%
Human Cardiovascular Disorders	671	1.8%
Human Nervous and Mental Disorders	17395	46.67%
Human Gastrointestinal Disorders including Liver	74	0.2%
Human Musculoskeletal Disorders	346	0.93%
Human Immune Disorders	264	0.71%
Human Urogenital/Reproductive Disorders	42	0.11%
Human Sensory Organ Disorders (skin, eyes and ears)	2462	6.6%
Human Endocrine/Metabolism Disorders	1066	2.86%
Other Human Disorders	198	0.53%
Animal Diseases and Disorders	6946	18.63%
Animal Welfare	133	0.36%
Diagnosis of diseases	459	1.23%
Non-regulatory toxicology and ecotoxicology	561	1.51%
Total	37275	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4478	59.86%
Other efficacy and tolerance testing	218	2.91%
Toxicity and other safety testing including pharmacology	1309	17.5%
Routine production	1476	19.73%
Total	7481	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4478	100%
Total	4478	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	15	1.15%
Repeated dose toxicity	102	7.79%
Kinetics	259	19.79%
Pharmaco-dynamics (incl safety pharmacology)	933	71.28%
Total	1309	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	15	100%
Total	15	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose	Number of	Percentage

toxicity	uses	
29 - 90 days	6	5.88%
> 90 days	96	94.12%
Total	102	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1349	22.46%
Legislation on medicinal products for veterinary use and their residues	4609	76.75%
Feed legislation including legislation for the safety of target animals, workers and environment	47	0.78%
Total	6005	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6005	100%
Total	6005	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1476	100%
Total	1476	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	105176	99.67%
Yes	350	0.33%
Total	105526	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	11048	10.47%
Mild [up to and including]	54237	51.4%
Moderate	33382	31.63%
Severe	6859	6.5%
Total	105526	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	81147	76.9%
Genetically altered without a harmful phenotype	19274	18.26%
Genetically altered with a harmful phenotype	5105	4.84%
Total	105526	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	3773		3773
Zebra fish	1139		1139
Total	4912		4912

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	272	5.54%
Mild [up to and including]	2845	57.92%
Moderate	1794	36.52%
Severe	1	0.02%
Total	4912	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	2007	40.86%
Genetically altered without a harmful phenotype	2758	56.15%
Genetically altered with a harmful phenotype	147	2.99%
Total	4912	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	115	2.84%
Cardiovascular Blood and Lymphatic System	17	0.42%
Nervous System	662	16.33%
Gastrointestinal System including Liver	69	1.7%
Immune System	1219	30.08%
Endocrine System/Metabolism	431	10.63%
Multisystemic	1540	38%
Total	4053	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	148	17.23%
Human Infectious Disorders	314	36.55%
Human Cardiovascular Disorders	13	1.51%
Human Nervous and Mental Disorders	77	8.96%
Human Immune Disorders	307	35.74%
Total	859	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	285		285
Total	285		285

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	196	68.77%

Moderate	89	31.23%
Total	285	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	37	12.98%
Genetically altered without a harmful phenotype	102	35.79%
Genetically altered with a harmful phenotype	146	51.23%
Total	285	100.00%

France

France: Narrative 2018

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

The 2018 survey comprises responses from the 630 establishments approved for the use of laboratory animals (user establishments), with a response rate of 100%. Of these 630 establishments, 86 stated that they had not used any animals in experimental procedures requiring project authorisation under the Directive in 2018.

The number of times animals were used fell again very slightly: 1 910 519 uses in 2018 as compared to 1 914 174 in 2017 and 1 918 481 in 2016. This stable level of around 1.9 million uses that has been observed since 2016 is due to the duration of authorised projects, which is usually 5 years. It corroborates the figures in the 2016 and 2017 reports; many user establishments for which the responses were missing did not have any use of animals to report.

As an indication, the number of uses reported per user establishment for 2018 is 3 033, as compared to 3 467 for 2017.

In general, the species used in procedures, the degree of severity and the proportion of genetically modified animals are very similar to previous years.

The 2018 figures confirm the dominance of the mouse model in experimental procedures (62% of uses, as compared to 59% in 2017). Rats (8%) and rabbits (7%) remain the next most popular species. All species of fish combined represent 13% of uses, as compared to 15% in 2017.

Logically, greater variation can be seen in species linked to specific procedures. No use of bats was reported in 2018, as compared to 18 000 in 2017, all of which were at one user establishment. Likewise, 219 uses of cephalopods were reported in 2018, for studies in ethology, as compared to one single use in 2017 by a national museum. There were 159 uses of prosimians reported in 2018, as compared to 86 in 2017, for basic research on neurogenesis, cortical organisation and the seasonal phenotype of these primates.

The number of uses of cats increased in 2018 from 867 to 1 185. The vast majority of these were regulatory tests of tolerance for veterinary medicines or studies regarding cat nutrition.

The use of primates decreased by 6.3%, from 3 746 to 3 510. In 67% of cases, primates used for the first time were individuals of generation F2, as compared to 63% in 2017. This represents progress towards the target of 100% by 2022. The proportion of primates being reused was 26% in 2018, as compared to 38% in 2017.

All species combined, the number of reuses increased by 6.2% to 42 771 in 2018. The trend is towards a reduction in the number of animals used in scientific procedures.

The number of uses of genetically modified animals increased, from 22.4% to 25.4%. As in 2017, the vast majority of these were mice (88.7%). The proportion of harmful phenotypes remained low (2.8% in 2017 and 3.0% in 2018).

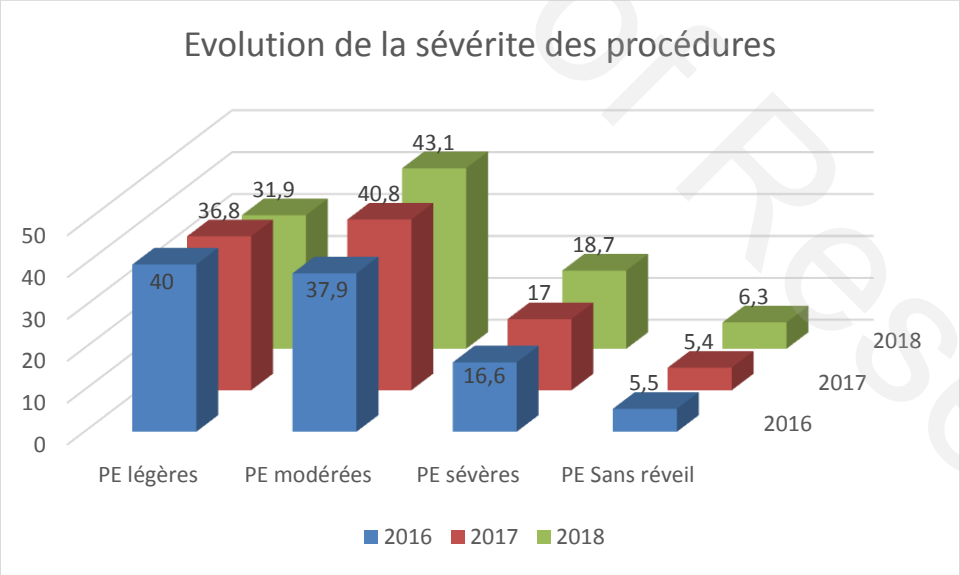
2. Information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof.

The three main areas of use remained relatively stable compared with the previous year. Basic research decreased slightly but remains the main area of use, at 36%. In contrast, use in applied research increased (from 25% to 28%) and in 2018 overtook development, production or quality and safety testing of medicines and food (which fell from 30% to 27%).

Among the other areas of use, which are less significant in terms of number, maintenance of colonies of genetically altered animals increased by 8%, teaching and professional development increased by 14% (while still representing only 2% of use), species conservation increased by 49% (2% of use) due to a project on allis shad and twaite shad (*Alosa alosa* and *Alosa fallax*) with 9 400 uses.

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

As in previous years, the vast majority of experimental procedures were of mild or moderate severity (75%). Severe and non-recovery procedures represented 18.7% and 6.3% of all procedures respectively.



The trend in the degree of severity from 2017 is for a decrease in the number of animals used in mild procedures and a slight increase in moderate, severe and non-recovery procedures. It is difficult to tell as yet whether this trend corresponds to a real trend in the severity of procedures or if it reflects a stricter application of the evaluation criteria for severity linked to increasing awareness among those working with the animals.

The increase in the number of severe procedures can also be explained by the increasing production of reagents for diagnostic tests for diseases such as toxoplasmosis, in connection with the national policy for detection of the disease in pregnant women. The French authorities are working with the user establishments to explore possible ways of refining the production techniques in order to reduce their severity for the animals concerned.

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

As in the previous year, France continues to actively promote the principles of replacement, refinement and reduction ('3R'). This commitment is demonstrated in particular through the project authorisation process. It also translates into increasingly robust training requirements for staff responsible for caring for animals or for carrying out and designing scientific projects. In addition, all those involved benefit from the exchange of best practice promoted by the professional associations for animal experimentation (AFSTAL, GIRCOR and OPAL) or at national meetings such as the conference of chairs of animal ethics committees on 7 October 2019 with 120 participants, organised by the Ministry of Research.

The recommendations for good experimental practice given by the national committee for consideration of ethics in animal experimentation (for example on ascites) also contribute to the correct application of the 3R principle.

The national platform for the development of alternative methods, FRANCOPA, which is a member of the European network ECOPA and brings together all stakeholders, also works actively to promote the three Rs.

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

This year a particular effort has been made to assign specific categories to the uses declared in 'other' categories. Hence, for basic research, the 'other' category represents only 0.3% of uses as compared to 3.2% in 2017. The only uses still categorised as 'other' concern research on embryo development.

As in 2017, the category 'other fish' is still very large, with 12% of uses (231 760 animals). This category includes farmed and wild fish such as European seabass (53 000), rainbow trout (20 000), eel (12 000), salmon (12 000) and shad (9 400), the reproduction, physiology and diet of which are the subject of numerous studies, particularly by user establishments within public research bodies such as the National Institute for Agricultural Research (INRA) and the National Institute for Ocean Science (Ifremer).

The category 'other birds' accounts for 1.5% of uses (29 095, compared to 46 029 chickens). The research carried out on these 'other birds' is basic or translational research or research in animal biology on domestic species such as turkey (24 000) or duck (900), or wild species such as albatross (500) or cormorant (60).

The routine production of products other than blood products or monoclonal antibodies (e.g. PR53) accounts for 56 184 uses. The two main projects in this category concern the production of proteins from milk for therapeutic use and the production of a vaccine strain for turkeys.

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 authorisation was issued in 2018 for applications exceeding the 'severe' classification with intense pain which is likely to be long-lasting and cannot be ameliorated.

France: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1073232	61.23%
Rats	150225	8.57%
Guinea-Pigs	41678	2.38%
Hamsters (Syrian)	5193	0.3%
Hamsters (Chinese)	20	0%
Mongolian gerbil	596	0.03%
Other rodents	2311	0.13%
Rabbits	129357	7.38%
Cats	437	0.02%
Dogs	2569	0.15%
Ferrets	28	0%
Other carnivores	29	0%
Horses, donkeys and cross-breeds	122	0.01%
Pigs	14714	0.84%
Goats	158	0.01%
Sheep	3137	0.18%
Cattle	1173	0.07%
Prosimians	159	0.01%
Marmoset and tamarins	59	0%
Cynomolgus monkey	2285	0.13%
Rhesus monkey	34	0%
Vervets (Chlorocebus spp.)	16	0%
Baboons	17	0%
Other species of Old World Monkeys (Cercopithecoidea)	22	0%
Other mammals	89	0.01%
Domestic fowl	45210	2.58%
Other birds	28798	1.64%
Reptiles	18	0%
Rana	256	0.01%
Xenopus	8844	0.5%
Other amphibians	458	0.03%
Zebra fish	20457	1.17%

Other fish	221002	12.61%
Cephalopods	203	0.01%
Total	1752906	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1476570	84.36%
Animals born in the EU but not at a registered breeder	184109	10.52%
Animals born in rest of Europe	63413	3.62%
Animals born in rest of world	26222	1.5%
Total	1750314	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	309	11.92%
Animals born in Asia	606	23.38%
Animals born in America	12	0.46%
Animals born in Africa	1611	62.15%
Animals born elsewhere	54	2.08%
Total	2592	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	709	27.35%
F2 or greater	1733	66.86%
Self-sustaining colony	150	5.79%
Total	2592	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1073232	14273	1087505
Rats	150225	5213	155438
Guinea-Pigs	41678	49	41727
Hamsters (Syrian)	5193		5193
Hamsters (Chinese)	20		20
Mongolian gerbil	596		596
Other rodents	2311	602	2913
Rabbits	129357	1972	131329
Cats	437	748	1185
Dogs	2569	1645	4214
Ferrets	28		28
Other carnivores	29		29
Horses, donkeys and cross-breeds	122	360	482
Pigs	14714	255	14969
Goats	158	552	710
Sheep	3137	1167	4304
Cattle	1173	1083	2256
Prosimians	159		159
Marmoset and tamarins	59	147	206
Cynomolgus monkey	2285	724	3009
Rhesus monkey	34	28	62
Vervets (Chlorocebus spp.)	16		16
Baboons	17	19	36
Other species of Old World Monkeys (Cercopithecoidea)	22		22
Other mammals	89	15	104
Domestic fowl	45210	819	46029
Other birds	28798	297	29095
Reptiles	18	2102	2120
Rana	256		256
Xenopus	8844	445	9289
Other amphibians	458		458
Zebra fish	20457	204	20661
Other fish	221002	9990	230992
Cephalopods	203	16	219
Total	1752906	42725	1795631

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	654346	36.44%
Translational and applied research	542128	30.19%
Regulatory use and Routine production	517169	28.8%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3665	0.2%
Preservation of species	36807	2.05%
Higher education or training for the acquisition, maintenance or improvement of vocational	41510	2.31%

skills		
Forensic enquiries	6	0%
Total	1795631	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	70077	10.71%
Cardiovascular Blood and Lymphatic System	35451	5.42%
Nervous System	128947	19.71%
Respiratory System	12492	1.91%
Gastrointestinal System including Liver	56309	8.61%
Musculoskeletal System	21896	3.35%
Immune System	112216	17.15%
Urogenital/Reproductive System	27795	4.25%
Sensory Organs (skin, eyes and ears)	13397	2.05%
Endocrine System/Metabolism	38905	5.95%
Multisystemic	13387	2.05%
Ethology / Animal Behaviour /Animal Biology	118675	18.14%
Other basic research	4799	0.73%
Total	654346	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	143266	26.43%
Human Infectious Disorders	40065	7.39%
Human Cardiovascular Disorders	14391	2.65%
Human Nervous and Mental Disorders	50273	9.27%
Human Respiratory Disorders	8811	1.63%
Human Gastrointestinal Disorders including Liver	9156	1.69%
Human Musculoskeletal Disorders	13652	2.52%
Human Immune Disorders	36851	6.8%
Human Urogenital/Reproductive Disorders	3243	0.6%
Human Sensory Organ Disorders (skin, eyes and ears)	3197	0.59%
Human Endocrine/Metabolism Disorders	14852	2.74%
Other Human Disorders	5786	1.07%
Animal Diseases and Disorders	82495	15.22%
Animal Welfare	2980	0.55%
Diagnosis of diseases	96675	17.83%
Plant diseases	14	0%
Non-regulatory toxicology and ecotoxicology	16421	3.03%
Total	542128	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	206430	39.92%
Other efficacy and tolerance testing	14347	2.77%
Toxicity and other safety testing including pharmacology	108325	20.95%
Routine production	188067	36.36%
Total	517169	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	35433	17.16%

Pyrogenicity testing	9578	4.64%
Batch potency testing	153524	74.37%
Other quality controls	7895	3.82%
Total	206430	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	3091	2.85%
Skin irritation/corrosion	1709	1.58%
Skin sensitisation	12141	11.21%
Eye irritation/corrosion	231	0.21%
Repeated dose toxicity	22719	20.97%
Carcinogenicity	1846	1.7%
Genotoxicity	498	0.46%
Reproductive toxicity	8051	7.43%
Developmental toxicity	5951	5.49%
Neurotoxicity	1133	1.05%
Kinetics	18063	16.67%
Pharmaco-dynamics (incl safety pharmacology)	5396	4.98%
Phototoxicity	411	0.38%
Ecotoxicity	25308	23.36%
Safety testing in food and feed area	983	0.91%
Target animal safety	232	0.21%
Other toxicity/safety testing	562	0.52%
Total	108325	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	735	23.78%
Other lethal methods	148	4.79%
Non lethal methods	2208	71.43%
Total	3091	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13312	58.59%
29 - 90 days	6133	27%
> 90 days	3274	14.41%
Total	22719	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	8548	33.78%
Chronic toxicity	16648	65.78%
Bioaccumulation	22	0.09%
Other ecotoxicity	90	0.36%
Total	25308	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of	Percentage

	uses	
Legislation on medicinal products for human use	228314	69.37%
Legislation on medicinal products for veterinary use and their residues	46456	14.12%
Medical devices legislation	22809	6.93%
Industrial chemicals legislation	6557	1.99%
Plant protection product legislation	4010	1.22%
Biocides legislation	1180	0.36%
Food legislation including food contact material	821	0.25%
Feed legislation including legislation for the safety of target animals, workers and environment	3011	0.91%
Other legislation	15944	4.84%
Total	329102	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	325287	98.84%
Legislation satisfying national requirements only [within EU]	1038	0.32%
Legislation satisfying Non-EU requirements only	2777	0.84%
Total	329102	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	79108	42.06%
Monoclonal antibody by mouse ascites method	53073	28.22%
Other product types	55886	29.72%
Total	188067	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1752906	97.62%
Yes	42725	2.38%
Total	1795631	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	116755	6.5%
Mild [up to and including]	548618	30.55%
Moderate	774226	43.12%
Severe	356032	19.83%
Total	1795631	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1413762	78.73%
Genetically altered without a harmful phenotype	333870	18.59%
Genetically altered with a harmful phenotype	47999	2.67%
Total	1795631	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	31965		31965
Rats	2489	4	2493
Rabbits	258		258
Zebra fish	3746		3746
Total	38458	4	38462

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	2742	7.13%
Mild [up to and including]	16668	43.34%
Moderate	17858	46.43%
Severe	1194	3.1%
Total	38462	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	12294	31.96%
Genetically altered without a harmful phenotype	21151	54.99%
Genetically altered with a harmful phenotype	5017	13.04%
Total	38462	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	1792	4.83%
Cardiovascular Blood and Lymphatic System	296	0.8%
Nervous System	16495	44.43%
Gastrointestinal System including Liver	99	0.27%
Musculoskeletal System	921	2.48%
Immune System	2098	5.65%
Urogenital/Reproductive System	15	0.04%
Sensory Organs (skin, eyes and ears)	434	1.17%
Endocrine System/Metabolism	125	0.34%
Multisystemic	12397	33.4%
Ethology / Animal Behaviour /Animal Biology	1561	4.21%
Other basic research	889	2.39%
Total	37122	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	137	10.22%
Human Infectious Disorders	545	40.67%
Human Cardiovascular Disorders	245	18.28%
Human Respiratory Disorders	23	1.72%
Human Immune Disorders	10	0.75%
Human Endocrine/Metabolism Disorders	248	18.51%
Animal Diseases and Disorders	132	9.85%
Total	1340	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	73036	42	73078
Rats	1855		1855
Dogs	5		5
Zebra fish	720		720
Other fish	768		768
Total	76384	42	76426

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	768	1%
Mild [up to and including]	44821	58.65%
Moderate	30710	40.18%
Severe	127	0.17%
Total	76426	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	73030	95.56%
Genetically altered with a harmful phenotype	3396	4.44%
Total	76426	100.00%

Germany

Germany: Narrative 2018

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

In 2018, some 2 million vertebrates were used in Germany in animal testing 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 test'. The figures are virtually unchanged compared to the previous year. Approximately 83% of the animals used for testing were rodents, mostly mice and rats, with mice accounting for around 72%. Approximately 9% of the animals were fish, around 4% were rabbits and around 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 requirements of the EU Laboratory Animals Directive, Germany also records animals 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. Some 686 000 animals were used for this purpose in 2018, which is approximately 51 000 fewer than in the previous year. These animals are not included in the number of laboratory 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. Around 1 295 000 animals of the total number of animals used were genetically modified. These animals thus accounted for approximately 44% (compared to 40% in 2017). This concerned in particular mice (92%) and fish (8%).

Primates

The number of primates used fell slightly. In 2018 a total of 3 324 primates were used, which is 201 fewer than in the previous year.

Dogs and cats

The number of dogs and cats used was 3 993 and 765, respectively, used in particular for statutory testing and for applied research. Compared to the previous year there was a slight increase in the number of dogs (3 334 in 2017) and cats (718 in 2017).

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. Specifically, approximately 47% of the animals used in animal testing 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. Around 23% of the animals were used in the production and quality control of medical products or for

toxicological safety tests. Around 15% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

Compared to 2017 there was thus a slight overall decrease in the area of basic research (around 3%) and for the production and quality control of medical products and toxicological safety tests (around 4%), while there was a significant increase of around 9% in other areas, in particular for the purpose of maintaining colonies of genetically modified animals.

- **Basic research**
  Within basic research, research into the nervous system (around 19%) and the immune system (around 19%) was particularly important in 2018. These figures are virtually unchanged compared to the previous year.

- **Human and animal diseases**
  In the area of research into human and animal diseases, there was an emphasis on human cancers. Approximately 39% of the animals used for testing in this field of research were used for this purpose. This is a slight decrease compared to 2017 (around 41%).

- **Toxicological safety tests**
  2018 saw an increase compared to the previous year, in particular in the area of testing medical products for pyrogens and in the production of monoclonal antibodies. Although alternative methods are increasingly being used in this field, testing on animals is still required to demonstrate that products are safe and effective due to the complex interaction between medicinal products and the organism.

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

The severity of tests within the meaning of Section 7(2) of the Animal Welfare Act was predominantly 'mild' (approximately 61%). Around 27% of the tests were classified as 'moderate' and 6% were classified as 'severe'. Compared to the previous year, there was a slight increase of 2% in tests whose severity was classified as 'mild' and a very small increase of about 1% in tests classified as 'severe'. The share of tests on animals carried out entirely under general anaesthesia and from which the animal never regained consciousness was around 6%, which is slightly lower than in the previous year (about 9%).

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 tests. Various projects are therefore being launched and supported with the aim of replacing animal testing with alternative methods as quickly as possible. These projects include setting up and running 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 Foundation for the promotion of alternate and complementary methods to reduce animal testing (*Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen*) 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'

This category, particularly 'other fish species' and 'other bird species', comprises a large number of animal species.

With regard to fish, primarily local wild fish (e.g. grayling, common roach, stickleback, brown trout, eel) were used for the purposes of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the test was finished. The severity classification was generally 'mild'.

Among birds, primarily turkeys and local wild bird species (e.g. tit, duck, common buzzard, pigeon, hawk) were used. While turkeys were mainly used for the purpose of researching various animal diseases, various wild bird species were used in the context of basic ethological research. This primarily concerned birds caught in the wild which were re-released after the test was finished. The severity classification for the animals involved was generally 'mild'.

Moreover, 'other rodents' and 'other amphibians' comprise a small number of additional species. Rodents, in particular voles, bank voles and yellow-necked mice, were primarily used in basic ethological research. This partially concerned animals caught in the wild which were re-released after the test was finished. The severity classification was generally 'mild'. Amphibians, in particular salamander and axolotl, were mainly used for research into species conservation and basic research. The severity classification was generally 'mild' to 'moderate'.

Category 'other uses'

The emphasis in this category is on '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 lines as models for human and animal diseases;
- research into molecular developmental genetics;
- research into molecular pathomechanisms;
- testing 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 field of gerontology.

The severity classification for the animals involved was generally 'mild' to 'moderate'.

In the area of **regulatory tests** the emphasis was mainly on the following topics:

- testing new diagnostic and therapeutic procedures in the field of human cancers;
- testing the effectiveness and mode of action of feed additives;
- testing the effectiveness and mode of action of substances in the field of obesity research;
- pharmacodynamic tests in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

The severity classification for the animals involved was generally 'mild' to 'moderate'.

Category 'other legal provisions'

The following other legal provisions are relevant in this category:

- testing of substances hazardous to water pursuant to the Administrative Regulation under the Water Resources Act *(Verwaltungsvorschrift zum Wasserhaushaltsgesetz);*
- testing of products under Regulation (EC) No 1272/2008 (fibre persistence test);
- testing of products under the Infection Protection Act *(Infektionsschutzgesetz)*;
- testing of products under the Animal Vaccine Regulation *(Tierimpfstoffverordnung)*.

The severity classification for the animals involved varied considerably (from 'mild' 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.

The 'severe' classification was not exceeded in any tests carried out in Germany in 2018.

Germany: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1104144	67.77%
Rats	214039	13.14%
Guinea-Pigs	13946	0.86%
Hamsters (Syrian)	932	0.06%
Mongolian gerbil	3283	0.2%
Other rodents	2895	0.18%
Rabbits	81185	4.98%
Cats	556	0.03%

Dogs	2108	0.13%
Ferrets	69	0%
Other carnivores	389	0.02%
Horses, donkeys and cross-breeds	431	0.03%
Pigs	17595	1.08%
Goats	475	0.03%
Sheep	4613	0.28%
Cattle	6828	0.42%
Prosimians	11	0%
Marmoset and tamarins	188	0.01%
Cynomolgus monkey	2314	0.14%
Rhesus monkey	51	0%
Baboons	10	0%
Squirrel monkey	25	0%
Other mammals	1423	0.09%
Domestic fowl	22596	1.39%
Other birds	6909	0.42%
Reptiles	146	0.01%
Rana	834	0.05%
Xenopus	1464	0.09%
Other amphibians	1459	0.09%
Zebra fish	58144	3.57%
Other fish	80107	4.92%
Cephalopods	59	0%
Total	1629228	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1495142	91.92%
Animals born in the EU but not at a registered breeder	91292	5.61%
Animals born in rest of Europe	24751	1.52%
Animals born in rest of world	15444	0.95%
Total	1626629	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	371	14.27%
Animals born in Asia	1791	68.91%
Animals born in Africa	437	16.81%
Total	2599	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	217	8.35%
F2 or greater	1724	66.33%
Self-sustaining colony	658	25.32%
Total	2599	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1104144	21420	1125564
Rats	214039	6301	220340
Guinea-Pigs	13946	283	14229
Hamsters (Syrian)	932	8	940
Mongolian gerbil	3283	83	3366
Other rodents	2895	47	2942
Rabbits	81185	3992	85177
Cats	556	209	765
Dogs	2108	1871	3979
Ferrets	69	22	91
Other carnivores	389		389
Horses, donkeys and cross-breeds	431	361	792
Pigs	17595	1255	18850
Goats	475	24	499
Sheep	4613	138	4751
Cattle	6828	479	7307
Prosimians	11	52	63
Marmoset and tamarins	188	31	219
Cynomolgus monkey	2314	561	2875
Rhesus monkey	51	14	65
Vervets (Chlorocebus spp.)		14	14
Baboons	10		10
Squirrel monkey	25		25
Other species of Old World Monkeys (Cercopithecoidea)		7	7
Other mammals	1423	16	1439
Domestic fowl	22596	247	22843
Other birds	6909	422	7331
Reptiles	146	6	152
Rana	834		834
Xenopus	1464	970	2434
Other amphibians	1459		1459
Zebra fish	58144		58144
Other fish	80107	415	80522
Cephalopods	59		59
Total	1629228	39248	1668476

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	792580	47.5%
Translational and applied research	313879	18.81%
Regulatory use and Routine production	484254	29.02%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8289	0.5%
Preservation of species	14088	0.84%
Higher education or training for the acquisition, maintenance or improvement of vocational	55386	3.32%

skills		
Total	1668476	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	79316	10.01%
Cardiovascular Blood and Lymphatic System	79709	10.06%
Nervous System	161311	20.35%
Respiratory System	19825	2.5%
Gastrointestinal System including Liver	29006	3.66%
Musculoskeletal System	15806	1.99%
Immune System	171780	21.67%
Urogenital/Reproductive System	16369	2.07%
Sensory Organs (skin, eyes and ears)	17582	2.22%
Endocrine System/Metabolism	52045	6.57%
Multisystemic	83899	10.59%
Ethology / Animal Behaviour /Animal Biology	65612	8.28%
Other basic research	320	0.04%
Total	792580	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	120911	38.52%
Human Infectious Disorders	26912	8.57%
Human Cardiovascular Disorders	15505	4.94%
Human Nervous and Mental Disorders	35144	11.2%
Human Respiratory Disorders	9565	3.05%
Human Gastrointestinal Disorders including Liver	10876	3.47%
Human Musculoskeletal Disorders	3154	1%
Human Immune Disorders	17298	5.51%
Human Urogenital/Reproductive Disorders	2069	0.66%
Human Sensory Organ Disorders (skin, eyes and ears)	5394	1.72%
Human Endocrine/Metabolism Disorders	17452	5.56%
Other Human Disorders	6226	1.98%
Animal Diseases and Disorders	23551	7.5%
Animal Welfare	5568	1.77%
Diagnosis of diseases	5113	1.63%
Plant diseases	18	0.01%
Non-regulatory toxicology and ecotoxicology	9123	2.91%
Total	313879	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	188944	39.02%
Other efficacy and tolerance testing	17656	3.65%
Toxicity and other safety testing including pharmacology	203965	42.12%
Routine production	73689	15.22%
Total	484254	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	12349	6.54%
Pyrogenicity testing	6291	3.33%

Batch potency testing	169182	89.54%
Other quality controls	1122	0.59%
Total	188944	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	6547	3.21%
Skin irritation/corrosion	515	0.25%
Skin sensitisation	6573	3.22%
Eye irritation/corrosion	100	0.05%
Repeated dose toxicity	20113	9.86%
Carcinogenicity	794	0.39%
Genotoxicity	3086	1.51%
Reproductive toxicity	16614	8.15%
Developmental toxicity	23570	11.56%
Neurotoxicity	152	0.07%
Kinetics	29617	14.52%
Pharmaco-dynamics (incl safety pharmacology)	70183	34.41%
Ecotoxicity	22152	10.86%
Safety testing in food and feed area	1859	0.91%
Target animal safety	1080	0.53%
Other toxicity/safety testing	1010	0.5%
Total	203965	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1631	24.91%
Other lethal methods	215	3.28%
Non lethal methods	4701	71.8%
Total	6547	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	13012	64.69%
29 - 90 days	4257	21.17%
> 90 days	2844	14.14%
Total	20113	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	10432	47.09%
Chronic toxicity	7623	34.41%
Endocrine activity	790	3.57%
Bioaccumulation	3267	14.75%
Other ecotoxicity	40	0.18%
Total	22152	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

Legislation on medicinal products for human use	311642	75.91%
Legislation on medicinal products for veterinary use and their residues	18048	4.4%
Medical devices legislation	8044	1.96%
Industrial chemicals legislation	38500	9.38%
Plant protection product legislation	30216	7.36%
Biocides legislation	426	0.1%
Food legislation including food contact material	510	0.12%
Feed legislation including legislation for the safety of target animals, workers and environment	1952	0.48%
Other legislation	1227	0.3%
Total	410565	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	400507	97.55%
Legislation satisfying national requirements only [within EU]	2624	0.64%
Legislation satisfying Non-EU requirements only	7434	1.81%
Total	410565	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	69804	94.73%
Monoclonal antibody by mouse ascites method	1565	2.12%
Other product types	2320	3.15%
Total	73689	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1629228	97.65%
Yes	39248	2.35%
Total	1668476	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	123863	7.42%
Mild [up to and including]	910142	54.55%
Moderate	526752	31.57%
Severe	107719	6.46%
Total	1668476	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1132375	67.87%
Genetically altered without a harmful phenotype	436493	26.16%
Genetically altered with a harmful phenotype	99608	5.97%
Total	1668476	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	103224	1014	104238
Rats	979		979
Rabbits	16		16
Ferrets		4	4
Pigs	29	4	33
Marmoset and tamarins	10		10
Other amphibians	100		100
Zebra fish	46203		46203
Other fish	2809		2809
Total	153370	1022	154392

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	14269	9.24%
Mild [up to and including]	109113	70.67%
Moderate	29291	18.97%
Severe	1719	1.11%
Total	154392	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	32945	21.34%
Genetically altered without a harmful phenotype	102454	66.36%
Genetically altered with a harmful phenotype	18993	12.3%
Total	154392	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	10098	6.96%
Cardiovascular Blood and Lymphatic System	14728	10.14%
Nervous System	26131	18%
Respiratory System	275	0.19%
Gastrointestinal System including Liver	2338	1.61%
Musculoskeletal System	8662	5.97%
Immune System	13542	9.33%
Urogenital/Reproductive System	11065	7.62%
Sensory Organs (skin, eyes and ears)	5861	4.04%
Endocrine System/Metabolism	8634	5.95%
Multisystemic	30136	20.76%
Ethology / Animal Behaviour /Animal Biology	827	0.57%
Other basic research	12879	8.87%
Total	145176	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	1238	13.43%
Human Infectious Disorders	203	2.2%

Human Cardiovascular Disorders	1653	17.94%
Human Nervous and Mental Disorders	996	10.81%
Human Respiratory Disorders	552	5.99%
Human Gastrointestinal Disorders including Liver	3138	34.05%
Human Immune Disorders	91	0.99%
Human Urogenital/Reproductive Disorders	107	1.16%
Human Sensory Organ Disorders (skin, eyes and ears)	783	8.5%
Human Endocrine/Metabolism Disorders	279	3.03%
Other Human Disorders	7	0.08%
Animal Welfare	169	1.83%
Total	9216	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	309563	210	309773
Rats	1492		1492
Domestic fowl	219		219
Zebra fish	3868		3868
Other fish	494		494
Total	315636	210	315846

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	545	0.17%
Mild [up to and including]	285190	90.29%
Moderate	14847	4.7%
Severe	15264	4.83%
Total	315846	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	278082	88.04%
Genetically altered with a harmful phenotype	37764	11.96%
Total	315846	100.00%

Greece

Greece: Narrative 2018

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

A further 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 as well as the increase of research interest in this field.

A further significant increase in the use of animals born in the EU but not by a registered breeder has been reported. This refers to fish of domestic species and cephalopods that have been captured in the Greek seas.

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 2018 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 increase in the use of domestic fowl is reported due to authorisation of relevant projects performed in 2018 by a user establishment. In 2017 there had been no relevant authorisation.

C) 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.

D) A continuous increase in the use of genetically altered animals without a harmful phenotype has been noted during the last years, due to the type of projects authorised and the research trends of recent years globally. This is also correlated with the relevant increase of the use of mice in 2018 in Greece.

F) It has to be noted that the purpose of animals used for scientific purposes differs among each year according to the protocols authorised and funding received by user establishments. Minor changing trends can be recorded.

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 further diminished due to a declared decrease in higher education trainings programs that are performed with the use of live animals in Greece.

B) Animals with “moderate” severity seem to have increased. This can be attributed to the training of project evaluation committees that took place in Greece in 2019 by the Greek National Committee for the protection of animals used for scientific purposes which has led to the implementation of better criteria for the assessment of severity and, thus, better enforcement of legislation.

C) In translational/applied research for human cancer a decrease back to previous levels has been noted in 2018 compared to 2017 which has resulted in the relevant decrease of the severe use of those animals.

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.

The Greek National Committee for the protection of animals used for scientific purposes has organised 2 trainings for members of Greek project evaluation committees in 2019 where many issues regarding the enforcement of legislation have been clarified including classification of severity.

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 2018 although with a decreasing trend compared to 2017. This can be attributed to the improvement of reporting procedures by the relevant user establishments as well as the improvement of the authorisation procedures followed for these projects by the local competent authorities. 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.

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 2018.

Greece: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	23768	65.96%
Rats	1769	4.91%
Guinea-Pigs	16	0.04%
Rabbits	402	1.12%
Dogs	9	0.02%
Pigs	375	1.04%
Sheep	8	0.02%
Rhesus monkey	1	0%
Domestic fowl	656	1.82%
Zebra fish	63	0.17%
Other fish	8932	24.79%
Cephalopods	33	0.09%
Total	36032	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	32938	91.42%
Animals born in the EU but not at a registered breeder	3093	8.58%
Total	36031	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	100%
Total	1	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	1	100%
Total	1	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	23768		23768
Rats	1769		1769
Guinea-Pigs	16		16
Rabbits	402		402
Dogs	9	12	21
Pigs	375		375
Sheep	8		8
Rhesus monkey	1		1
Domestic fowl	656		656
Zebra fish	63		63
Other fish	8932	88	9020
Cephalopods	33		33
Total	36032	100	36132

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	19063	52.76%
Translational and applied research	6238	17.26%
Regulatory use and Routine production	6815	18.86%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3093	8.56%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	923	2.55%
Total	36132	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2346	12.31%
Cardiovascular Blood and Lymphatic System	867	4.55%
Nervous System	1411	7.4%
Respiratory System	894	4.69%
Gastrointestinal System including Liver	357	1.87%
Musculoskeletal System	445	2.33%
Immune System	3635	19.07%
Urogenital/Reproductive System	352	1.85%
Sensory Organs (skin, eyes and ears)	1201	6.3%
Endocrine System/Metabolism	376	1.97%
Multisystemic	135	0.71%
Ethology / Animal Behaviour /Animal Biology	6028	31.62%
Other basic research	1016	5.33%
Total	19063	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1099	17.62%

Human Infectious Disorders	423	6.78%
Human Cardiovascular Disorders	725	11.62%
Human Nervous and Mental Disorders	422	6.76%
Human Respiratory Disorders	40	0.64%
Human Gastrointestinal Disorders including Liver	508	8.14%
Human Musculoskeletal Disorders	239	3.83%
Human Immune Disorders	1645	26.37%
Human Sensory Organ Disorders (skin, eyes and ears)	226	3.62%
Other Human Disorders	461	7.39%
Animal Diseases and Disorders	310	4.97%
Diagnosis of diseases	44	0.71%
Non-regulatory toxicology and ecotoxicology	96	1.54%
Total	6238	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	37	0.54%
Toxicity and other safety testing including pharmacology	6778	99.46%
Total	6815	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Other quality controls	37	100%
Total	37	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation	79	1.17%
Repeated dose toxicity	66	0.97%
Safety testing in food and feed area	6633	97.86%
Total	6778	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
> 90 days	66	100%
Total	66	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	182	2.67%
Food legislation including food contact material	6633	97.33%
Total	6815	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6815	100%
Total	6815	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	36032	99.72%
Yes	100	0.28%
Total	36132	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2159	5.98%
Mild [up to and including]	16680	46.16%
Moderate	12899	35.7%
Severe	4394	12.16%
Total	36132	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	24722	68.42%
Genetically altered without a harmful phenotype	9611	26.6%
Genetically altered with a harmful phenotype	1799	4.98%
Total	36132	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	7724		7724
Total	7724		7724

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	7404	95.86%
Moderate	320	4.14%
Total	7724	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	320	4.14%
Genetically altered without a harmful phenotype	7404	95.86%
Total	7724	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	140	2.15%
Cardiovascular Blood and Lymphatic System	700	10.73%
Nervous System	1690	25.9%
Gastrointestinal System including Liver	1350	20.69%
Immune System	2324	35.62%
Other basic research	320	4.9%
Total	6524	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Nervous and Mental Disorders	1200	100%
Total	1200	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	831		831
Total	831		831

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	315	37.91%
Moderate	516	62.09%
Total	831	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	265	31.89%
Genetically altered with a harmful phenotype	566	68.11%
Total	831	100.00%

Hungary

Hungary: Narrative 2018

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 2018 was 120.522 which represents 14.4% decrease compared of 2017 and 29.14 % decrease compared the same figure of 2016. The number of re-used animals was 3.447 which represent 55% decrease compared of 2017 and 138 % increase compared with the data of 2016.

The number of genetically altered animal used without a harmful phenotype in 2018 was 8.677 which represent about 109.86% increase compared with the previous years. The used of genetically altered animal with a harmful phenotype shows significant increase in 2018 compared with the previous years.

The data of origin of animals do not show significant difference compare with the previous years.

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 (94.62%) of used animals were warm-blooded vertebrates. There was decrease in the proportion of mammals (form 78.21% to 70.47%), while the proportion of birds and fish increased (the birds from 19.36% to 24.16% and the fish from 2.42% to 5.38%).

The proportion of rodents among mammals decreased from 95.92% to 94.39%. There was 20.58% decrease in the number of mice and 32.32% in the number of rats. In case of guinea-pigs was 16% decrease. Hamsters were not used for scientific purposes in neither 2017 nor 2018. The number of rabbits used for scientific purposes increased by 127% in 2018.

The number of used cats in experiments was a small decrease (16 compared to 15). The number of dogs decreased by 8%. 5 non-human primate was used in 2018 (compared to the 2 Rhesus monkeys in 2017).

The number of horses, donkeys and cross-breeds used for scientific purpose represents significant increase in 2018 compare with the previous years (from 0 to 15).

There was 7% decrease in the number of pigs. The use of cattle for scientific purposes was the same in 2017 and 2018.

The number of domestic fowl increased by 112%, and the number of other birds show significant decrease (from 2.084 to 786).

The proportion of zebra fish increased from 2.443 to 3.744 and other fish increased by 233%.

When analysed by the purposes of the use of animals a decrease can be observed in regulatory use and routine production (about 7%). The proportion of basic research, animals in applied and translational research shows decrease than in 2017.

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

The proportion of mild uses was increased from 50.00% to 54.32% and moderate uses decreased from 28.38% to 23.37%, while severe uses increased from 12.80% to 13.33%. On the other hand non-recoveries increased from 8.82% to 8.98%.

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.

There were two projects with Poecilia reticulata using concerning a national legislation to control of discharges of used water and wastewater and from the other hand the field of environmental protection.

Two projects with mice and one with rabbits: Proprietary transgenic animals are used for the production of antibodies (rabbit, mouse). These transgenic animals have a much better immune response capacity to produce antibodies than the wild type for the production of antibodies to the wild-type. These animals cannot be replaced by any alternative method due to their ability to provide a special immune response. In the case of an exceptionally high number of animals, the company is considered to be responsible for the development of antibodies, which mainly uses rabbits. A minimum number of animals are sought for the production of a sufficient quantity of serum, but a significant amount of blood serum is required for the production of certain specific heavy antibodies, which justifies the inclusion of more animals in the experiment.

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.

Number of 'severe' cases shows decrease compared with 2018 and 2017 from 18.016 % to 16.065%.

Hungary: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	52116	44.59%
Rats	22951	19.64%
Guinea-Pigs	4850	4.15%

Rabbits	1957	1.67%
Cats	15	0.01%
Dogs	369	0.32%
Horses, donkeys and cross-breeds	10	0.01%
Pigs	2103	1.8%
Cattle	33	0.03%
Domestic fowl	28326	24.23%
Other birds	786	0.67%
Zebra fish	781	0.67%
Other fish	2585	2.21%
Total	116882	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	110559	94.59%
Animals born in the EU but not at a registered breeder	4473	3.83%
Animals born in rest of Europe	1516	1.3%
Animals born in rest of world	334	0.29%
Total	116882	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	52116	47	52163
Rats	22951	24	22975
Guinea-Pigs	4850	17	4867
Rabbits	1957	28	1985
Cats	15		15
Dogs	369	59	428
Horses, donkeys and cross-breeds	10	5	15
Pigs	2103	145	2248
Cattle	33		33
Rhesus monkey		5	5
Domestic fowl	28326	2	28328
Other birds	786		786
Zebra fish	781	1628	2409
Other fish	2585	152	2737
Total	116882	2112	118994

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	36826	30.95%
Translational and applied research	26122	21.95%
Regulatory use and Routine production	54016	45.39%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2030	1.71%
Total	118994	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	4388	11.92%
Cardiovascular Blood and Lymphatic System	3622	9.84%
Nervous System	16176	43.93%
Respiratory System	372	1.01%
Gastrointestinal System including Liver	1901	5.16%
Musculoskeletal System	334	0.91%
Immune System	3189	8.66%
Urogenital/Reproductive System	2471	6.71%
Sensory Organs (skin, eyes and ears)	329	0.89%
Endocrine System/Metabolism	835	2.27%
Multisystemic	1811	4.92%
Ethology / Animal Behaviour /Animal Biology	436	1.18%
Other basic research	962	2.61%
Total	36826	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	5410	20.71%

Human Infectious Disorders	641	2.45%
Human Cardiovascular Disorders	37	0.14%
Human Nervous and Mental Disorders	748	2.86%
Human Gastrointestinal Disorders including Liver	7	0.03%
Human Musculoskeletal Disorders	141	0.54%
Human Immune Disorders	2240	8.58%
Human Urogenital/Reproductive Disorders	28	0.11%
Human Sensory Organ Disorders (skin, eyes and ears)	488	1.87%
Human Endocrine/Metabolism Disorders	110	0.42%
Animal Diseases and Disorders	11409	43.68%
Animal Welfare	2863	10.96%
Diagnosis of diseases	1657	6.34%
Non-regulatory toxicology and ecotoxicology	343	1.31%
Total	26122	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	24109	44.63%
Other efficacy and tolerance testing	873	1.62%
Toxicity and other safety testing including pharmacology	28416	52.61%
Routine production	618	1.14%
Total	54016	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	9318	38.65%
Pyrogenicity testing	20	0.08%
Batch potency testing	14379	59.64%
Other quality controls	392	1.63%
Total	24109	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	12039	42.37%
Skin irritation/corrosion	556	1.96%
Skin sensitisation	2532	8.91%
Eye irritation/corrosion	288	1.01%
Repeated dose toxicity	7165	25.21%
Carcinogenicity	85	0.3%
Genotoxicity	96	0.34%
Reproductive toxicity	1181	4.16%
Developmental toxicity	122	0.43%
Kinetics	1548	5.45%
Ecotoxicity	2533	8.91%
Target animal safety	16	0.06%
Other toxicity/safety testing	255	0.9%
Total	28416	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	11499	95.51%

Non lethal methods	540	4.49%
Total	12039	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3314	46.25%
29 - 90 days	2051	28.63%
> 90 days	1800	25.12%
Total	7165	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2533	100%
Total	2533	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	17252	32.31%
Legislation on medicinal products for veterinary use and their residues	26854	50.29%
Industrial chemicals legislation	423	0.79%
Plant protection product legislation	6331	11.86%
Food legislation including food contact material	255	0.48%
Feed legislation including legislation for the safety of target animals, workers and environment	342	0.64%
Other legislation	1941	3.63%
Total	53398	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	50527	94.62%
Legislation satisfying national requirements only [within EU]	1941	3.63%
Legislation satisfying Non-EU requirements only	930	1.74%
Total	53398	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	95	15.37%
Monoclonal antibody by mouse ascites method	134	21.68%
Other product types	389	62.94%
Total	618	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	116882	98.23%
Yes	2112	1.77%
Total	118994	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	10773	9.05%

Mild [up to and including]	64770	54.43%
Moderate	27386	23.01%
Severe	16065	13.5%
Total	118994	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	110318	92.71%
Genetically altered without a harmful phenotype	7960	6.69%
Genetically altered with a harmful phenotype	716	0.6%
Total	118994	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	157		157
Rabbits	36		36
Zebra fish		1335	1335
Total	193	1335	1528

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	54	3.53%
Mild [up to and including]	692	45.29%
Moderate	782	51.18%
Total	1528	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	154	10.08%
Genetically altered without a harmful phenotype	717	46.92%
Genetically altered with a harmful phenotype	657	43%
Total	1528	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	36	2.36%
Nervous System	133	8.7%
Urogenital/Reproductive System	24	1.57%
Multisystemic	1335	87.37%
Total	1528	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Ireland

Ireland: Narrative 2018

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

- There was an 18% decrease in animal use from the previous year (2017).
- Translational and Applied research increased by 29% and Regulatory use and Routine Production decreased by 26%, with the other project purposes remaining stable.
- The use of mice has dropped by 28% from the previous year but remains the most commonly used species at 75%. Rabbits have dropped by 58%, sheep by 51% and dogs by 100%.
- The use of zebrafish has increased by 1300% and the use of other fish by 182%.
- There was a 73% decrease on reuse from 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.

- This decrease in total animal use (from 2017 to 2018) is mainly accounted for by a 26% decrease in regulatory testing. However, this followed an increase in regulatory testing by 14% from 2016 to 2017. The increase in the previous period was largely due to the breakdown of a cell based assay resulting in the need to revert to a mouse assay. The shift downwards seen in 2018 is likely due to the issues with this particular cell based assay being rectified, as well as a shift to non-animal alternatives for other similar products, due to regulatory approval being received for other cell based assays.
- The increase in Translational and Applied research in 2018 may be due to a greater emphasis being put on ensuring animal research is translatable, but may also be related to users becoming more familiar with the reporting requirements.
- The reduction in dogs from 2017 to 2018 was due to the closure of a large dog facility. The decrease in rabbits relates primarily to a reduction in pyrogen testing on rabbits due to the transition to non-animal alternative tests. The increased use of 'other fish' represents a greater research focus on the behaviour and conservation of wild fish. The increase in zebrafish is due to a large zebrafish project being authorised during 2018. The HPRA is not aware of any significant factor underlying the reduction in the numbers of sheep undergoing procedures in 2018. It should be noted however that to date in Ireland sheep have only been used for agricultural research (ovine nutritional studies, ovine reproductive studies etc.), and it may be possible that in 2018 studies of this nature were conducted, but the techniques utilised did not reach the threshold of a procedure.

- The 73% decrease on reuse from 2017 to 2018 is part of a trend as reuse has been decreasing consistently over the past 5 years. This is likely due to a reduction in the use of species that are more traditionally reused, e.g. rabbits, dogs and cats.

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

There was a 17% drop from the previous year in the number of severe procedures reported. The reduction in the proportion of procedures reported as severe is attributed to the reduction in regulatory use of animals, as well as efforts made by the HPRA, animal welfare bodies, and animal users to reduce the severity of procedures through the implementation of refinements and earlier humane endpoints.

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

- We have focused significant efforts (over the past number of years) in ensuring that there is a move to non-animal alternatives for batch potency testing; and this is now reflected in the 2018 figures as batch potency testing dropped by 28% from 2017. For the animals that still must be used for this type of testing, we have also mandated the implementation of humane endpoints for these tests. This has resulted in the percentage of animals used for batch potency testing, which were reported as 'severe', having decreased to 25% in 2018, down from 37% in 2017. We have also endeavoured to ensure that rabbit pyrogen testing is replaced where possible, and have had extensive communications with pharmaceutical companies that historically utilised this type of animal test to ensure this is the case. Since 2014 there has been a 76% 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 9% of animal use and 'other birds' less than 1%. These relate 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 2018.

Ireland: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	149256	75.05%
Rats	21595	10.86%
Guinea-Pigs	589	0.3%
Rabbits	171	0.09%
Ferrets	288	0.14%
Horses, donkeys and cross-breeds	54	0.03%
Pigs	1662	0.84%
Goats	19	0.01%
Sheep	644	0.32%
Cattle	2957	1.49%
Other mammals	1	0%
Domestic fowl	30	0.02%
Other birds	654	0.33%
Xenopus	42	0.02%
Zebra fish	3054	1.54%
Other fish	17854	8.98%
Total	198870	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	185182	93.12%
Animals born in the EU but not at a registered breeder	4908	2.47%
Animals born in rest of Europe	7680	3.86%
Animals born in rest of world	1100	0.55%
Total	198870	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	149256		149256
Rats	21595		21595
Guinea-Pigs	589		589
Rabbits	171		171
Ferrets	288		288
Horses, donkeys and cross-breeds	54		54
Pigs	1662		1662
Goats	19		19
Sheep	644		644
Cattle	2957	180	3137
Other mammals	1		1
Domestic fowl	30		30
Other birds	654		654
Xenopus	42		42
Zebra fish	3054		3054
Other fish	17854		17854
Total	198870	180	199050

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	7734	3.89%
Translational and applied research	38337	19.26%
Regulatory use and Routine production	143895	72.29%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8741	4.39%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	343	0.17%
Total	199050	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	30	0.39%
Cardiovascular Blood and Lymphatic System	59	0.76%
Nervous System	2968	38.38%
Respiratory System	82	1.06%
Gastrointestinal System including Liver	511	6.61%
Musculoskeletal System	46	0.59%
Immune System	1707	22.07%
Urogenital/Reproductive System	28	0.36%
Sensory Organs (skin, eyes and ears)	24	0.31%
Endocrine System/Metabolism	6	0.08%
Multisystemic	107	1.38%
Ethology / Animal Behaviour /Animal Biology	2166	28.01%
Total	7734	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1202	3.14%
Human Infectious Disorders	768	2%
Human Cardiovascular Disorders	971	2.53%
Human Nervous and Mental Disorders	9369	24.44%
Human Respiratory Disorders	227	0.59%
Human Gastrointestinal Disorders including Liver	1063	2.77%
Human Musculoskeletal Disorders	788	2.06%
Human Immune Disorders	5838	15.23%
Human Urogenital/Reproductive Disorders	122	0.32%
Human Sensory Organ Disorders (skin, eyes and ears)	4110	10.72%
Human Endocrine/Metabolism Disorders	1347	3.51%
Animal Diseases and Disorders	3425	8.93%
Animal Welfare	9095	23.72%
Diagnosis of diseases	12	0.03%
Total	38337	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	143578	99.78%
Toxicity and other safety testing including pharmacology	300	0.21%
Routine production	17	0.01%
Total	143895	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4587	3.19%
Pyrogenicity testing	145	0.1%
Batch potency testing	138846	96.7%
Total	143578	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	300	100%
Total	300	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	300	100%
Total	300	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	143556	99.78%
Legislation on medicinal products for veterinary use and their residues	22	0.02%
Other legislation	300	0.21%
Total	143878	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	143878	100%
Total	143878	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	17	100%
Total	17	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	198870	99.91%
Yes	180	0.09%
Total	199050	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	1065	0.54%
Mild [up to and including]	109654	55.09%
Moderate	54606	27.43%
Severe	33725	16.94%
Total	199050	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	189518	95.21%
Genetically altered without a harmful phenotype	5991	3.01%
Genetically altered with a harmful phenotype	3541	1.78%
Total	199050	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	253		253
Rats	40		40
Total	293		293

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	211	72.01%
Moderate	82	27.99%
Total	293	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	40	13.65%
Genetically altered without a harmful phenotype	186	63.48%
Genetically altered with a harmful phenotype	67	22.87%
Total	293	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Gastrointestinal System including Liver	91	59.48%
Immune System	22	14.38%
Multisystemic	40	26.14%
Total	153	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cardiovascular Disorders	33	23.57%
Human Nervous and Mental Disorders	67	47.86%
Human Musculoskeletal Disorders	40	28.57%
Total	140	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	457		457
Total	457		457

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	337	73.74%
Moderate	99	21.66%
Severe	21	4.6%
Total	457	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	428	93.65%

Genetically altered with a harmful phenotype	29	6.35%
Total	457	100.00%

Italy

Italy: Narrative 2018

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

The downward trend in the total number of animals used for scientific purposes for the first time ('naive' animals) continued also in 2018. In total, 553 208 animals were used in scientific procedures in 2018, a decline of 3.76% compared to the previous year (see Figure 1).

Figure 1

Total number of animals used in Italy in the period 2015-2018

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

In terms of species, rodents and rabbits accounted for 86% of the animals, including reused animals, used in testing in 2015-2018 (see Table 1). Within these species, the number of rodents fell compared to the previous year.

There was a decrease in the number of non-human primates compared to 2017. Non-human primates are primarily used for regulatory tests (toxicity and other safety tests) required by European and international law, at a rate which has continued increasing (from 86.75% in 2015 to 99% in 2018). Accordingly there has been a percentage decrease in non-human primates used in basic research over the three-year period (from 11.67% in 2015 to 1% in 2018).

The most frequently used species was Macaca *fascicularis*. In 2018 generation F1 animals accounted for 24% of the animals used owing to reduced availability of generation F2 animals from breeders and suppliers of non-human primates and the simultaneous increase in the number of regulatory tests.

Table 1

Animal species	% of 2015 total	% of 2016 total	% of 2017 total	% of 2018 total	Mean (%) 2015-2018	% difference between years 2015-2018
Rodents	89.02%	87.43%	84.73%	83.49%	86.17%	-5.53%
Rabbits	1.66%	2.49%	3.33%	2.19%	2.42%	+0.53%
Total rodents + rabbits	**90.68%**	**89.82%**	**88.06%**	**85.68%**	**88.56%**	-5.00%
Total other animal species	**9.32%**	**10.18%**	**11.94%**	**14.32%**	**11.44%**	+5.00%
Total (all species)	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	

The breakdown for all animal species was as follows in 2018 (see Table 2):

29.11% of the animals were used in basic biological studies.
32.74% were used in translational or applied research.
37.36% were used for regulatory use and routine production.
79% were used for other purposes.
No animals were used for forensic studies.

Table 2
Animal use by purpose of study

Purpose of study	2015	2016	2017	2018
Basic research	37.26%	35.42%	33.55%	29.11%
Translational research	24.92%	26.54%	26.48%	32.74%
Regulatory testing	36.07%	37.11%	38.96%	37.36%
Other	1.75%	0.93%	1.01%	0.79%

The downward trend in the number of animals used for basic research and the increase in animals used for translational or applied research was confirmed in 2018.

Regulatory testing (experiments that are compulsory under national, European or 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 on the level of suffering felt by animals (see Table 3) was recorded for the fifth time in 2018.

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%
2018	4.12%	50.10%	28.62%	17.16%

Comparing the data for 2015 to 2018 shows that:

- there were slight variations in the 'non-recovery' and 'mild' suffering levels, which together account for 54%;
- there was a slight decrease in the 'moderate' suffering level;
- there was an increase of 1.66% in the 'severe' category.

Mice accounted for 78% of the increase in the 'severe' suffering level and was thus the most affected species.

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 Directive, designated the **laboratory of the Department for cell substrates and cellular immunology** 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 procedures proposed for validation studies.

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 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.

In 2018 the National Committee organised a first convention of animal welfare bodies (*Organismi Preposti al Benessere Animale*), the outcome of which was that animal welfare bodies should be coordinated nationally with the aim of harmonising their work and sharing best practice, in particular as

regards preliminary assessment of research projects with a view to issuing the reasoned opinion needed for authorisation applications for such projects.

Animal welfare bodies

In general terms, 2018 confirmed the trend towards greater awareness among and increased capacity for intervention by the animal welfare bodies 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 '3Rs' principle, particularly as regards the replacement or reduction of animal use, with clear results in the basic research area.

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 numerous 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 (regarding immunogenicity for human vaccines)

Other efficacy and tolerance testing (regarding production of inactivated antigens for animal vaccines)

Animals used in the toxicity/ecotoxicity testing sector:

Other tests: Diagnostic ecotoxicity testing on waste

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	330716	60.45%
Rats	111057	20.3%
Guinea-Pigs	13852	2.53%
Hamsters (Syrian)	288	0.05%

Other rodents	698	0.13%
Rabbits	12141	2.22%
Dogs	365	0.07%
Ferrets	9	0%
Pigs	1457	0.27%
Goats	16	0%
Sheep	96	0.02%
Cattle	638	0.12%
Cynomolgus monkey	473	0.09%
Other mammals	25	0%
Domestic fowl	40382	7.38%
Other birds	409	0.07%
Xenopus	222	0.04%
Zebra fish	12115	2.21%
Other fish	22124	4.04%
Cephalopods	46	0.01%
Total	547129	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	503191	92.05%
Animals born in the EU but not at a registered breeder	42027	7.69%
Animals born in rest of Europe	60	0.01%
Animals born in rest of world	1378	0.25%
Total	546656	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	2	0.42%
Animals born in Asia	251	53.07%
Animals born in Africa	220	46.51%
Total	473	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	114	24.1%
F2 or greater	359	75.9%
Total	473	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	330716	517	331233
Rats	111057	209	111266
Guinea-Pigs	13852	226	14078
Hamsters (Syrian)	288		288
Other rodents	698		698
Rabbits	12141	859	13000
Dogs	365	76	441
Ferrets	9		9
Horses, donkeys and cross-breeds		15	15
Pigs	1457	69	1526
Goats	16	20	36
Sheep	96	60	156
Cattle	638	55	693
Marmoset and tamarins		1	1
Cynomolgus monkey	473	38	511
Other mammals	25		25
Domestic fowl	40382	1771	42153
Other birds	409		409
Xenopus	222	23	245
Zebra fish	12115		12115
Other fish	22124	279	22403
Cephalopods	46		46
Total	547129	4218	551347

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	158745	28.79%
Translational and applied research	180790	32.79%
Regulatory use and Routine production	208263	37.77%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2110	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1439	0.26%
Total	551347	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	38504	24.26%
Cardiovascular Blood and Lymphatic System	9258	5.83%
Nervous System	66746	42.05%
Respiratory System	727	0.46%
Gastrointestinal System including Liver	2445	1.54%
Musculoskeletal System	7302	4.6%
Immune System	11504	7.25%
Urogenital/Reproductive System	2279	1.44%

Sensory Organs (skin, eyes and ears)	4731	2.98%
Endocrine System/Metabolism	4044	2.55%
Multisystemic	1637	1.03%
Ethology / Animal Behaviour /Animal Biology	4245	2.67%
Other basic research	5323	3.35%
Total	158745	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	53139	29.39%
Human Infectious Disorders	20268	11.21%
Human Cardiovascular Disorders	2163	1.2%
Human Nervous and Mental Disorders	23263	12.87%
Human Respiratory Disorders	16517	9.14%
Human Gastrointestinal Disorders including Liver	3533	1.95%
Human Musculoskeletal Disorders	11459	6.34%
Human Immune Disorders	4256	2.35%
Human Urogenital/Reproductive Disorders	1728	0.96%
Human Sensory Organ Disorders (skin, eyes and ears)	1884	1.04%
Human Endocrine/Metabolism Disorders	4788	2.65%
Other Human Disorders	3104	1.72%
Animal Diseases and Disorders	20489	11.33%
Animal Welfare	1183	0.65%
Diagnosis of diseases	12839	7.1%
Non-regulatory toxicology and ecotoxicology	177	0.1%
Total	180790	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	106515	51.14%
Other efficacy and tolerance testing	38468	18.47%
Toxicity and other safety testing including pharmacology	60938	29.26%
Routine production	2342	1.12%
Total	208263	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	27200	25.54%
Pyrogenicity testing	2243	2.11%
Batch potency testing	73895	69.38%
Other quality controls	3177	2.98%
Total	106515	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	10171	16.69%
Skin irritation/corrosion	870	1.43%
Skin sensitisation	10636	17.45%
Eye irritation/corrosion	153	0.25%
Repeated dose toxicity	7516	12.33%
Genotoxicity	623	1.02%
Reproductive toxicity	790	1.3%
Developmental toxicity	4355	7.15%

Neurotoxicity	600	0.98%
Kinetics	6298	10.34%
Pharmaco-dynamics (incl safety pharmacology)	968	1.59%
Ecotoxicity	6083	9.98%
Safety testing in food and feed area	9456	15.52%
Target animal safety	654	1.07%
Other toxicity/safety testing	1765	2.9%
Total	60938	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	1453	14.29%
Other lethal methods	62	0.61%
Non lethal methods	8656	85.1%
Total	10171	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3293	43.81%
29 - 90 days	3691	49.11%
> 90 days	532	7.08%
Total	7516	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	4424	72.73%
Other ecotoxicity	1659	27.27%
Total	6083	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	125134	60.77%
Legislation on medicinal products for veterinary use and their residues	41415	20.11%
Medical devices legislation	16788	8.15%
Industrial chemicals legislation	6935	3.37%
Plant protection product legislation	140	0.07%
Biocides legislation	56	0.03%
Food legislation including food contact material	10981	5.33%
Feed legislation including legislation for the safety of target animals, workers and environment	412	0.2%
Other legislation	4060	1.97%
Total	205921	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	191112	92.81%
Legislation satisfying national requirements only [within EU]	3027	1.47%
Legislation satisfying Non-EU requirements only	11782	5.72%
Total	205921	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1582	67.55%
Other product types	760	32.45%
Total	2342	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	547129	99.23%
Yes	4218	0.77%
Total	551347	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	22749	4.13%
Mild [up to and including]	277150	50.27%
Moderate	156763	28.43%
Severe	94685	17.17%
Total	551347	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	441685	80.11%
Genetically altered without a harmful phenotype	92540	16.78%
Genetically altered with a harmful phenotype	17122	3.11%
Total	551347	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	4426		4426
Rats	18		18
Pigs	25		25
Zebra fish	556		556
Other fish	226		226
Total	5251		5251

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	226	4.3%
Mild [up to and including]	1369	26.07%
Moderate	2669	50.83%
Severe	987	18.8%
Total	5251	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	970	18.47%
Genetically altered without a harmful phenotype	3052	58.12%
Genetically altered with a harmful phenotype	1229	23.41%
Total	5251	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	2485	70.08%
Cardiovascular Blood and Lymphatic System	71	2%
Nervous System	501	14.13%
Gastrointestinal System including Liver	6	0.17%
Musculoskeletal System	84	2.37%
Immune System	99	2.79%
Urogenital/Reproductive System	10	0.28%
Endocrine System/Metabolism	254	7.16%
Multisystemic	36	1.02%
Total	3546	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	130	7.62%
Human Cardiovascular Disorders	4	0.23%
Human Nervous and Mental Disorders	605	35.48%
Human Respiratory Disorders	33	1.94%
Human Gastrointestinal Disorders including Liver	31	1.82%
Human Musculoskeletal Disorders	49	2.87%
Human Urogenital/Reproductive Disorders	40	2.35%
Other Human Disorders	813	47.68%
Total	1705	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	828		828
Total	828		828

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	719	86.84%
Moderate	104	12.56%
Severe	5	0.6%
Total	828	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	583	70.41%
Genetically altered with a harmful phenotype	245	29.59%
Total	828	100.00%

Latvia

Latvia: Narrative 2018

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

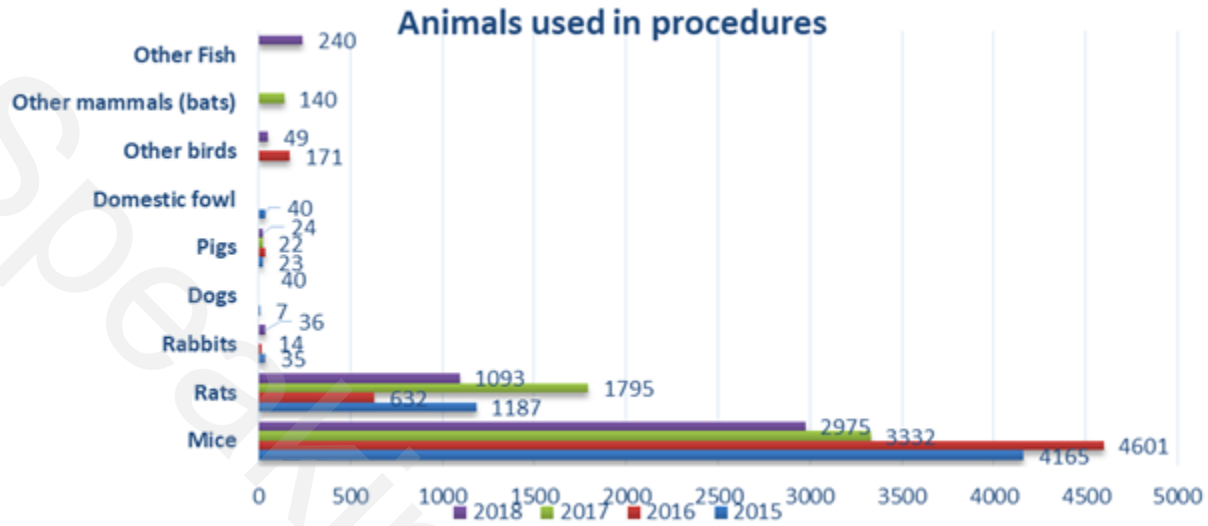
In 2016 competent authority has approved 3 projects, in 2017 – 13, but in 2018 - 8. Since the previous years, animal amount used for scientific purposes have not significantly changed (5458 in 2016 and 5289 in 2017), but decreased 4417 –in 2018. During the 2016 active licence was for 17 projects, in 2017 – for 25, but in 2018 – for 29 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.

In 2018 increased the use of genetically altered animals without harmful phenotype. In previous two years 60 genetically altered animals were used per year, however in 2018 -315 (total increase from 1.13% to 7.13%). The main reason for this is related to studies concerned specific diseases and their treatment. As to evaluate new substances for treatment and new methods of therapy, the pathological model is needed. As the science continuously develops, now is less harmful to use already genetically altered animal as a model instead of making pathological state model using specific diet or surgery. In most of cases by using genetically altered animals we can get the very beginning of the disease/pathological state that has no clinical signs, but can be detected only by specific diagnostic devices or analysis. However thus very beginning of pathological state is enough for the study and in result animals are exposed to a lighter procedure. Moreover, in some cases using animals as the models for studies of vaccines and immunological treatment of cancer, there is a need for model that is very close to human in some specific nuances (for example some cell receptors). Using genetically altered animals we can replace the use of species with higher sensitivity with species with lover sensitivity (for example instead of using primates is possible to use mice or rats).

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 decreased from 84.3% in 2016 (n=4601) to 63.0% (3332) in 2016 but in 2018 – increased percentage distribution however total amount of using this species decreased 67.4% (2975) (see Fig.1). The total amount of used rats have increased from 11.58% (n=632) in 2016 to 33.94% (1795) in 2017, but decreased in 2018 to 24.7% (1093). 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 allow to use less animals and get more necessary data. Compeering previous years in 2018 49 wild birds were used for study concerned to protection of natural environment in the interests of health of animals. In 2018 the project was continued from previous years.

Figure 1

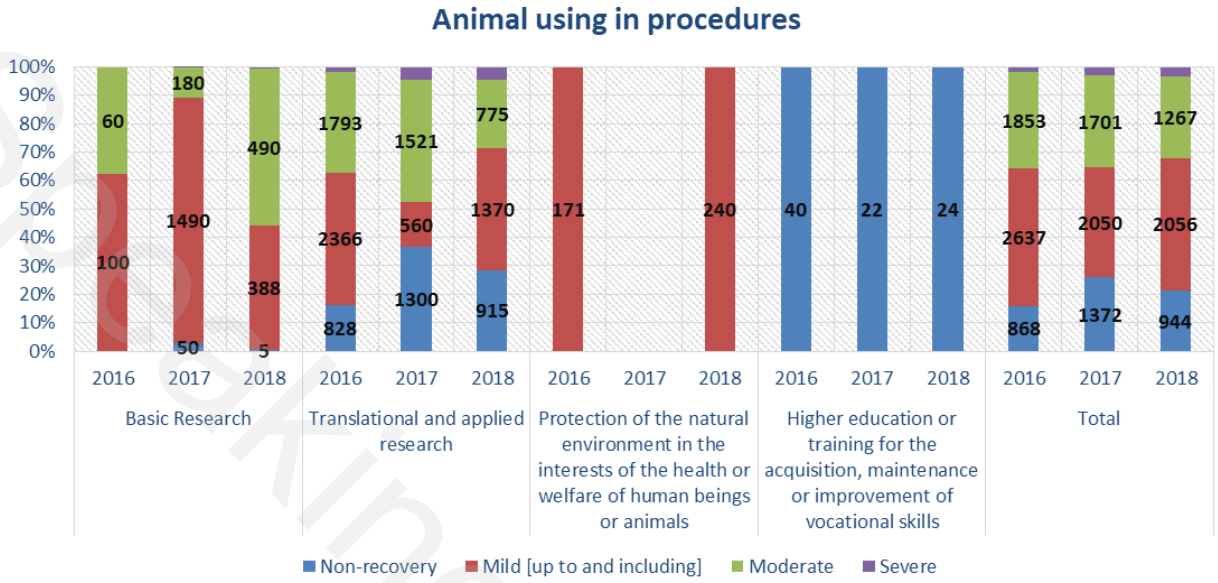


3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

All animals used in procedures come from EU origin, and the biggest part 93.46% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2 and Fig. 3) – 46.55. (n=2056 from which 1996 were used for planned mild procedures, but 30 mice (Purpose - Basic Research (Nervous System)) and 24 rats (Purpose - Trans/Appl Research (Human Nervous and Mental Disorders)) were used as control group in moderate procedure and were shame operated that finally did not cause further disabilities or dysfunctions except skin cut and finally resulted as a mild procedure.

Figure 2

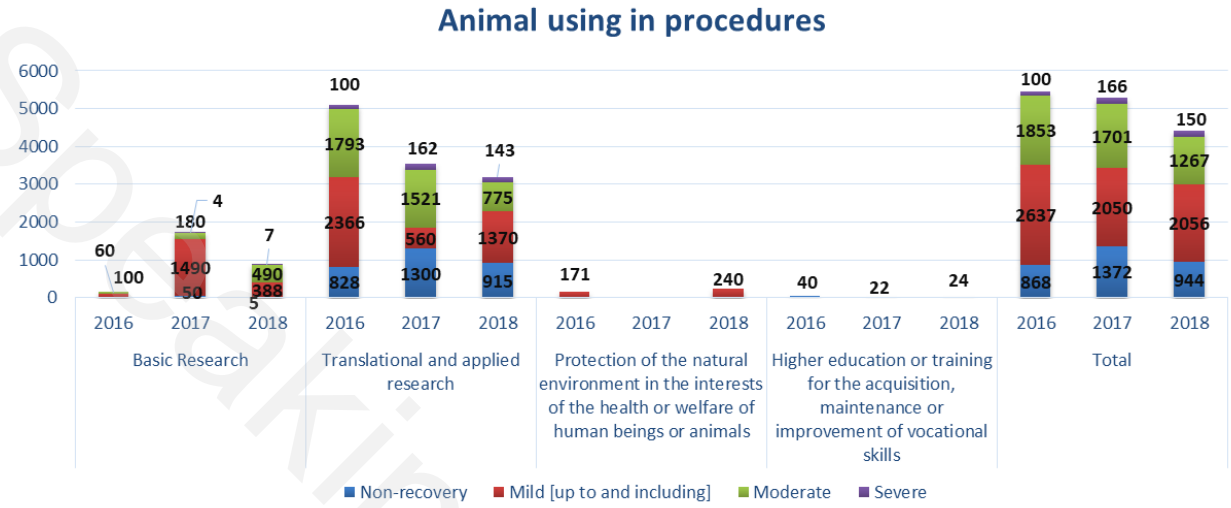


In total 150 (3.4%) animals in 2018 were used in severe procedures from which 135 animals were used for planned severe procedures 4 mice (for purpose Trans/Appl Research (Human Nervous and Mental Disorders)) and 48 rats from three projects went through severe planned procedure(for purpose Trans/Appl Research (Human Cardiovascular Disorders)).

1. During moderate procedure (Basic Research (Oncology)) 7 mice developed urinary obstruction due to the tumour mass growth into urethra, and resulted in *hydronephrosis.*

2. During moderate procedure (Trans/Appl Research (Human Cancer)) 8 mice lost weight more than 25% and therefore animals were humanely killed and were not included in further manipulations

Figure 3



In moderate procedures in 2018 were used 1267 (28.68%) animals from which 878 mice and 286 rats were exposed to previous planned moderate procedures, but

1. 72 mice used in Basic Research (Oncology) purpose underwent moderate procedure instead of planned severe because of the formation of metastases was smaller as planned previous and thus easer for animals.
2. one mice from planned mild procedure (Trans/Appl Research (Animal Diseases and Disorders)) died without previously detectable signs of suffering.

In 2018 in non-recovery procedures were used 944 animals from which 932 were used for planned non-recovery procedures – a)Higher education or training for the acquisition, maintenance or improvement of vocational skills – 24 pigs, b) Trans/Appl Research (Human Cardiovascular Disorders) – 563 rats, c) Trans/Appl Research (Human Nervous and Mental Disorders) – 310 mice and 30 rats.

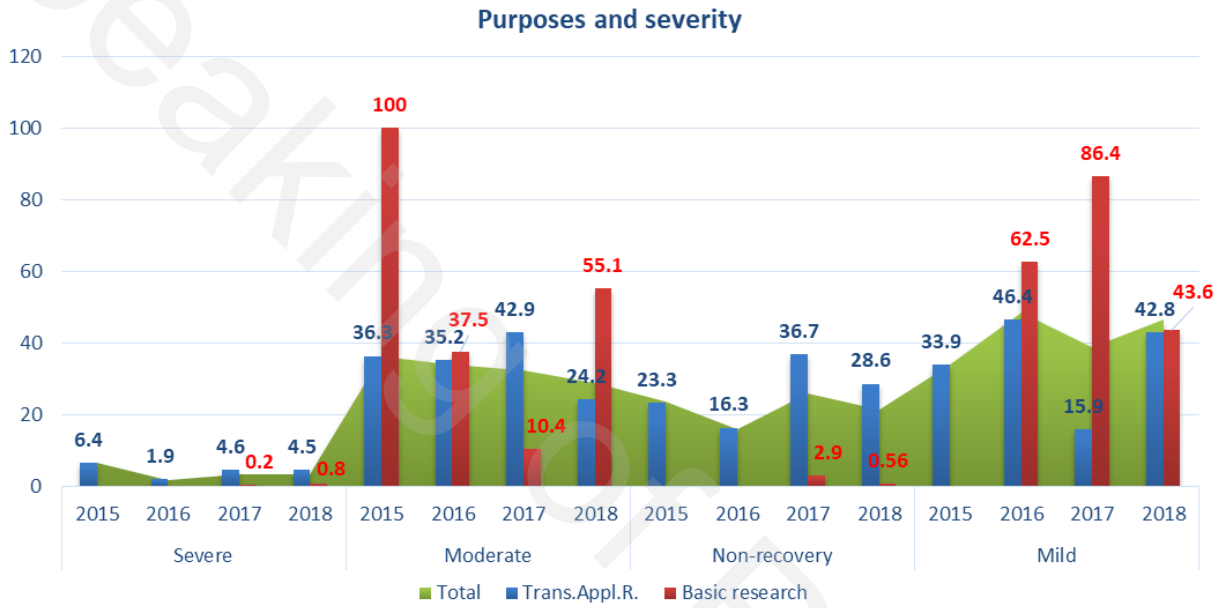
Animals from planned severe procedures – 2 rats from procedure with Trans/Appl Research (Human Cardiovascular Disorders) purpose and mice from previous planned moderate procedure – 5 from procedure with Trans/Appl Research (Human Nervous and Mental Disorders) purpose and 2 from procedure with Trans/Appl Research (Human Cardiovascular Disorders) purpose died during the surgical manipulations before any other tests therefore actually were exposed to non-recovery procedures.

In general observation there are evident changes in severity of procedures. Comparing previous year in 2018 decreased animal using in severe and non-recovery procedures. That is explained by continuous advising and asking scientists to use more lighter procedures, as well as they use consult each other and take a part in international projects in this way getting best experience and practice from foreign colleagues.

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 (translation and applied research)for the last year decreased animal using, especially in harder procedures (see Fig. 4), but in 2018 increased animal using in mild procedures. However in basic research field decreased total amount of used animals as well as decreased amount of used animals in mild procedures, but increased animal using for moderate procedures. That is because of several studies devoted to basic cancer development processes with additional aim to detect immunological aspects that could serve as a next step for discovering new immunological treatment for this serious disease.

Figure 4



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures from 2015 to 2018) 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. As well as scientists uses organs and tissue from animals that were used in other procedures as a control group animals after euthanasia.

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 2018, as the project was continued from 2014, 28 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 manipulations (cuts, trainings of surgical techniques) were done with each animal under anaesthesia and narcosis to decrease a total amount of animals.

Also in 2018 120 *Salmo salar* and 120 *Salmo trutta* was used for study concerned to protection of natural environment in the interests of health of animals. Study was devoted for finding more effective ways to contribute the survival of juvenile fish after release into wild water bodies.

Comparing previous year, in 2018 49 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 2017, but in 2018 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 2018 there have not been any cases or detected information from users that the 'severe' classification was exceeded in any of procedures.

In 2018 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	2975	67.35%
Rats	1093	24.75%
Rabbits	36	0.82%
Pigs	24	0.54%
Other birds	49	1.11%
Other fish	240	5.43%
Total	4417	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4128	93.46%
Animals born in the EU but not at a registered breeder	49	1.11%
Animals born in rest of Europe	240	5.43%
Total	4417	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	2975		2975
Rats	1093		1093
Rabbits	36		36
Pigs	24		24
Other birds	49		49
Other fish	240		240
Total	4417		4417

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	890	20.15%
Translational and applied research	3203	72.52%
Regulatory use and Routine production	60	1.36%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	240	5.43%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	24	0.54%
Total	4417	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	141	15.84%
Cardiovascular Blood and Lymphatic System	30	3.37%
Nervous System	265	29.78%
Musculoskeletal System	88	9.89%
Endocrine System/Metabolism	72	8.09%
Ethology / Animal Behaviour /Animal Biology	294	33.03%
Total	890	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	352	10.99%
Human Infectious Disorders	30	0.94%
Human Cardiovascular Disorders	653	20.39%
Human Nervous and Mental Disorders	1795	56.04%
Human Urogenital/Reproductive Disorders	145	4.53%
Animal Diseases and Disorders	216	6.74%
Non-regulatory toxicology and ecotoxicology	12	0.37%
Total	3203	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	60	100%
Total	60	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Skin sensitisation	60	100%
Total	60	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	60	100%
Total	60	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	60	100%
Total	60	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	4417	100%
Total	4417	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	944	21.37%
Mild [up to and including]	2056	46.55%
Moderate	1267	28.68%
Severe	150	3.4%
Total	4417	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	4102	92.87%
Genetically altered without a harmful phenotype	315	7.13%
Total	4417	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Lithuania

Lithuania: Narrative 2018

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

In 2018, there were 3286 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, 520 (were 2766) 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 to 14 in 2017 and to 15 in 2019.

In 2018 were the large increase in the use of fish for “Basic Research”, “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and “(Regulatory use/Toxicity and..) Genotoxicity”.

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 regulatory use / toxicity / routine production (Genotoxicity, Non lethal methods, Pharmaco-dynamics, Blood based products) (~ 45 %), then basic research (Oncology, Nervous System, Immune System) (~ 22 %), for the purpose “Translational and applied research” (~ 12,9%), and for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” (~ 10,4 %).

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 2018 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 (~92 %) were used for the procedures classified as mild [up to and including] severity, (~6 %) for the procedures classified as moderate and (~ 2 %) for non-recovery severity.

Decrease in use of animals for the procedures classified as moderate and non-recovery during year 2018-2019. More animals were used for the procedures classified as mild because some establishment did not perform any projects due to reconstruction of premises for some time.

There were no exceeding of the ‘severe’ classification reported in 2018 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 fish (Oncorhynchus mykiss 89,5%, Salmo salar 10,5% from total fish amount) (~ 41 % from total animals amount) were used during the reporting in 2018.

The clearest trend in 2018 was the large increase in the use of fish for research. The main reason is, that established started performing projects with specific focus on fish.

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 2018.

Lithuania: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1573	47.87%
Rats	311	9.46%
Guinea-Pigs	15	0.46%
Rabbits	31	0.94%
Pigs	4	0.12%
Other fish	1352	41.14%
Total	3286	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	3286	100%
Total	3286	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1573		1573
Rats	311		311
Guinea-Pigs	15		15
Rabbits	31		31
Pigs	4		4
Other fish	1352		1352
Total	3286		3286

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1005	30.58%
Translational and applied research	551	16.77%
Regulatory use and Routine production	348	10.59%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1382	42.06%
Total	3286	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	387	38.51%
Nervous System	142	14.13%
Musculoskeletal System	4	0.4%
Immune System	472	46.97%
Total	1005	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	199	36.12%
Human Nervous and Mental Disorders	54	9.8%
Human Sensory Organ Disorders (skin, eyes and ears)	13	2.36%
Other Human Disorders	28	5.08%
Non-regulatory toxicology and ecotoxicology	257	46.64%
Total	551	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	45	12.93%
Routine production	303	87.07%
Total	348	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	30	66.67%
Skin sensitisation	15	33.33%
Total	45	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	30	100%
Total	30	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for veterinary use and their residues	45	100%
Total	45	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	45	100%
Total	45	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	303	100%
Total	303	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	3286	100%
Total	3286	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	71	2.16%
Mild [up to and including]	3016	91.78%
Moderate	199	6.06%
Total	3286	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	3286	100%
Total	3286	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Luxembourg

Luxembourg: Narrative 2018

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

In Luxembourg we could observe a decrease in the total number of uses from 25.841 total uses in 2017 to 14 656 in 2018. This trend is due to the completion of a big project with the use of zebrafish.

Considering the distribution among the species, a total number of 5 572 mammals were used in procedures in 2017 and 7 817 mammals 2019. These figures represent an increase of 40,3% of the total uses of mammals from 2017 to 2018.

In 2017, 20 173 zebrafishes were used and zebrafishes represented the most used species.

In 2018, mice are the most used species with 7 817 number of uses and the number uses of zebrafishes drops to 6 728 uses.

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 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 (5 facilities in total), the development of the animal facilities has a strong impact on the total number of animals used. In particular a big project with zebrafish was completed in 2017, which has an impact on the decrease of 43, 28% of the total number of uses in 2018.

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

Comparing the actual severities from 2017 to 2018 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 meeting with the animal welfare bodies took place focusing on the 3Rs,

- 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 appropriate general or local anaesthesia and that appropriate 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 2018 there was no case where the severe-classification has been exceeded.

Luxembourg: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	7019	51.04%
Rats	111	0.81%
Zebra fish	6621	48.15%
Total	13751	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	13751	100%
Total	13751	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	7019	650	7669
Rats	111		111
Zebra fish	6621		6621
Total	13751	650	14401

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	13294	92.31%
Translational and applied research	936	6.5%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	171	1.19%
Total	14401	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2691	20.24%
Nervous System	7584	57.05%
Immune System	3019	22.71%
Total	13294	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	867	92.63%
Human Immune Disorders	69	7.37%
Total	936	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	13751	95.49%
Yes	650	4.51%
Total	14401	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	594	4.12%
Mild [up to and including]	10447	72.54%
Moderate	3153	21.89%
Severe	207	1.44%
Total	14401	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	8048	55.89%
Genetically altered without a harmful phenotype	5400	37.5%
Genetically altered with a harmful phenotype	953	6.62%
Total	14401	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	148		148
Total	148		148

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	39	26.35%
Moderate	109	73.65%
Total	148	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	148	100%
Total	148	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	148	100%
Total	148	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Zebra fish	107		107
Total	107		107

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	107	100%
Total	107	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	107	100%
Total	107	100.00%

Malta

Malta: Narrative 2018

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

   A scientific program involving live fish has been approved in 2017. Another scientific research has been approved in the same year and will have a duration period of 3 years.

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

   In view of the above fact, it was a significant increase of the use of live animals for scientific purposes. The animals involved for the second approved research were 250,000 fish and it was chosen as the minimum requirement for accurate statistical testing.

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

   The severity of the research program in the second study has increased due to the nature of the proposal (study on toxicity in fish).

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

   The two scientific project manager actually ongoing declared that the three principle are being observed.

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. Both the studies have a severity classified as mild pain.

Malta: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Other fish	119	100%
Total	119	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	119	100%
Total	119	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Other fish	119		119
Total	119		119

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Translational and applied research	119	100%
Total	119	100.00%

Basic research related uses

Basic research	Number of uses	Percentage

No data reported

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	119	100%
Total	119	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage

No data reported

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

No data reported

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

No data reported

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	119	100%
Total	119	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Mild [up to and including]	119	100%
Total	119	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	119	100%
Total	119	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Netherlands

Netherlands: Narrative 2018

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

In 2018, the Dutch establishments reported 401,895 animals used in procedures. This is 75,655 (15.8%) less than in 2017. Especially the number of mice (-50,469), and zebrafish (-32,089) and other birds (-7,598) was reduced. The number of other fish (+9,399), guinea pigs (+5,627) and rabbits (+4,024) and dogs (+107) was increased.

In 2018 animals were 10,522 times reused, which is 616 animals less than in 2017 (11,138). Reuse mainly takes place for the purpose of fundamental research and 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.

The total number of animal uses in 2018 is within the normal range of fluctuation of previous years. The increase in the number of rabbits is attributed to the increased use of genetically modified rabbits for the treatment of genetic disorders in humans. The increase in guinea pigs is related to the relocation of activities of a commercial breeder to the Netherlands. The increase in the number of dogs is caused by an increase of trials for the development of drugs against various types of cancer, neurological-, cardiovascular- and immunological diseases.

In 2018, 71,710 procedures were reported with the use of genetically altered animals. This is a reduction of 61,655 animals compared to 2017 (133,365). Most animal testing on genetically modified animals have carried out on mice (79.9%) and zebrafish (17.3%).

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

The actual severities reported in 2018 (mild 61.9%, moderate 25.7%, severe 1.5%, and non-recovery: 10.9%) are generally in line with the actual severities reported in 2017.

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: 74 Mustela lutreola (European (Russian) mink), 5 Martes martes (European pine marten), 5 Meles meles (European badger).

Other birds: 4091 Parus major (great tit), 1372 Limosa limosa (black tailed godwit), 1261 Ficedula hypoleuca (European pied flycatcher**)**, 1041 Cyanistes caeruleus (Eurasian blue tit).

Other fish: 11,723 Anguilla anguilla (European eel), 2195 Pimephales promelas (fathead minnow), 1890 Gasterosteus aculeatus (three horned stickleback), 1540 Oreochromis niloticus (tilapia), 1417 Cyprinus carpio, 1339 Rutilus rutilus (common roach).

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 2018 exceedance of the severity classification 'severe' has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	142687	37.34%
Rats	90275	23.62%
Guinea-Pigs	11372	2.98%
Hamsters (Syrian)	911	0.24%
Mongolian gerbil	105	0.03%
Other rodents	668	0.17%
Rabbits	13622	3.56%
Cats	69	0.02%
Dogs	542	0.14%
Ferrets	437	0.11%
Other carnivores	84	0.02%
Horses, donkeys and cross-breeds	84	0.02%
Pigs	10502	2.75%
Goats	114	0.03%
Sheep	543	0.14%
Cattle	1634	0.43%
Marmoset and tamarins	42	0.01%
Rhesus monkey	109	0.03%
Other mammals	225	0.06%
Domestic fowl	49131	12.86%
Other birds	13514	3.54%
Reptiles	125	0.03%
Xenopus	273	0.07%
Zebra fish	19881	5.2%
Other fish	25206	6.6%
Total	382155	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	284949	74.59%
Animals born in the EU but not at a registered breeder	88610	23.2%
Animals born in rest of world	8445	2.21%
Total	382004	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	151	100%
Total	151	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
Self-sustaining colony	151	100%
Total	151	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	142687	3671	146358
Rats	90275	1304	91579
Guinea-Pigs	11372	71	11443
Hamsters (Syrian)	911		911
Mongolian gerbil	105		105
Other rodents	668		668
Rabbits	13622	166	13788
Cats	69	51	120
Dogs	542	474	1016
Ferrets	437	38	475
Other carnivores	84		84
Horses, donkeys and cross-breeds	84	62	146
Pigs	10502	92	10594
Goats	114	11	125
Sheep	543	100	643
Cattle	1634	1973	3607
Marmoset and tamarins	42	3	45
Rhesus monkey	109	51	160
Other mammals	225		225
Domestic fowl	49131	1875	51006
Other birds	13514	370	13884
Reptiles	125		125
Xenopus	273	128	401
Zebra fish	19881		19881
Other fish	25206	80	25286
Total	382155	10520	392675

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	144093	36.7%
Translational and applied research	112229	28.58%
Regulatory use and Routine production	118310	30.13%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1678	0.43%
Preservation of species	1548	0.39%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	14801	3.77%
Forensic enquiries	16	0%
Total	392675	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	30247	20.99%
Cardiovascular Blood and Lymphatic System	3203	2.22%
Nervous System	16269	11.29%

Respiratory System	1389	0.96%
Gastrointestinal System including Liver	2360	1.64%
Musculoskeletal System	642	0.45%
Immune System	10472	7.27%
Urogenital/Reproductive System	1307	0.91%
Sensory Organs (skin, eyes and ears)	1398	0.97%
Endocrine System/Metabolism	4684	3.25%
Multisystemic	1284	0.89%
Ethology / Animal Behaviour /Animal Biology	26367	18.3%
Other basic research	44471	30.86%
Total	144093	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	12651	11.27%
Human Infectious Disorders	12246	10.91%
Human Cardiovascular Disorders	5642	5.03%
Human Nervous and Mental Disorders	8121	7.24%
Human Respiratory Disorders	872	0.78%
Human Gastrointestinal Disorders including Liver	1216	1.08%
Human Musculoskeletal Disorders	558	0.5%
Human Immune Disorders	3285	2.93%
Human Urogenital/Reproductive Disorders	678	0.6%
Human Sensory Organ Disorders (skin, eyes and ears)	761	0.68%
Human Endocrine/Metabolism Disorders	1064	0.95%
Other Human Disorders	459	0.41%
Animal Diseases and Disorders	20987	18.7%
Animal Welfare	34468	30.71%
Diagnosis of diseases	1419	1.26%
Plant diseases	3	0%
Non-regulatory toxicology and ecotoxicology	7799	6.95%
Total	112229	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	41765	35.3%
Other efficacy and tolerance testing	2798	2.36%
Toxicity and other safety testing including pharmacology	73495	62.12%
Routine production	252	0.21%
Total	118310	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1326	3.17%
Batch potency testing	40179	96.2%
Other quality controls	260	0.62%
Total	41765	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1452	1.98%
Skin irritation/corrosion	25	0.03%
Skin sensitisation	2752	3.74%

Eye irritation/corrosion	34	0.05%
Repeated dose toxicity	8304	11.3%
Carcinogenicity	508	0.69%
Genotoxicity	32	0.04%
Reproductive toxicity	28678	39.02%
Developmental toxicity	24923	33.91%
Kinetics	858	1.17%
Pharmaco-dynamics (incl safety pharmacology)	2	0%
Phototoxicity	108	0.15%
Ecotoxicity	3680	5.01%
Safety testing in food and feed area	1120	1.52%
Target animal safety	1019	1.39%
Total	73495	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
Non lethal methods	1452	100%
Total	1452	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	3936	47.4%
29 - 90 days	3605	43.41%
> 90 days	763	9.19%
Total	8304	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	1283	34.86%
Chronic toxicity	1935	52.58%
Reproductive ecotoxicity	240	6.52%
Bioaccumulation	222	6.03%
Total	3680	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	27385	23.2%
Legislation on medicinal products for veterinary use and their residues	26549	22.49%
Medical devices legislation	17	0.01%
Industrial chemicals legislation	60022	50.84%
Plant protection product legislation	1674	1.42%
Biocides legislation	126	0.11%
Food legislation including food contact material	1165	0.99%
Feed legislation including legislation for the safety of target animals, workers and environment	1120	0.95%
Total	118058	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

Legislation satisfying EU requirements	115945	98.21%
Legislation satisfying Non-EU requirements only	2113	1.79%
Total	118058	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	252	100%
Total	252	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	382155	97.32%
Yes	10520	2.68%
Total	392675	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	43764	11.15%
Mild [up to and including]	240879	61.34%
Moderate	102214	26.03%
Severe	5818	1.48%
Total	392675	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	324356	82.6%
Genetically altered without a harmful phenotype	65538	16.69%
Genetically altered with a harmful phenotype	2781	0.71%
Total	392675	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	7978	2	7980
Total	7978	2	7980

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	7078	88.7%
Moderate	880	11.03%
Severe	22	0.28%
Total	7980	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	5829	73.05%
Genetically altered without a harmful phenotype	2151	26.95%
Total	7980	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	4005	51.43%
Cardiovascular Blood and Lymphatic System	824	10.58%
Nervous System	404	5.19%
Respiratory System	65	0.83%
Gastrointestinal System including Liver	584	7.5%
Musculoskeletal System	12	0.15%
Immune System	806	10.35%
Urogenital/Reproductive System	73	0.94%
Multisystemic	28	0.36%
Other basic research	987	12.67%
Total	7788	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	104	54.17%
Human Nervous and Mental Disorders	88	45.83%
Total	192	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	1186		1186
Zebra fish	54		54
Total	1240		1240

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	988	79.68%
Moderate	240	19.35%
Severe	12	0.97%

Total	1240	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	1240	100%
Total	1240	100.00%

Poland

Poland: Narrative 2018

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

In 2018, the slight downward trend in the number of animals used continued in Poland. Thanks to the training provided, there is a noticeably better understanding of the definition of the procedure and of reporting rules, resulting in more accurate and measurable reports. There is also a clear shift away from teaching with live animals.

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

The fluctuation observed in the number of animals used of certain species seems to be a natural consequence of the end of one type of experiment and the start of others, connected to the receipt of research grants linked to an increase in the popularity of a given field of research or, for example, to orders from external parties. This is also likely to be the reason why the number of farm animals being used decreased significantly in 2018.

In experiments, there was a noticeable trend away from various species of fish to *Danio rerio*. This is clear from the proportion of *Danio rerio* in the total number of fish used in research in Poland, which increased from 15% in 2017 to 53.88% in 2018.

There is also a clear shift away from teaching with live animals. For most species, the number of animals used in teaching has decreased by between 50% and 98.5% since 2015 and there are individual species where it has stopped altogether.

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

In 2018 there was a noticeable upward trend in severe and moderate experiments. However, these changes are not significant; in rodents, for instance, severe procedures have increased from 32.32% to 36.50% to 39.92% over the last three years.

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

The statutory tasks of the National Ethics Committee on Animal Experiments (NEC) are to pursue the three Rs and promote alternative research. The NEC supports training courses for persons planning or carrying out experiments in programmes that incorporate this topic. This information is also provided to local ethics committees on animal experiments (during annual training courses, via the NEC's website and through direct contact). Unit welfare teams also use the NEC's website, advice and recommendations. When issuing authorisation for experiments to be carried out, Ethics Committees are required to take into account the existence of alternative methods and the application of the three Rs in specific experiments. To this end, the application template for authorisation contains a specific field in

which the user must enter the method of applying the three Rs in a given experiment. In 2018 applications also included an additional obligation, as a reminder that procedures must not be carried out, or must be terminated immediately, if alternative methods to the procedure set out in the application are approved in the European Union during the period in which the Commission's authorisation is valid. In 2017 the NEC also took the initiative to set up a cooperation network between units and bodies involved in the application of alternative methods.

Furthermore, welfare teams monitor how the three Rs principle is applied. Their activities are monitored by the NEC, which prepares a comprehensive analysis of their activity reports each year.

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

In Poland a fairly 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 user which, under routine manufacturing procedures required by law, employs tests not included in the list provided in the report (API). This user tests herbal medicinal products and its activities in Poland account for 88.1% of tests under the category 'legally required/routine production'.

In 2018, the animal species included in the 'other' category, accounting for over 10% of a given group, were:

- 'Other' species of carnivore (other *Carnivora*): *Mustela nivalis, Mustella lutreola, Vulpes* and *Nyctereutes procyonoides.* These species account for 93.51% of all species of carnivore and are used in basic research related to species biology and behaviour, and in translational and applied research in the field of animal diseases and disorders.

- 'Other' species of mammal (other *Mammalia*): *Capreolus, Cervus elaphus, Eptesicus serotinus, Monodelphis domestica, Muntiacus reevesi, Myotis alcathoe, Myotis bechsteinii, Myotis brandtii, Myotis, Myotis mystacinus, Neomys anomalus, Neomys fodiens, Nyctalus leisleri, Nyctalus leisleri, Sorex araneus, Talpa europaea* and *Talpa europaea.* These species account for 23.33% of all species of mammal and are used in basic research related to species biology and behaviour and the protection of the natural environment in the interests of the health or welfare of human beings or animals.

- 'Other' species of bird (other *Aves*): *Acanthis cabaret, Acanthis flammea, Acrocephalus paludicola, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris canutus, Calidris falcinellus, Calidris ferruginea, Calidris pugnax, Caprimulgus europaeus, Charadrius dubius, Charadrius hiaticula, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia, Columba livia, Coturnix, Coturnix japonica, Cyanistes caeruleus, Cygnus olor, Dromaiinae, Emberiza citrinella, Emberiza schoeniclus, Erithacus rubecula, Ficedula hypoleuca, Fringilla*

coelebs, Fringilla montifringilla, Fulica atra, Gallinago, Garrulus glandarius, Haliaeetus albicilla, Hirundo rustica, Laniuscollurio, Larus argentatus, Meleagris gallopavo, Milvus migrans, Milvus, Motacilla alba, Motacilla flava, Parus major, Passer domesticus, Pyrrhula, Spinus, Sterna hirundo, Sylvia atricapilla, Taeniopygia guttata, Tetrao urogallus, Tringa glareola, Tringa ochropus, Tringa totanus and *Turdus merula,* These species account for 75.01% of all species of bird used in research. They are mainly used in basic research related to the cardiovascular blood and lymphatic system, the gastrointestinal system including the liver, the immune system, the urogenital and reproductive system, to multisystemic research, ethology, animal behaviour or animal biology, and to the differentiation of blood parasites. In addition, they are used in translational research on human immune disorders, animal diseases and disorders, animal welfare, and the diagnosis of diseases. They are also used in manufacturing, including of medicinal products, API and herbal starting material, and in regulatory testing (quality control, including batch safety and potency testing, batch efficacy testing, single-dose acute toxicity testing, LD50 or LC50 testing and batch animal immunology product testing). In addition, they are used in research concerning the protection of the natural environment in the interests of the health or welfare of human beings or animals, and research into species behaviour.

- 'Other' species of fish (other *Pisces*): *Acipenser gueldenstadtii, Carassius auratus, Carassius, Cobitis elongatoides, Cobitis taenia, hybrids Cobitis, Coregonus lavaretus, Cyprinus carpio, Gadus morhua, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Poecilia reticulata, Sander lucioperca* and *Scardinius erythrophthalmus*. These species account for 46.11% of all fish species used in research. They are mainly used in basic research related to the cardiovascular blood and lymphatic system, immune system, urogenital and reproductive system, ethology and animal behaviour and biology. They are also used in translational research and in research on animal welfare. Six individuals of the species *Carassius auratus* were also used for higher education or training for the acquisition or improvement of vocational skills.

- 'Other' species of amphibian (other *Amphibia*): *Rana arvalis*. These species account for 96.49% of all amphibian species used in research. They are mainly used in basic research related to ethology and animal behaviour and or animal biology.

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.

Poland: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	81028	53.03%
Rats	27787	18.19%
Guinea-Pigs	5596	3.66%
Hamsters (Syrian)	25	0.02%
Mongolian gerbil	122	0.08%
Other rodents	5928	3.88%
Rabbits	812	0.53%
Cats	7	0%
Dogs	5	0%
Other carnivores	216	0.14%
Horses, donkeys and cross-breeds	18	0.01%
Pigs	601	0.39%
Goats	52	0.03%
Sheep	447	0.29%
Cattle	198	0.13%
Other mammals	388	0.25%
Domestic fowl	2352	1.54%
Other birds	7818	5.12%
Reptiles	12	0.01%
Other amphibians	330	0.22%
Zebra fish	10262	6.72%
Other fish	8781	5.75%
Total	152785	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	135297	88.55%
Animals born in the EU but not at a registered breeder	16890	11.05%
Animals born in rest of Europe	56	0.04%
Animals born in rest of world	542	0.35%
Total	152785	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	81028	67	81095
Rats	27787	39	27826
Guinea-Pigs	5596		5596
Hamsters (Syrian)	25		25
Mongolian gerbil	122		122
Other rodents	5928	237	6165
Rabbits	812	128	940
Cats	7		7
Dogs	5	3	8
Other carnivores	216		216
Horses, donkeys and cross-breeds	18	29	47
Pigs	601	2	603
Goats	52	7	59
Sheep	447	147	594
Cattle	198	4	202
Other mammals	388		388
Domestic fowl	2352	310	2662
Other birds	7818	173	7991
Reptiles	12		12
Other amphibians	330		330
Zebra fish	10262		10262
Other fish	8781		8781
Total	152785	1146	153931

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	113559	73.77%
Translational and applied research	13695	8.9%
Regulatory use and Routine production	24666	16.02%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	215	0.14%
Preservation of species	679	0.44%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1117	0.73%
Total	153931	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6882	6.06%
Cardiovascular Blood and Lymphatic System	7172	6.32%
Nervous System	58550	51.56%
Respiratory System	377	0.33%
Gastrointestinal System including Liver	4183	3.68%
Musculoskeletal System	754	0.66%
Immune System	5961	5.25%

Urogenital/Reproductive System	2592	2.28%
Sensory Organs (skin, eyes and ears)	731	0.64%
Endocrine System/Metabolism	3481	3.07%
Multisystemic	9577	8.43%
Ethology / Animal Behaviour /Animal Biology	12132	10.68%
Other basic research	1167	1.03%
Total	113559	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3732	27.25%
Human Infectious Disorders	100	0.73%
Human Cardiovascular Disorders	534	3.9%
Human Nervous and Mental Disorders	166	1.21%
Human Respiratory Disorders	1065	7.78%
Human Gastrointestinal Disorders including Liver	324	2.37%
Human Musculoskeletal Disorders	11	0.08%
Human Immune Disorders	70	0.51%
Human Urogenital/Reproductive Disorders	12	0.09%
Human Sensory Organ Disorders (skin, eyes and ears)	20	0.15%
Human Endocrine/Metabolism Disorders	612	4.47%
Other Human Disorders	198	1.45%
Animal Diseases and Disorders	222	1.62%
Animal Welfare	2015	14.71%
Diagnosis of diseases	2845	20.77%
Non-regulatory toxicology and ecotoxicology	1769	12.92%
Total	13695	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16195	65.66%
Other efficacy and tolerance testing	52	0.21%
Toxicity and other safety testing including pharmacology	7915	32.09%
Routine production	504	2.04%
Total	24666	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	2400	14.82%
Pyrogenicity testing	192	1.19%
Batch potency testing	12812	79.11%
Other quality controls	791	4.88%
Total	16195	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	1053	13.3%
Skin irritation/corrosion	189	2.39%
Skin sensitisation	673	8.5%
Eye irritation/corrosion	25	0.32%
Repeated dose toxicity	210	2.65%
Reproductive toxicity	217	2.74%
Developmental toxicity	1312	16.58%

Kinetics	1331	16.82%
Ecotoxicity	2673	33.77%
Safety testing in food and feed area	112	1.42%
Other toxicity/safety testing	120	1.52%
Total	7915	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	519	49.29%
Non lethal methods	534	50.71%
Total	1053	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
29 - 90 days	210	100%
Total	210	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2551	95.44%
Chronic toxicity	122	4.56%
Total	2673	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	15938	65.96%
Legislation on medicinal products for veterinary use and their residues	1542	6.38%
Medical devices legislation	2137	8.84%
Industrial chemicals legislation	1714	7.09%
Plant protection product legislation	2731	11.3%
Feed legislation including legislation for the safety of target animals, workers and environment	100	0.41%
Total	24162	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23709	98.13%
Legislation satisfying national requirements only [within EU]	360	1.49%
Legislation satisfying Non-EU requirements only	93	0.38%
Total	24162	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	60	11.9%
Other product types	444	88.1%
Total	504	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	152785	99.26%
Yes	1146	0.74%
Total	153931	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	6126	3.98%
Mild [up to and including]	35881	23.31%
Moderate	50547	32.84%
Severe	61377	39.87%
Total	153931	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	144148	93.64%
Genetically altered without a harmful phenotype	7557	4.91%
Genetically altered with a harmful phenotype	2226	1.45%
Total	153931	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	99		99
Rats	21		21
Other mammals	70		70
Total	190		190

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	24	12.63%
Mild [up to and including]	2	1.05%
Moderate	163	85.79%
Severe	1	0.53%
Total	190	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	111	58.42%
Genetically altered without a harmful phenotype	79	41.58%
Total	190	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Nervous System	185	97.37%
Multisystemic	5	2.63%
Total	190	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	136		136
Total	136		136

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	136	100%
Total	136	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	136	100%
Total	136	100.00%

Portugal

Portugal: Narrative 2018

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

In 2018 there was an increase in animal use compared to the previous year (2017). The total number of animals used in 2018 is 81107, which constitutes a 34,7% increase in animal use, compared to 2017 (total uses: 52983).

Mice continue to be the most used animal species (72,77%), followed by the entry Other fish (15,38%), Rats (6,62%) and Zebra fish (4,57%).

There is a significant increase in the use of Fish (19,95%) compared to 2017 (3,98%).

All animal species used in 2018 showed an increase compared to 2017, except Other rodents, Other mammals and Cephalopods that decreased. Domestic fowl was not used in 2018.

The use of Mammals dropped 14,90% but the the use of Fish increased 15,97% compared to the previous year.

There was a decrease on reuse (total reuses: 300) compared to the previous year (total reuses: 1509).

Compared to the previous year, there was an obvious increase in the use of animals in Basic research, Translational and applied research, Maintenance of colonies of established genetically altered animals, not used in other procedure and in the Protection of the natural environment in the interests of the health or welfare of human beings or animals.

Regulatory use and Routine prodution represents only 0,4% of all uses and animals used in Higher education or training for the acquisition, maintenance or improvement of vocational skills had a slight decrease compared to 2017, representing only 0,28% of all uses in 2018.

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

The increase in animal numbers in 2018 is mainly due to increased Basic research (64,73% of all use), Maintenance of colonies of established genetically altered animals, not used in other procedures (19,99% of all use), Translational and applied research (13,47% of all use) and Protection of the natural environment in the interests of the health or welfare of human beings or animals (1,13% of all use).

The increase in Basic reseach is related to the increase of studies in Oncology, Nervous System, Respiratory System, Sensory organs, Endocrine System/Metabolism, Multisystemic, Ethology/Animal behaviour/Animal Biology and Other Basic research (Animal nutrition, Nutrition, Infection, Embryonic development, for example).

The increase in Translational and applied research is related to the increase of studies in Human Infectious disorders, Human Cardiovascular Disorders, Human cancer, Human Gastrointestinal Disorders including Liver, Human Endocrine/metabolism Disorders and Other Human Disorders. Despite there was a very slight drop in the use of animals for studying Human Nervous and Mental Disorders, compared to the previous year, this is the second category of purposes for which more animals were used in Translational and applied research, representing 20,62% of all uses in this category.

The reason for an increase in uses reported in the category Maintenance of colonies of established genetically altered animals not used in other procedures, compared to the previous year, may be due to an increase in the existance of more genetically lines.

In fact, in the latest years, there has been an increase on the use of genetically altered animals (with or without a harmful phenotype) and, in 2018, the percentage of use of genetically altered animals is 49,71% of all uses.

The significant increase in the use of Other fish (15,38% of all uses) is mainly due to an increase in studies in the areas of Animal nutrition, digestibility and infectious diseases to support the field of Aquaculture an in studies of Basic research linked to the Immune system and Ethology, Animal behaviour and Animal biology.

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

In 2018, the percentages reported for each of the categories of actual severities experienced by the animals were as follows:

- Non-recovery: 3,16%
- Mild: 67,96%
- Moderate: 18,98%
- Severe: 9,90%

Compared to the previous year, this represents an increase of 15,45% in Mild procedures (52,51% to 67,96%), a decrease of 0,65% in Non-recovery procedures (3,81% to 3,16%), a decrease of 5,05% in Moderate procedures (24,03% to 18,98%) and a decrease of 9,76% in Severe procedures (19,66% to 9,90%).

In general terms, We consider that this might probably due to a much wider and expressive aplication of human endpoints and to aquisition of knowledge and competence in monitoring the animals by the Animal Welfare Bodies.

Concerning the Non-recovery procedures, we have had an effort for clarifying the confusions that usually rise with the attribution of this category of severity.

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

Despite not always being evident that the principle of replacemnet, reduction and refinement has an obvious impact and reflex on the statistics, somehow, we think it is the case.

The promotion and the implementation of the 3Rs is always present in all the authorisation processes and in the details that involve the use of animals for scientific purposes and is somehow applied by all the persons who in the course of the performance of their responsibilities are confronted with its application.

The competent authority has always contributed to the promotion of 3Rs, whether when carrying out inspections to establishments, when evaluating scientific projects submitted for subsequent authorization or in any opportunity it has to talk about the theme.

On the other hand, at the level of an establishment where animals are bred, used or from which are supplied for scientific purposes, the Animal Welfare Body has implicit functions for implementing measures to improve animal welfare and to promote 3Rs on a daily basis.

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

In 2018, the further breakdown on the use of “other” categories is as follows:

On Animal species:

“Other birds” include pigeons (*Columba livia*);

“Other fish” include:

Goby (*Pomatoschistus microps*)

Seabass *(Dicentrarchus labrax)*

Seabream *(Sparus aurata)*

Argyrosomus argirosomus regius

Atherina presbyter

Onchorrynchy mykis

Oreochromis mossambicus

Oreochromis niloticus

Scyliorhinus canicula

On Purpose:

In Basic Research, *"Other" include:*

Nutrition

Animal nutrition/Digestibility

Obesity studies

Infectious disease / Infection

Malaria studies

Embrionic development

Intestinal microbiota composition

Genetic disorders

Bacterial metabolite profile *in vivo*

In Translational and applied research, *"Other Human Disorders"* include Aging.

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.

These cases have not occurred.

Portugal: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	41745	66.98%
Rats	5361	8.6%
Other rodents	37	0.06%
Rabbits	55	0.09%
Pigs	175	0.28%
Sheep	18	0.03%
Other mammals	2	0%
Zebra fish	2448	3.93%
Other fish	12474	20.02%
Cephalopods	8	0.01%
Total	62323	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	56569	90.77%
Animals born in the EU but not at a registered breeder	4829	7.75%
Animals born in rest of Europe	199	0.32%
Animals born in rest of world	726	1.16%
Total	62323	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	41745	60	41805
Rats	5361		5361
Other rodents	37		37
Rabbits	55		55
Cats		2	2
Dogs		18	18
Horses, donkeys and cross-breeds		9	9
Pigs	175		175
Goats		88	88
Sheep	18	22	40
Cattle		20	20
Other mammals	2		2
Other birds		66	66
Xenopus		15	15
Zebra fish	2448		2448
Other fish	12474		12474
Cephalopods	8		8
Total	62323	300	62623

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	50231	80.21%
Translational and applied research	10924	17.44%
Regulatory use and Routine production	322	0.51%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	918	1.47%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	228	0.36%
Total	62623	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	5190	10.33%
Cardiovascular Blood and Lymphatic System	1045	2.08%
Nervous System	5773	11.49%
Respiratory System	517	1.03%
Gastrointestinal System including Liver	298	0.59%
Musculoskeletal System	104	0.21%
Immune System	16068	31.99%
Urogenital/Reproductive System	52	0.1%
Sensory Organs (skin, eyes and ears)	73	0.15%
Endocrine System/Metabolism	1908	3.8%
Multisystemic	430	0.86%
Ethology / Animal Behaviour /Animal Biology	4116	8.19%
Other basic research	14657	29.18%

Total	50231	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	307	2.81%
Human Infectious Disorders	3785	34.65%
Human Cardiovascular Disorders	1901	17.4%
Human Nervous and Mental Disorders	2252	20.62%
Human Gastrointestinal Disorders including Liver	515	4.71%
Human Musculoskeletal Disorders	196	1.79%
Human Urogenital/Reproductive Disorders	35	0.32%
Human Sensory Organ Disorders (skin, eyes and ears)	256	2.34%
Human Endocrine/Metabolism Disorders	122	1.12%
Other Human Disorders	256	2.34%
Animal Diseases and Disorders	20	0.18%
Diagnosis of diseases	995	9.11%
Non-regulatory toxicology and ecotoxicology	284	2.6%
Total	10924	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	322	100%
Total	322	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage

No data reported

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics	245	76.09%
Safety testing in food and feed area	77	23.91%
Total	322	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	245	76.09%

Food legislation including food contact material	77	23.91%
Total	322	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	322	100%
Total	322	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	62323	99.52%
Yes	300	0.48%
Total	62623	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	2566	4.1%
Mild [up to and including]	37968	60.63%
Moderate	14158	22.61%
Severe	7931	12.66%
Total	62623	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	39563	63.18%
Genetically altered without a harmful phenotype	19209	30.67%
Genetically altered with a harmful phenotype	3851	6.15%
Total	62623	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	1038		1038
Zebra fish	1230		1230
Total	2268		2268

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	1127	49.69%
Moderate	1043	45.99%
Severe	98	4.32%
Total	2268	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	1221	53.84%
Genetically altered without a harmful phenotype	526	23.19%
Genetically altered with a harmful phenotype	521	22.97%
Total	2268	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	1488	65.61%
Cardiovascular Blood and Lymphatic System	145	6.39%
Nervous System	221	9.74%
Immune System	184	8.11%
Endocrine System/Metabolism	195	8.6%
Other basic research	35	1.54%
Total	2268	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	16177		16177
Rats	9		9
Zebra fish	30		30
Total	16216		16216

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	16026	98.83%
Moderate	190	1.17%
Total	16216	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	15501	95.59%
Genetically altered with a harmful phenotype	715	4.41%
Total	16216	100.00%

Romania

Romania: Narrative 2018

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

Since the previous reporting year, there was a decrease in the number of total animals used for scientific purposes, from 14642 in 2017 to 12195 in 2018.

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 drop in oncology within the basic research.

There was a decrease in batch potency testing within regulatory use and routine production due to a drop in the vaccines production. There was also a drop in acute and sub-acute within regulatory use and routine production. Moreover, there was an increase in pyrogenicity testing due to a high number of tests performed for countries using the Russian Pharmacopoeia.

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

There were no significant variations in terms of severity of the projects.

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

The decrease in the number of total animals used for scientific purposes is a mirror of the promotion of the principle of replacement, reduction and refinement.

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	6758	57.86%
Rats	3642	31.18%
Guinea-Pigs	380	3.25%
Hamsters (Syrian)	18	0.15%
Rabbits	371	3.18%
Pigs	48	0.41%
Sheep	109	0.93%
Domestic fowl	114	0.98%
Rana	240	2.05%
Total	11680	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	10071	86.22%
Animals born in the EU but not at a registered breeder	1541	13.19%
Animals born in rest of world	68	0.58%
Total	11680	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	6758		6758
Rats	3642		3642
Guinea-Pigs	380	66	446
Hamsters (Syrian)	18		18
Rabbits	371	248	619
Horses, donkeys and cross-breeds		2	2
Pigs	48		48
Sheep	109	140	249
Cattle		3	3
Domestic fowl	114	56	170
Rana	240		240
Total	11680	515	12195

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	4559	37.38%
Translational and applied research	4615	37.84%
Regulatory use and Routine production	1908	15.65%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1113	9.13%
Total	12195	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	766	16.8%
Cardiovascular Blood and Lymphatic System	849	18.62%
Nervous System	969	21.25%
Respiratory System	70	1.54%
Gastrointestinal System including Liver	60	1.32%
Musculoskeletal System	24	0.53%
Immune System	563	12.35%
Urogenital/Reproductive System	55	1.21%
Sensory Organs (skin, eyes and ears)	133	2.92%
Endocrine System/Metabolism	54	1.18%
Multisystemic	844	18.51%
Ethology / Animal Behaviour /Animal Biology	172	3.77%
Total	4559	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	95	2.06%
Human Infectious Disorders	90	1.95%
Human Cardiovascular Disorders	310	6.72%
Human Nervous and Mental Disorders	10	0.22%
Human Gastrointestinal Disorders including Liver	50	1.08%

Human Musculoskeletal Disorders	70	1.52%
Human Immune Disorders	306	6.63%
Human Sensory Organ Disorders (skin, eyes and ears)	192	4.16%
Human Endocrine/Metabolism Disorders	305	6.61%
Animal Diseases and Disorders	48	1.04%
Diagnosis of diseases	2312	50.1%
Non-regulatory toxicology and ecotoxicology	827	17.92%
Total	4615	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1534	80.4%
Toxicity and other safety testing including pharmacology	24	1.26%
Routine production	350	18.34%
Total	1908	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	681	44.39%
Pyrogenicity testing	372	24.25%
Batch potency testing	385	25.1%
Other quality controls	96	6.26%
Total	1534	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Ecotoxicity	24	100%
Total	24	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Chronic toxicity	24	100%
Total	24	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1023	65.66%
Legislation on medicinal products for veterinary use and their residues	511	32.8%
Medical devices legislation	24	1.54%
Total	1558	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1330	85.37%
Legislation satisfying Non-EU requirements only	228	14.63%
Total	1558	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	350	100%
Total	350	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	11680	95.78%
Yes	515	4.22%
Total	12195	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	1959	16.06%
Mild [up to and including]	4196	34.41%
Moderate	5202	42.66%
Severe	838	6.87%
Total	12195	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	11756	96.4%
Genetically altered without a harmful phenotype	439	3.6%
Total	12195	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Slovakia

Slovakia: Narrative 2018

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

Increased number of animals used in the projects was also caused by the fact that more approved establishments of the users have merged into larger law organizations, e.g. to the Biomedical Center SAS Bratislava, the Centre of Bioscience SAS or Centre of Experimental Science SAS Bratislava. Therefore, the possibilities of performance of the projects have raised. In 2018, more establishments started to use more actively 2 large new establishments serving as complexes for the users, e.g. Central Animal establishment of the Pavilion of Medical Science Bratislava and Establishment for Immunodeficient Mice. By merging more approved user establishments into one organization several originally approved user establishments have lost their legal subjectivity and became only organizational units of the given subject. This is also the reason of decreased number of approved user establishments in comparison to the previous years. The number of approved projects for 2018 has decreased due to the legislative requirements regarding length of approval of the project, which has raised up to 5 years, since 2013. This has caused decrease of the number of new applications because the users already had projects approved for quite a long time of 5 years. Nevertheless, increased number of animals used in the projects has been recorded of approved user establishments approved since 2017 could fully perform the projects. These establishments have been undergone reconstruction changes, they were in a transitional period to reach 1 January 2017 for harmonization of Annex III of the Directive No.: 2010/63/EU./

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 animals used in regulated project performed for the purpose of control of effectiveness and safety of chemical substances, medical products has increased significantly up to 27,44% of the total number of used animals in comparison to 2017. Multiple orders for performance of these projects were from the foreign sponsors. In 2018, the number of user establishments, performing also regulated projects, related to orders from the foreign sponsors, increased. In the Slovak Republic, the most of animals are used in the area of basic research (up to 64,60% of the total number of animals.

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

In comparison to 2017, the number of projects classified as "mild" decreased to 21,46 % of the overall number from 2017, when the projects with mild severity used 33,21% of overall number of used animals. At the same time, the percentage of animals used in projects classified as "moderate" represented 68,02% of the overall number compared to 2017. That year, the number of animals used in projects classified as moderate was 57,47% of overall number of used animals. The reason is , that several projects in 2018 have got the purpose of the project in the area of nervous system research and urogenital system research. In several cases, the animals are subject to pathological changes in health, paying maximum attention to 3R, analgesia and human endpoint. The percentage of animals used in

projects classified as “severe” increased to 7,82 % from the total number. In 2017, in severe projects only 2,27 % of the total number of animals was used. Based on the retrospective assessments and mainly regulated projects it was found that some regulated projects after their performance were classified as severe, what increased the percentage of animals used in the severe projects.

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

In SK, high efforts are being made to the submission of applications for approval of the project, where the applicant must describe in details steps 3R, human end point and used analgesia and anaesthesia, apart from the other requirements. High attention is paid to 3R principles, human endpoint and searching of alternative methods at each training of the users, breeders and suppliers.

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

The common animal species for performance of the projects are used in SK; only in “other birds” category one approved user establishment is using species Taeniopygia guttata and Lonchura striata domestica.

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 no cases of exceeding the “severe” classification in projects was reported in 2018. This is not even possible that such a case would occurs. Rather the contrary, several projects classified as “severe”, after retrospective assessment have got the actual severity “moderate” or “mild”. All projects are authorized by the Decision, where the exact process of execution of the project is described in details and classification of severity of each procedure performed on the animal and its consequences. In case of execution of the project wilfully outside the approved methodology, the user would be punished by a financial fine, cancellation of the project or by other repressive means according to the type of violation of the law

Slovakia: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	6666	39.62%
Rats	8878	52.77%
Guinea-Pigs	752	4.47%
Mongolian gerbil	9	0.05%
Rabbits	244	1.45%
Cats	12	0.07%

Pigs	2	0.01%
Domestic fowl	237	1.41%
Other birds	23	0.14%
Total	16823	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	16823	100%
Total	16823	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	6666		6666
Rats	8878		8878
Guinea-Pigs	752		752
Mongolian gerbil	9		9
Rabbits	244	31	275
Cats	12		12
Pigs	2		2
Domestic fowl	237	6	243
Other birds	23		23
Total	16823	37	16860

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	11364	67.4%
Translational and applied research	638	3.78%
Regulatory use and Routine production	4828	28.64%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	30	0.18%
Total	16860	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	916	8.06%
Cardiovascular Blood and Lymphatic System	1075	9.46%
Nervous System	4414	38.84%
Respiratory System	471	4.14%
Gastrointestinal System including Liver	171	1.5%
Musculoskeletal System	23	0.2%
Immune System	624	5.49%
Urogenital/Reproductive System	1910	16.81%
Sensory Organs (skin, eyes and ears)	9	0.08%
Endocrine System/Metabolism	543	4.78%
Ethology / Animal Behaviour /Animal Biology	481	4.23%
Other basic research	727	6.4%
Total	11364	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	42	6.58%
Human Cardiovascular Disorders	124	19.44%
Human Nervous and Mental Disorders	226	35.42%
Human Musculoskeletal Disorders	17	2.66%
Human Urogenital/Reproductive Disorders	63	9.87%
Human Sensory Organ Disorders (skin, eyes and ears)	16	2.51%
Human Endocrine/Metabolism Disorders	100	15.67%

Other Human Disorders	50	7.84%
Total	638	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	665	13.77%
Toxicity and other safety testing including pharmacology	4132	85.58%
Routine production	31	0.64%
Total	4828	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	542	81.5%
Batch potency testing	123	18.5%
Total	665	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	492	11.91%
Skin sensitisation	418	10.12%
Repeated dose toxicity	168	4.07%
Genotoxicity	4	0.1%
Reproductive toxicity	2499	60.48%
Developmental toxicity	542	13.12%
Other toxicity/safety testing	9	0.22%
Total	4132	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	492	100%
Total	492	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	78	46.43%
29 - 90 days	90	53.57%
Total	168	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	542	11.3%
Legislation on medicinal products for veterinary use and their residues	123	2.56%
Medical devices legislation	9	0.19%
Industrial chemicals legislation	3487	72.69%
Food legislation including food contact material	542	11.3%

Feed legislation including legislation for the safety of target animals, workers and environment	90	1.88%
Other legislation	4	0.08%
Total	4797	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4797	100%
Total	4797	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	31	100%
Total	31	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	16823	99.78%
Yes	37	0.22%
Total	16860	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	475	2.82%
Mild [up to and including]	3044	18.05%
Moderate	11966	70.97%
Severe	1375	8.16%
Total	16860	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	15347	91.03%
Genetically altered without a harmful phenotype	501	2.97%
Genetically altered with a harmful phenotype	1012	6%
Total	16860	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	473		473
Rats	259		259
Total	732		732

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	732	100%
Total	732	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	534	72.95%
Genetically altered without a harmful phenotype	11	1.5%
Genetically altered with a harmful phenotype	187	25.55%
Total	732	100.00%

Slovenia

Slovenia: Narrative 2018

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

In 2018, 5.104 animals were used for scientific purposes, which is quite similar to the previous year. 93% of all used animals were rodents (mice and rats) and rabbits. Mice is still the most commonly used species (88%). Other animals (pigs, sheep, cattle, horses, poultry and fish) were used in very low number (approx. 7%). No cats, dogs and non-human primates were used for scientific purposes in 2018.

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

The majority of animals (approx. 57%) were used for the purpose of oncology, endocrine, immune and gastrointestinal system including liver. The highest number of rodents was used for the research of endocrine system. Further on, 115 mice were used for the purpose of preservation of species, more specifically, cryopreservation for the preservation of two lines of mice – fat and slim line. These two lines are unique in the world and are of major importance for further research in the field of discovering new genes for obesity and slimness, which could lead to development of medicine for obesity related diabetes.

There was a slight drop in the number of animals in regulatory use and routine production, where less than 40% were used. The reason is in the replacement of in vivo methods, which follows the 3R principle of replacement and the termination of certain projects for certain markets, which leads in reduction of use of animals for regulatory purposes

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

Majority of procedures in Slovenia are classified as mild (over 87%), around 12% are moderate and less than 1% severe or non-recovery. All animals used in procedures classified as severe were used for basic research.

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

3R principle is generally followed, e.g. use of minimal number of animals, use of rodents, re-use, application of new techniques. We try to promote reduction, replacement and refinement principle during training courses for persons dealing with laboratory animals, meetings with animal welfare officers, different workshops, etc. In 2018, there was a poster on new methods of handling mice published. Scientists compared the use of tunnels and open hand towards handling by the tail. The conclusion was that the use of tunnels and open hand ease daily handling and lowers the discomfort of laboratory mice.

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 number of use under category “other” in 2018. 50 fish (Rainbow trout) were used in procedures for the purpose of higher education.

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.

“Severe” classification was never exceeded.

Slovenia: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	3841	86.55%
Rats	235	5.3%
Rabbits	6	0.14%
Pigs	48	1.08%
Sheep	45	1.01%
Cattle	2	0.05%
Domestic fowl	211	4.75%
Other fish	50	1.13%
Total	4438	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	4380	98.69%
Animals born in rest of world	58	1.31%
Total	4438	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	3841	599	4440
Rats	235		235
Rabbits	6	64	70
Horses, donkeys and cross-breeds		2	2
Pigs	48		48
Sheep	45	1	46
Cattle	2		2
Domestic fowl	211		211
Other fish	50		50
Total	4438	666	5104

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	1069	20.94%
Translational and applied research	1832	35.89%
Regulatory use and Routine production	1982	38.83%
Preservation of species	115	2.25%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	106	2.08%
Total	5104	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	226	21.14%
Cardiovascular Blood and Lymphatic System	60	5.61%
Nervous System	45	4.21%
Gastrointestinal System including Liver	309	28.91%
Immune System	112	10.48%
Urogenital/Reproductive System	46	4.3%
Endocrine System/Metabolism	265	24.79%
Multisystemic	6	0.56%
Total	1069	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1487	81.17%
Human Endocrine/Metabolism Disorders	140	7.64%
Animal Diseases and Disorders	136	7.42%
Diagnosis of diseases	69	3.77%
Total	1832	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1982	100%
Total	1982	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	45	2.27%
Pyrogenicity testing	64	3.23%
Batch potency testing	1873	94.5%
Total	1982	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1982	100%
Total	1982	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1982	100%
Total	1982	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	4438	86.95%
Yes	666	13.05%
Total	5104	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	32	0.63%
Mild [up to and including]	4460	87.38%

Moderate	607	11.89%
Severe	5	0.1%
Total	5104	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	4603	90.18%
Genetically altered without a harmful phenotype	411	8.05%
Genetically altered with a harmful phenotype	90	1.76%
Total	5104	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total

No data reported

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage

No data reported

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage

No data reported

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage

No data reported

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage

No data reported

Spain

Spain: Narrative 2018

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

Information can be collected by the breeders, suppliers or users of animals used for scientific purposes, or by the competent authorities in the Autonomous Communities. Information collected at regional level is submitted to the State authorities responsible for managing it for the purpose of complying with the obligation laid down in Article 54(2) of Directive 2010/63/EU.

The procedure for collecting, managing and processing the information was launched in 2014. Nevertheless, there are various factors that cast doubt on any comparison between data from different years. The following factors are particularly significant: the large amount of data to be recorded; the collection system that includes the establishments; the regional authorities, which sometimes also have systems in place with different levels of communication; and the large turnover of staff involved.

The number of projects authorised slightly decreased, but this decrease does not affect the number of uses. This is due, among other circumstances, to the increase in the number of projects involving productive species in feeding studies and vaccine testing. Such projects account for the relatively high numbers of animals.

The use of mammals has not changed substantially. There are, however, variations in the use of fish, amphibians, reptiles and cephalopods.

With regard to the use of fish, there is a significant increase under the heading 'other fish', largely due to studies carried out on animals at the stage of independently feeding larval forms.

Use of **amphibians** remains stable in the case of animals of the genus Xenopus in projects that make use of its greater regeneration capacity or the fact that its organs function at an early stage. Animals designated 'other amphibians' are used in research into conservation biology, as well as the impact of invasive species on the natural environment. Such research uses larval forms at various stages and involves groups of individuals in varying numbers.

For **reptiles**, given the low number of centres that use them, four in total, and the limited number of projects, the completion of a single project produces an apparently significant variation in use.

Use of **cephalopods** has increased due to the development of various lines of research into diseases, and greater understanding of their biology and reproduction.

In the information on how to report severity, as a consequence of the amount of work under way, severity is being reported more accurately.

In assessing the figures on uses, it must be taken into account that, as in previous years, 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 animals in any of the specific areas and analysis of the reasons thereof.

With regard to the **origins of the animals**, the number of animals born in registered establishments in the EU appears to have decreased with a corresponding increase in those born in unregistered establishments, in accordance with the rules on animals used for scientific purposes. In reality, however, this does not reflect an actual change but rather the confusion created by this classification among those responsible for providing the information. In Spain, any establishments that might at any time house animals must be registered in accordance with the rules on animal health. Information providers often classify animals as coming from 'centres registered in the EU' when they come from centres registered for health-related purposes only, and not specifically from establishments registered under the rules on protection of animals used for scientific and teaching purposes.

There is a notably high number of uses of hens and 'other fish' born in registered establishments. In these cases, the animals were born in the same establishment in which they will be used. Hens are used in studies that simulate commercial situations and therefore involve large flocks. Studies involving 'other fish' often take place at very early stages, on independently feeding larval forms, during which all of the fish involved come from the same batch of eggs. Furthermore, it is often necessary to simulate commercial breeding conditions, which increases the number of animals included in the studies.

There has been an increase in the proportion of animals involved in the creation of new lines of genetically altered animals. This is probably linked to the development of new techniques for creating such lines.

With regard to the **purposes**, there is a notable sustained increase in animals involved in maintaining lines of genetically altered animals. This is due both to greater use of genetically altered animals, and to animals subject to invasive tissue sampling techniques being included in the numbers.

In the case of the use of animals in translational and applied research, there is an increase within the group of human diseases related especially to the respiratory system, followed by the group of diseases of the nervous and endocrine system. It is possible that this alteration is due to the funding lines for research projects, as well as to the interest and impact of such diseases on public health and society.

There is also an increase in use for the purpose of research into 'animal diseases'. This is due to interest in improvement and competitiveness in various production sectors and, above all, to concern for the health situation of European and North African livestock. In particular, there is an increase in the number of uses of the porcine species, especially in studies related to diseases affecting the species. This is linked to the considerable economic importance of pigs within national livestock production, and concern within the sector to improve the quality and competitiveness of production.

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

Looking at trends in actual severities, there is a continued decline in the proportion of animals subject to non-recovery procedures. However, this is not considered an actual change but rather is due to a better understanding of what a non-recovery procedure is, along with better evaluation of actual severities rather than reporting the prospective severities authorised for projects.

In addition, there is also emphasis on improving the design and implementation of monitoring protocols adapted to the particular circumstances of experimental procedures, for example including relevant clinical parameters for evaluation. This involves establishing end-point criteria clearly defined according to the type of procedure, and also applying such specific end-point criteria at an early stage.

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

Work has continued in the direction taken in previous years.

General measures:

- Appropriate training for staff with ongoing training to maintain skills;
- Stressing the importance of researchers establishing preliminary statistical studies in order to determine the number of animals to be used;
- Requesting researchers to expand and supplement project authorisation files, especially with regard to monitoring protocols and critical factors;
- In some Autonomous Communities, decisions to authorise projects include reminders that project managers are required to replace, reduce and refine their methods during their projects in order to ensure that any changes in the availability of alternatives are duly considered and used as soon as possible;
- In teaching, use of animals has been replaced by other techniques. In research, it has been reduced to the minimum necessary in order for results to be statistically significant;
- Samples have been reduced to the minimum necessary in order for results to be statistically significant;
- Active promotion of a culture of ethical evaluation, including promoting the practice of the Ethics Committee reviewing any activities involving animals or animal samples, even if they are outside the scope of Directive 2010/63/EU of 22 September;
- There was emphasis on the requirement to review the literature to assess the possibilities of replacing, reducing and refining, and also on thorough assessment during project evaluation of the suitability of the sources consulted;
- Establishing and revising standard operating procedures with regard to animals.

On replacement:

- Promoting the use of carcasses in teaching and research, coordinating acts of euthanasia where possible in order to optimise use of carcasses, or using organs and parts from slaughterhouses, carcasses from butchers/fishmongers, and remains of samples provided for teaching purposes. In universities, carcasses are used prior to using live animals;
- Promoting alternatives, such as audio-visual methods and use of artificial bio-models in teaching;
- Promoting and checking use of prior in vitro testing where procedures allow.

On reduction:

- Thorough checking of sample sizes in prior evaluations of projects;
- Promoting use of pilot studies that can help, for example, in selecting the correct size for groups;
- Reducing the sources of variation: procedural conditions, conditions of the animals and environmental conditions;
- Recently there has been emphasis on correctly selecting the sex of animals in studies and including a balance;
- Sequencing of procedures in order to use the least number of animals.

On refinement:

- Improving websites with information on refining the most common procedures;
- Monitoring of anaesthetic and analgesic techniques in procedures;
- Establishing and checking monitoring protocols and end-point criteria (in evaluation and execution of projects);
- Improvements at facilities: e.g. providing thermal blankets for rodents, both for surgery and post-operatively;
- Introducing and maintaining measures for enhancing the environment;
- In teaching, the practice has begun of establishing individual records in order to monitor the involvement of animals in teaching. Records are kept not only for species for which it is a regulatory requirement, such as dogs, but is also for equines used in teaching. This has allowed the use of animals to be standardised across courses. It has also allowed a maximum age to be set for animals in teaching, together with efforts to find outcomes such as adoption once the teaching procedures have finished.

These measures are applied during project evaluation and authorisation, and during inspections and in the communications among those involved.

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

- The following can be reported with regard to ‘other animal species’:

Use of other animal species represented over 11% of all uses of animals in 2018 in Spain. This was a significant increase compared to previous levels. Most of the uses were of ‘other fish’ (over 96%), often at very early stages of development and in large groups.

In general, in the majority of cases, the research conducted using these animals was for the following purposes: protecting the environment; preserving bio-diversity; and studying the biology and behaviour of the species itself, e.g. wild animals, marine mammals and lynxes.

In some cases, they are used in research projects concerning the nervous system (deer) or reproduction issues (mouflon).

Some groups of birds were used in studies on animal diseases, for example pigeons in studies of highly pathogenic avian influenza, as well as on non-regulatory toxicology and, very occasionally, for training, maintaining and developing professional skills.

Most of the fish involved belong to species in commercial production or species being reared in aquaculture. For this reason, in addition to research on their particular biology, studies are also being conducted into diseases that affect them, their prevention and treatment.

- In the case of ‘used for other purposes’, please note the following:

In the 2018 report, in the section on basic research, the use of animals reported as ‘other’ represents a significant increase. Use of these animals was partly accounted for by studies on mitochondrial dysfunction, the influence of environmental factors on the proportion of sexes and in studies on the palatability of veterinary products.

For the purpose ‘regulatory use and routine production’, the following are significant: producing antigens; using animals to validate analytical methods; and establishing and testing periods for suppressing medication and detecting development of abnormal toxicities.

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	411189	57.64%
Rats	51183	7.17%
Guinea-Pigs	9289	1.3%
Hamsters (Syrian)	669	0.09%
Other rodents	539	0.08%
Rabbits	18932	2.65%
Cats	89	0.01%
Dogs	856	0.12%
Ferrets	130	0.02%
Other carnivores	3	0%
Horses, donkeys and cross-breeds	112	0.02%
Pigs	11828	1.66%
Goats	198	0.03%
Sheep	2024	0.28%
Cattle	1349	0.19%
Cynomolgus monkey	271	0.04%
Baboons	3	0%
Other mammals	179	0.03%
Domestic fowl	79631	11.16%
Other birds	2446	0.34%
Reptiles	192	0.03%
Xenopus	1246	0.17%
Other amphibians	266	0.04%
Zebra fish	30174	4.23%
Other fish	86687	12.15%
Cephalopods	3919	0.55%
Total	713404	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	665394	93.31%
Animals born in the EU but not at a registered breeder	45971	6.45%
Animals born in rest of world	1765	0.25%
Total	713130	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	3	1.09%
Animals born in Asia	73	26.64%
Animals born in Africa	198	72.26%
Total	274	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	4	1.46%
F2 or greater	270	98.54%
Total	274	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	411189	6251	417440
Rats	51183	360	51543
Guinea-Pigs	9289	230	9519
Hamsters (Syrian)	669	97	766
Other rodents	539		539
Rabbits	18932	3534	22466
Cats	89	187	276
Dogs	856	276	1132
Ferrets	130		130
Other carnivores	3		3
Horses, donkeys and cross-breeds	112	57	169
Pigs	11828	155	11983
Goats	198	207	405
Sheep	2024	164	2188
Cattle	1349	223	1572
Cynomolgus monkey	271	129	400
Baboons	3		3
Other mammals	179	5	184
Domestic fowl	79631	32	79663
Other birds	2446	48	2494
Reptiles	192		192
Xenopus	1246		1246
Other amphibians	266		266
Zebra fish	30174	735	30909
Other fish	86687	1155	87842
Cephalopods	3919		3919
Total	713404	13845	727249

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	373829	51.4%
Translational and applied research	217798	29.95%
Regulatory use and Routine production	118868	16.34%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6245	0.86%
Preservation of species	488	0.07%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	10021	1.38%
Total	727249	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	49488	13.24%
Cardiovascular Blood and Lymphatic System	34819	9.31%
Nervous System	68108	18.22%

Respiratory System	2530	0.68%
Gastrointestinal System including Liver	7625	2.04%
Musculoskeletal System	9417	2.52%
Immune System	23838	6.38%
Urogenital/Reproductive System	7292	1.95%
Sensory Organs (skin, eyes and ears)	4224	1.13%
Endocrine System/Metabolism	19953	5.34%
Multisystemic	52330	14%
Ethology / Animal Behaviour /Animal Biology	89243	23.87%
Other basic research	4962	1.33%
Total	373829	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	36911	16.95%
Human Infectious Disorders	12610	5.79%
Human Cardiovascular Disorders	7809	3.59%
Human Nervous and Mental Disorders	35370	16.24%
Human Respiratory Disorders	3439	1.58%
Human Gastrointestinal Disorders including Liver	7231	3.32%
Human Musculoskeletal Disorders	3386	1.55%
Human Immune Disorders	6198	2.85%
Human Urogenital/Reproductive Disorders	1591	0.73%
Human Sensory Organ Disorders (skin, eyes and ears)	9800	4.5%
Human Endocrine/Metabolism Disorders	17939	8.24%
Other Human Disorders	82	0.04%
Animal Diseases and Disorders	54941	25.23%
Animal Welfare	5186	2.38%
Diagnosis of diseases	6963	3.2%
Plant diseases	3	0%
Non-regulatory toxicology and ecotoxicology	8339	3.83%
Total	217798	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	67259	56.58%
Other efficacy and tolerance testing	1779	1.5%
Toxicity and other safety testing including pharmacology	45885	38.6%
Routine production	3945	3.32%
Total	118868	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	23829	35.43%
Pyrogenicity testing	8802	13.09%
Batch potency testing	32174	47.84%
Other quality controls	2454	3.65%
Total	67259	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	7891	17.2%
Skin irritation/corrosion	80	0.17%

Skin sensitisation	1165	2.54%
Eye irritation/corrosion	3	0.01%
Repeated dose toxicity	8814	19.21%
Developmental toxicity	2038	4.44%
Neurotoxicity	2352	5.13%
Kinetics	1878	4.09%
Pharmaco-dynamics (incl safety pharmacology)	692	1.51%
Ecotoxicity	756	1.65%
Safety testing in food and feed area	19917	43.41%
Target animal safety	211	0.46%
Other toxicity/safety testing	88	0.19%
Total	45885	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	6435	81.55%
Other lethal methods	30	0.38%
Non lethal methods	1426	18.07%
Total	7891	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	4466	50.67%
29 - 90 days	1506	17.09%
> 90 days	2842	32.24%
Total	8814	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	284	37.57%
Chronic toxicity	472	62.43%
Total	756	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	33847	29.45%
Legislation on medicinal products for veterinary use and their residues	55458	48.26%
Medical devices legislation	823	0.72%
Industrial chemicals legislation	4583	3.99%
Plant protection product legislation	245	0.21%
Food legislation including food contact material	19917	17.33%
Other legislation	50	0.04%
Total	114923	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	108420	94.34%
Legislation satisfying national requirements only [within EU]	4759	4.14%
Legislation satisfying Non-EU requirements only	1744	1.52%
Total	114923	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	60	1.52%
Monoclonal antibody by mouse ascites method	65	1.65%
Other product types	3820	96.83%
Total	3945	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	713404	98.1%
Yes	13845	1.9%
Total	727249	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	38547	5.3%
Mild [up to and including]	346395	47.63%
Moderate	282027	38.78%
Severe	60280	8.29%
Total	727249	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	509494	70.06%
Genetically altered without a harmful phenotype	191065	26.27%
Genetically altered with a harmful phenotype	26690	3.67%
Total	727249	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	31915	86	32001
Rats	1605		1605
Pigs	4		4
Zebra fish	2257		2257
Other fish	1126		1126
Total	36907	86	36993

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	1142	3.09%
Mild [up to and including]	21920	59.25%
Moderate	13854	37.45%
Severe	77	0.21%
Total	36993	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	12759	34.49%
Genetically altered without a harmful phenotype	19450	52.58%
Genetically altered with a harmful phenotype	4784	12.93%
Total	36993	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	9546	38.11%
Cardiovascular Blood and Lymphatic System	166	0.66%
Nervous System	5428	21.67%
Respiratory System	9	0.04%
Gastrointestinal System including Liver	147	0.59%
Musculoskeletal System	143	0.57%
Immune System	400	1.6%
Sensory Organs (skin, eyes and ears)	4285	17.11%
Endocrine System/Metabolism	259	1.03%
Multisystemic	4491	17.93%
Other basic research	174	0.69%
Total	25048	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	1463	12.25%
Human Nervous and Mental Disorders	123	1.03%
Human Gastrointestinal Disorders including Liver	55	0.46%
Human Musculoskeletal Disorders	168	1.41%
Human Immune Disorders	21	0.18%
Human Endocrine/Metabolism Disorders	9993	83.66%
Animal Diseases and Disorders	122	1.02%
Total	11945	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	68801		68801
Rats	1		1
Zebra fish	3052		3052
Total	71854		71854

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	67495	93.93%
Moderate	4318	6.01%
Severe	41	0.06%
Total	71854	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	7399	10.3%
Genetically altered without a harmful phenotype	57059	79.41%
Genetically altered with a harmful phenotype	7396	10.29%
Total	71854	100.00%

Sweden

Sweden: Narrative 2018

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 2018 (274,655 uses) compared to 2017 (324,771 uses) and 2016 (344,766 uses).

Genetic status
The use of genetically altered animals with a harmful phenotype decreased 2018 (27,341 uses) compared to 2017 (36,929 uses); but were proportionally similar (10% and 11%). The corresponding use for 2016 was 22,293 uses (6%).

Place of birth
Fewer of the animal uses in 2018 were with animals born in the EU but not at a registered breeder (29,671 uses) compared to 2017 (64,675 uses) and 2016 (67,459 uses). More of the animal uses in 2018 were with animals born in rest of Europe (15,975 uses) compared to 2017 (1,608 uses) and 2016 (5,884 uses).

Non-human Primate Source
All the 14 uses of non-reused non-human primates in 2018 were of primates born in Asia. This differs from 2017 where most uses (19 uses, 76%) were of primates born in America, but is the same as 2016 were all were born in Asia (38 uses).

Species
Mice had 173,998 uses in 2018, which is a decrease compared to 2017 (220,281 uses) and 2016 (255,949 uses). The main purpose for 2018 as well as 2017 and 2016 was *Basic research,* on *Immune System, Cardiovascular Blood and Lymphatic System, Nervous System, Oncology,* and *Endocrine System/Metabolism*.

Rats had 15,438 uses in 2018, which is a decrease compared to 2017 (19,321 uses) and 2016 (21,218 uses). For 2018 as well as for 2017 and 2016, *Basic Research,* especially about the *Nervous System,* was the main purpose (although about 3,000 fewer uses were reported as *Nervous System* for 2018 compared to 2017).

Cats had four uses in 2018, which is a decrease compared to 2017 (104 uses) and 2016 (94 uses). All four cats in 2018 were reported as *Basic Research, Musculoskeletal System*; this category had no uses in 2017 but 54 uses in 2016.

Dogs had 531 uses in 2018, which is an increase compared to 2017 (386 uses) and 2016 (204 uses). The main difference from 2017 and 2016 is the increase in *Basic Research* to 304 uses (29 and 12 uses in

2017 respectively 2016) of which 150 uses were *Oncology* and 150 uses *Ethology/Animal Behaviour/Animal Biology*.

Other carnivores had 237 uses in 2018, which is an increase compared to 2017 (140 uses) and 2016 (167 uses). In contrast to 2017 and 2016, none was recorded as *Basic Research* and more were reported as *Preservation of Species* (2018: 201 uses, 2017: 73 uses, 2016: no uses).

Horses, donkeys and cross-breeds had 146 uses in 2018 which is an increase compared to 2017 (41 uses) but a large decrease compared to 2016 (824 uses). The increase compared to 2017 is mainly in *Higher Education or Training for the Acquisition, Maintenance or Improvement of Vocational Skills* (2018: 100 uses, 2017: 26 uses). Most uses in 2016 are from a single user who reported 741 uses (in *Translational and Applied Research*, more specifically *Animal Diseases and Disorders*).

Goats had 261 uses in 2018, which is an increase compared to both 2017 (30 uses) and 2016 (58 uses). The main use in 2018 was in *Translational and Applied Research* (228 uses) foremost in *Animal Diseases and Disorders* (213 uses).

Cattle had 2,394 uses in 2018, which is an increase compared to both 2017 (1,420 uses) and 2016 (1,436 uses). The use of cattle is rather similar for the three years except the 930 uses in *Animal Diseases and Disorders* (*Translational and Applied Research*) in 2018 (2017: 49 uses, 2016: 32 uses).

Rhesus monkeys had 10 uses in 2018, which is a decrease compared to both 2017 (23 uses) and 2016 (28 uses). All uses in 2018 were reported as *Basic Research* about the *Nervous System* (5 uses) and about the *Immune System* (5 uses). This contrasts to 2017 and 2016 where all uses were in *Translational and Applied Research, Human Infectious Disorders.*

The frogs *Rana temporaria* och *Rana pipiens* had 2 uses in 2018, which is a decrease compared to both 2017 (308 uses) and 2016 (623 uses). For 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 2016 most uses (600) were reported as *Protection of the Natural Environment in the Interests of the Health or Welfare of Human Beings or Animals.* The 2018 uses were in *Translational and Applied Research, Animal Diseases and Disorders*, specifically testing for prevalence of *Batrachochytrium*.

Zebra fish has gradually increased since 2016. For 2018 36,476 uses were reported (2017: 29,158 uses, 2016: 24,607 uses). A main change is the increase of uses within *Basic Research* within *Cardiovascular Blood and Lymphatic System* (2018: 16,799 uses, 2017: 7,282 uses and 2016: 1,758 uses).

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

The uses in overall are similar 2016-2018. One change is the gradual decrease of *Basic Research* to 212,517 uses in 2018 (2017: 232,174 uses, 2016: 283,240 uses). Another change is that the category

Preservation of species has increased to 6,295 uses in 2018 compared to 617 uses in 2017 and no uses in 2016. In 2018, 79% of these uses were *Other fish*. Another change is that *Maintenance of Colonies of Established Genetically Altered Animals, not used in other Procedures* decreased to 69 uses in 2018 compared to 1,679 uses in 2017 and 445 uses in 2016. Regarding maintenance, the previous main user has not reported any uses for 2018, significantly lowering the total number.

The number of uses in 2018 for many of the categories under *Basic Research* are either similar to 2017 or to 2016. A change is that *Nervous System* decreased to 35,775 uses in 2018 compared to 53,425 uses in 2017 and 51,837 uses in 2016. Furthermore, *Multisystemic* decreased to 7,257 uses from 10,201 uses in 2017 and 31,111 uses in 2016. In addition, *Sensory Organs (skin, eyes and ears)* has gradually decreased to 2,262 uses in 2018 (2017: 3,150 uses, 2016: 4,523 uses).

The number of uses in 2018 for many of the categories under *Translational and Applied Research* are either similar to 2017 or to 2016. A change is that *Human Cancer* has gradually decreased to 7,737 uses in 2018 compared to 10,841 uses in 2017 and 14,014 uses in 2016.

In addition, *Non-regulatory Toxicology and Ecotoxicology* increased to 6,253 uses in 2018 compared to 1,998 uses in 2017 and 1,955 uses in 2016. Furthermore, *Other Human Disorders* decreased to 1,020 uses in 2018 compared to 2,323 uses in 2017 and 3,802 uses in 2016.

Although there are no conclusive data, one could speculate that the decrease in uses under *Other Human Disorders* in part is due to a better understanding of the reporting system, leading to more detailed categorization.

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

The actual severities were proportionally very similar 2018 and 2016. For 2017, a larger proportion of severe uses was reported compared to 2018 and 2016. The uses with severe severity decreased to 25,492 uses (9%) in 2018, compared to 41,058 uses (13%) in 2017, and 29,577 uses (9%) in 2016.

Most uses classified as severe in 2018 were reported as *Basic Research* (85%), foremost about the *Immune System* and *Nervous System*. The number of severe uses in the subcategory *Immune System* increased to 7,306 in 2018 from 4,558 uses in 2017 and 5,935 uses in 2016. The number of severe uses in the subcategory *Nervous System* decreased to 4,398 in 2018 from 12,466 uses in 2017 and 7,744 uses in 2016.

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.

The Swedish 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.

At the end of 2017, the Swedish National Committee tasked the Swedish 3Rs Center with developing guidelines for group housing of male mice. The project consists of three parts: a questionnaire, local workshops, and a systematic literature review. Ten laboratory animal facilities, whose use of mice corresponds to more than 95% of the total use of laboratory mice in Sweden, take part in the project. During 2018, the questionnaire were sent out and eight local workshops were held in various locations around Sweden. During the workshops, information was collected about the current situation, including experienced problems. Measures tested by the facilities, and what these measures have resulted in, were also discussed and recorded. More workshops was held in 2019, after which the material was compiled. A systematic literature search was conducted in 2018 with the help of the Karolinska Institute's library and was further processed in 2019.

On November 15, 2018, the Swedish 3Rs Center co-organised a meeting for the Swedish animal welfare bodies. The meeting had two main purposes. The first purpose was to promote collaboration between the animal welfare bodies, as well as between the animal welfare bodies and the 3Rs Center. The second purpose of the meeting was to support the animal welfare bodies in moving their work forward.

During 2018, the 3Rs Center developed its website structure and published new pages on the website about animal welfare bodies, how to apply for research funding for 3R-projects, and links to other organisations that work with animal welfare and issues related to the 3Rs. The 3Rs Center has also posted news about 3R on the website.

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

Other carnivores

31% of the carnivores were recorded as other carnivores. These 237 uses consist of Arctic fox (*Vulpes lagopus*, 126 uses), brown bear (*Ursus arctos*, 58 uses), raccoon dog (*Nyctereutes procyonoides*, 36 uses), wolf (*Canis lupus,* 8 uses), wolverine (*Gulo gulo*, 5 uses), and lynx (*Lynx lynx*, 4 uses). The uses of other carnivores were reported as *Preservation of Species* (202 uses) and *Protection of the Natural Environment in the Interests of the Health or Welfare of Human Beings or Animals* (36 uses).

Other birds

90% of the birds were reported as other birds. These 10,625 uses consist mostly of Eurasian blue tit (*Cyanistes caeruleus*, 3,842 uses), collared flycatcher (*Ficedula albicollis*, 1,932 uses) and great tit (*Parus*

major, 1,421 uses). Most uses of other birds were reported as *Basic research* (9,653 uses, of which 8,578 was specified as *Ethology/Animal Behaviour/Animal Biology*).

Other fish

41% of the reported fish constitutes other fish. Of the 25,539 uses of other fish most are reported as Atlantic salmon (*Salmo salar*, 4,605 uses), European perch (*Perca fluvialis*, 3,431), brown trout (*Salmo trutta*, 3,297 uses), Atlantic herring (*Clupea harengus*, 2,679 uses) and goldsinny wrasse (*Ctenolabrus rupestris*, 2,500 uses). Most uses of other fish were reported as *Basic Research* (11,850 uses, of which 5,922 were in *Ethology/Animal Behaviour/Animal Biology*) and *Translational and Applied Research* (6,095 uses, of which 5,530 were in *Non-regulatory Toxicology and Ecotoxicology*).

Other amphibians

89% of the amphibians are registered as other amphibians. This category (2,538 uses) consists mostly of moor frog (*Rana arvalis*, 2,100 uses), Iberian ribbed newt (*Pleurodeles waltl*, 279 uses) and common toad (*Bufo bufo*, 122 uses). Most uses of other amphibians were reported as *Basic Research* (2,396 uses, of which 2,100 was in *Ethology/Animal Behaviour/Animal Biology*).

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 statistics for 2016 and 2017. After being in contact with those users, we have adjusted their reports. We have used the updated numbers in the present narrative.

Animal group	Animal species	2016	2017	2018
Rodents	Mice	255,946	220,281	173,998
	Rats	21,218	19,321	15,438
	Guinea-Pigs	422	409	623
	Hamsters (Syrian)	0	34	39
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	63	5	181
Lagomorphs	Rabbits	1,447	1,574	1,738
Carnivores	Cats	94	104	4
	Dogs	204	386	531
	Ferrets	0	0	0
	Other carnivores	167	140	237

Ungulates	Horses, donkeys & cross-breeds	824	41	146
	Pigs	1,840	1,557	1,579
	Goats	58	30	261
	Sheep	27	35	46
	Cattle	1,436	1,420	2,394
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	10	2	10
	Rhesus monkey	28	23	10
	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	427	327	483
Birds	Domestic fowl	971	1,452	1,153
	Other birds	11,583	11,269	10,625
Reptiles	Reptiles	380	0	529
Amphibians	Rana	623	308	2
	Xenopus	441	261	298
	Other amphibians	3,923	2,694	2,538
Fish	Zebra fish	24,607	29,158	36,476
	Other fish	18,024	33,940	25,539
Cephalopods	Cephalopods	0	0	0
	Total uses	**344,766**	**324,771**	**274,655**

Severity	2016		2017		2018	
	Number of	*%*	*Number of*	*%*	*Number of*	*%*
Non-recovery	6,427	2	9,324	3	6,128	2
Mild (up to and including)	111,460	32	109,850	34	88,829	32
Moderate	197,302	57	164,539	51	154,206	56
Severe	29,577	9	41,058	13	25,492	9
Totally	**344,766**	**100**	**324,771**	**100**	**274,655**	**100**

Genetic Status	2016		2017		2018	
	Number of	*%*	*Number of*	*%*	*Number of*	*%*
Not genetically altered	145,476	42	149,970	46	132,720	48
Genetically altered without a harmful phenotype	176,997	51	137,872	42	114,594	42
Genetically altered with a harmful phenotype	22,293	6	36,929	11	27,341	10
Totally	**345,433**	**100**	**325,838**	**100**	***274,655***	***100***

Regulatory use and routine production	2016		2017		2018	
	Number of	*%*	*Number of*	*%*	*Number of*	*%*
Quality control (incl batch safety and potency testing)	1,048	40	773	32	1,080	83
Other efficacy and tolerance testing	120	5	235	10	120	9
Toxicity and other safety testing including pharmacology	1,426	55	1,416	58	106	8
Routine production	5	<1	0	0	0	0
Totally	**2,599**	***100***	**2,424**	**100**	**1,306**	**100**

Re-use	2016		2017		2018	
	Number of	**%**	**Number of**	**%**	**Number of**	**%**
No	338,632	98	318,169	98	267,057	97
Yes	6,134	2	6,602	2	7,598	3
Totally	**344,766**	**100**	**324,771**	**100**	**274,655**	**100**

Basic research (first use and re-use)	2016		2017		2018	
	Number of	*%*	*Number of*	*%*	*Number of*	*%*
Oncology	28,930	10	22,549	10	24,836	12
Cardiovascular Blood and Lymphatic System	39,229	14	44,502	19	47,707	22
Nervous System	51,837	18	53,425	23	35,775	17
Respiratory System	2,732	1	7,362	3	1,697	1
Gastrointestinal System including Liver	6,256	2	1,531	1	2,180	1
Musculoskeletal System	7,120	3	4,220	2	4,471	2
Immune System	41,870	15	23,194	10	32,131	15
Urogenital/Reproductive System	2,658	1	6,543	3	2,073	1

Sensory Organs (skin, eyes and ears)	4,523	2	3,150	1	2,262	1
Endocrine System/Metabolism	25,651	9	28,055	12	20,334	10
Multisystemic	31,111	11	10,201	4	7,257	3
Ethology / Animal Behaviour /Animal Biology	16,487	6	16,914	7	18,397	9
Other basic research	24,836	9	10,528	5	13,397	6
Totally	**283,240**	**100**	**232,174**	**100**	**212,517**	**100**

Translational and applied research (first use and re-use)	**2016**		**2017**		**2018**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Human Cancer	14,014	28	10,841	19	7,737	17
Human Infectious Disorders	973	2	1,328	2	1,350	3
Human Cardiovascular Disorders	5,606	11	6,483	12	4,660	10
Human Nervous and Mental Disorders	4,523	9	9,737	17	10,942	24
Human Respiratory Disorders	5,806	11	5,077	9	4,279	9
Human Gastrointestinal Disorders including Liver	279	1	0	0	56	<1
Human Musculoskeletal Disorders	246	<1	862	2	504	1
Human Immune Disorders	1,441	3	9,271	17	1,161	3
Human Urogenital/Reproductive Disorders	75	<1	255	<1	74	<1
Human Sensory Organ Disorders (skin, eyes and ears)	292	1	500	1	48	<1
Human Endocrine/Metabolism Disorders	3,288	7	5,687	10	5,491	12
Other Human Disorders	3,802	8	2,323	4	1,020	<1
Animal Diseases and Disorders	1,160	2	704	1	1,799	4
Animal Welfare	6,578	13	105	<1	528	1
Diagnosis of diseases	530	1	542	1	355	1
Plant diseases	0	0	0	0	0	0
Non-regulatory toxicology and ecotoxicology	1,955	4	1,998	4	6,253	14
Totally	**50,568**	**100**	**55,713**	**100**	**46,257**	**100**

Sweden: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	158425	67%
Rats	14034	5.94%
Guinea-Pigs	623	0.26%
Hamsters (Syrian)	39	0.02%
Other rodents	41	0.02%
Rabbits	1730	0.73%

Cats	4	0%
Dogs	409	0.17%
Other carnivores	192	0.08%
Horses, donkeys and cross-breeds	24	0.01%
Pigs	1308	0.55%
Goats	249	0.11%
Sheep	46	0.02%
Cattle	1426	0.6%
Cynomolgus monkey	4	0%
Rhesus monkey	10	0%
Other mammals	174	0.07%
Domestic fowl	1153	0.49%
Other birds	10550	4.46%
Reptiles	529	0.22%
Rana	2	0%
Xenopus	276	0.12%
Other amphibians	2538	1.07%
Zebra fish	17476	7.39%
Other fish	25189	10.65%
Total	236451	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	188974	79.93%
Animals born in the EU but not at a registered breeder	29449	12.46%
Animals born in rest of Europe	15975	6.76%
Animals born in rest of world	2039	0.86%
Total	236437	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born in Asia	14	100%
Total	14	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	14	100%
Total	14	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	158425	692	159117
Rats	14034	772	14806
Guinea-Pigs	623		623
Hamsters (Syrian)	39		39
Other rodents	41	140	181
Rabbits	1730	8	1738
Cats	4		4
Dogs	409	122	531
Other carnivores	192	45	237
Horses, donkeys and cross-breeds	24	122	146
Pigs	1308	271	1579
Goats	249	12	261
Sheep	46		46
Cattle	1426	968	2394
Cynomolgus monkey	4	6	10
Rhesus monkey	10		10
Other mammals	174	86	260
Domestic fowl	1153		1153
Other birds	10550	75	10625
Reptiles	529		529
Rana	2		2
Xenopus	276	22	298
Other amphibians	2538		2538
Zebra fish	17476	3789	21265
Other fish	25189	350	25539
Total	236451	7480	243931

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	182154	74.67%
Translational and applied research	45965	18.84%
Regulatory use and Routine production	1306	0.54%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3253	1.33%
Preservation of species	6295	2.58%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4958	2.03%
Total	243931	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	23921	13.13%
Cardiovascular Blood and Lymphatic System	29181	16.02%
Nervous System	34045	18.69%
Respiratory System	1536	0.84%

Gastrointestinal System including Liver	2180	1.2%
Musculoskeletal System	4114	2.26%
Immune System	25999	14.27%
Urogenital/Reproductive System	1093	0.6%
Sensory Organs (skin, eyes and ears)	2262	1.24%
Endocrine System/Metabolism	19464	10.69%
Multisystemic	7139	3.92%
Ethology / Animal Behaviour /Animal Biology	18397	10.1%
Other basic research	12823	7.04%
Total	182154	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	7736	16.83%
Human Infectious Disorders	1350	2.94%
Human Cardiovascular Disorders	4370	9.51%
Human Nervous and Mental Disorders	10942	23.81%
Human Respiratory Disorders	4279	9.31%
Human Gastrointestinal Disorders including Liver	56	0.12%
Human Musculoskeletal Disorders	504	1.1%
Human Immune Disorders	1161	2.53%
Human Urogenital/Reproductive Disorders	74	0.16%
Human Sensory Organ Disorders (skin, eyes and ears)	48	0.1%
Human Endocrine/Metabolism Disorders	5490	11.94%
Other Human Disorders	1020	2.22%
Animal Diseases and Disorders	1799	3.91%
Animal Welfare	528	1.15%
Diagnosis of diseases	355	0.77%
Non-regulatory toxicology and ecotoxicology	6253	13.6%
Total	45965	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1080	82.7%
Other efficacy and tolerance testing	120	9.19%
Toxicity and other safety testing including pharmacology	106	8.12%
Total	1306	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch potency testing	1080	100%
Total	1080	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	30	28.3%
Kinetics	76	71.7%
Total	106	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	30	100%
Total	30	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage

No data reported

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	226	17.3%
Legislation on medicinal products for veterinary use and their residues	1080	82.7%
Total	1306	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1306	100%
Total	1306	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage

No data reported

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	236451	96.93%
Yes	7480	3.07%
Total	243931	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	5763	2.36%
Mild [up to and including]	80258	32.9%
Moderate	134046	54.95%
Severe	23864	9.78%
Total	243931	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	131611	53.95%
Genetically altered without a harmful phenotype	99103	40.63%
Genetically altered with a harmful phenotype	13217	5.42%
Total	243931	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	14629		14629
Rats	632		632
Zebra fish	15093	118	15211
Total	30354	118	30472

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	365	1.2%
Mild [up to and including]	8388	27.53%
Moderate	20091	65.93%
Severe	1628	5.34%
Total	30472	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	926	3.04%
Genetically altered without a harmful phenotype	15491	50.84%
Genetically altered with a harmful phenotype	14055	46.12%
Total	30472	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	915	3.03%
Cardiovascular Blood and Lymphatic System	18526	61.39%
Nervous System	1730	5.73%
Respiratory System	161	0.53%
Musculoskeletal System	357	1.18%
Immune System	5949	19.71%
Urogenital/Reproductive System	980	3.25%
Endocrine System/Metabolism	870	2.88%
Multisystemic	118	0.39%
Other basic research	574	1.9%
Total	30180	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	1	0.34%
Human Cardiovascular Disorders	290	99.32%
Human Endocrine/Metabolism Disorders	1	0.34%
Total	292	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	69		69
Total	69		69

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Moderate	69	100%
Total	69	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered with a harmful phenotype	69	100%
Total	69	100.00%

United Kingdom

United Kingdom: Narrative 2018

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2018 data for Great Britain on the 18 July 2019 and the statistical release can be accessed online here:
https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2018.

The Northern Ireland Department for Health (NIDH) published their 2018 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 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 2018, a total of 2.44 million procedures were completed. This represents a decrease of 5% (137,000) compared with the 2.57 million procedures completed in 2017.

Of the 2.44 million procedures, 1.83 million (75%) were experimental procedures and 612,000 (25%) related to the creation and breeding of genetically altered animals that were not used in further procedures. Since 2017, experimental procedures have decreased by 4% (80,000) and creation and breeding procedures have decreased by 9% (57,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to be due to a decrease in the number of mice bred but not used compared to 2017

There were 2.36 million animals used for the first time in completed procedures in 2018, representing a decrease of 6% (146,000) compared with 2017. 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 1.83 million experimental procedures completed in 2018, the majority involved the use of mice

(60%), fish (16%) and rats (9%). Comparing with 2017, there were notable changes[1] to the number of procedures involving:

- rats, which decreased by 63,000 (-27%) to 171,000 procedures in 2018;
- guinea pigs, which decreased by 16,000 (-71%) to 6,400 procedures in 2018;
- birds[2], which increased by 16,000 (+12%) to 147,000 procedures in 2018;
- rana, which increased by 570 (+525%) to 680 procedures in 2018;
- goats, which decreased by 250 (-81%) to 60 procedures in 2018;

Of the 612,000 procedures in 2018 related to the creation and breeding of genetically altered animals not used in further procedures, the majority involved mice (79%), fish[3], (21%), and rats (0.5%). Comparing with 2017, there were notable changes[4] to the number of procedures involving:

- mice, which decreased by 80,000 (-14%) to 480,000 procedures in 2018;
- fish[5], which increased by 22,000 (+21%) to 126,000 procedures in 2018;
- xenopus, which increased by 1,100 (+168%) to 1,700 procedures in 2018;
- sheep, which increased by 160 (+918%) to 170 procedures in 2018;
- pigs, which increased by 90 (+70%) to 210 procedures in 2018;

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

Of the 1.83 million experimental procedures completed in 2018:

- 5% (90,000) were assessed as non-recovery, compared with 7% (135,000) in 2017;
- 63% (1.16 million) were assessed as (up to and including) mild, compared with 61% (1.17 million) in 2017;
- 27% (489,000) were assessed as moderate, compared with 26% (504,000) in 2017;
- 5% (88,000) were assessed as severe, compared with 5% (95,000) in 2017.

Of the 612,000 procedures in 2018 related to the creation and breeding of genetically altered animals not used in further procedures:

- 0.08% (510) were assessed as non-recovery, compared with 0.07% (470) in 2017;
- 87% (532,000) were assessed as (up to and including) mild, compared with 85% (570,000) in 2017;
- 7% (41,000) were assessed as moderate, compared with 8% (55,000) in 2017;
- 6% (38,000) were assessed as severe, compared with 6% (43,000) in 2017.

In relation to the creation and 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

[1] Covers the three largest numeric and the three largest percentage changes between 2017 and 2018.
[2] Specifically, domestic fowl and other bird species.
[3] Specifically, Zebrafish and other fish species.
[4] Covers the three largest numeric and the three largest percentage changes between 2017 and 2018.
[5] Specifically, Zebrafish and other fish species.

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 2018 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;
- Nutrition
- Provision of material for ex vivo use (unspecified)
- Infectious disease

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;
- Cell line characterisation.

Regulatory use Other efficacy

Testing of traps
Diagnostics for OIE.

Regulatory use, legislative purpose “other”:

- Mainly production of reagents, controls and validation standards.
- Diagnostics for OIE
- REACH
- EU Water Framework Directive

Regulatory use, toxicity “other”:

- Effects on non-target (i.e. ASPA non-Schedule 2) species;
- Metabolism, DMPK
- Internal validation and pilot studies.
- Also testing of ballast water (ecotoxicity)
- Use of this category appears to indicate some confusion in the classification of toxicity testing

Regulatory Use: Other legislative requirements

- Mainly production to meet industry specifications.
- Provision of standard reagents, controls
- Trap approval
- EU Water Framework Directive
- REACH
- Diagnostics OIE

Many researchers appear to have problems in deciding how to classify some common procedures, in particular the re-derivation.cyropreservation of GA lines. Either additional categories or guidance would be beneficial.

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 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	1094432	62.54%
Rats	169340	9.68%
Guinea-Pigs	6445	0.37%
Hamsters (Syrian)	1416	0.08%
Mongolian gerbil	492	0.03%
Other rodents	839	0.05%
Rabbits	10691	0.61%
Cats	37	0%
Dogs	2909	0.17%
Ferrets	466	0.03%
Other carnivores	308	0.02%
Horses, donkeys and cross-breeds	86	0%
Pigs	4298	0.25%
Goats	58	0%
Sheep	4973	0.28%
Cattle	5073	0.29%
Marmoset and tamarins	92	0.01%
Cynomolgus monkey	2270	0.13%
Rhesus monkey	110	0.01%
Other mammals	861	0.05%
Domestic fowl	140049	8%
Other birds	6481	0.37%
Reptiles	104	0.01%
Rana	675	0.04%
Xenopus	1742	0.1%
Other amphibians	768	0.04%
Zebra fish	202053	11.55%
Other fish	92833	5.31%
Total	1749901	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1621088	92.77%
Animals born in the EU but not at a registered breeder	117091	6.7%
Animals born in rest of Europe	1557	0.09%
Animals born in rest of world	7693	0.44%
Total	1747429	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	383	15.49%
Animals born in Asia	538	21.76%
Animals born in Africa	1551	62.74%
Total	2472	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	246	9.95%
F2 or greater	714	28.88%
Self-sustaining colony	1512	61.17%
Total	2472	100.00%

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	1094432	988	1095420
Rats	169340	2062	171402
Guinea-Pigs	6445		6445
Hamsters (Syrian)	1416		1416
Mongolian gerbil	492	18	510
Other rodents	839		839
Rabbits	10691	468	11159
Cats	37	193	230
Dogs	2909	1636	4545
Ferrets	466		466
Other carnivores	308		308
Horses, donkeys and cross-breeds	86	10356	10442
Pigs	4298	105	4403
Goats	58		58
Sheep	4973	49338	54311
Cattle	5073	1055	6128
Marmoset and tamarins	92	21	113
Cynomolgus monkey	2270	664	2934
Rhesus monkey	110	50	160
Other mammals	861	28	889
Domestic fowl	140049	68	140117
Other birds	6481	497	6978
Reptiles	104		104
Rana	675		675
Xenopus	1742	3642	5384
Other amphibians	768	9	777
Zebra fish	202053	3130	205183
Other fish	92833	1544	94377
Total	1749901	75872	1825773

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	995914	54.55%
Translational and applied research	318241	17.43%
Regulatory use and Routine production	495378	27.13%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	13800	0.76%
Preservation of species	1037	0.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1327	0.07%
Forensic enquiries	76	0%
Total	1825773	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	124761	12.53%
Cardiovascular Blood and Lymphatic System	68674	6.9%
Nervous System	214090	21.5%
Respiratory System	12524	1.26%
Gastrointestinal System including Liver	28796	2.89%
Musculoskeletal System	30519	3.06%
Immune System	225497	22.64%
Urogenital/Reproductive System	38277	3.84%
Sensory Organs (skin, eyes and ears)	25388	2.55%
Endocrine System/Metabolism	35486	3.56%
Multisystemic	68975	6.93%
Ethology / Animal Behaviour /Animal Biology	73137	7.34%
Other basic research	49790	5%
Total	995914	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	91543	28.77%
Human Infectious Disorders	76475	24.03%
Human Cardiovascular Disorders	5368	1.69%
Human Nervous and Mental Disorders	51154	16.07%
Human Respiratory Disorders	7000	2.2%
Human Gastrointestinal Disorders including Liver	3335	1.05%
Human Musculoskeletal Disorders	5746	1.81%
Human Immune Disorders	5275	1.66%
Human Urogenital/Reproductive Disorders	2727	0.86%
Human Sensory Organ Disorders (skin, eyes and ears)	7111	2.23%
Human Endocrine/Metabolism Disorders	2733	0.86%
Other Human Disorders	8723	2.74%
Animal Diseases and Disorders	15087	4.74%
Animal Welfare	5299	1.67%
Diagnosis of diseases	4636	1.46%
Non-regulatory toxicology and ecotoxicology	26029	8.18%
Total	318241	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	136935	27.64%
Other efficacy and tolerance testing	27922	5.64%
Toxicity and other safety testing including pharmacology	147636	29.8%
Routine production	182885	36.92%
Total	495378	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	8445	6.17%
Pyrogenicity testing	638	0.47%
Batch potency testing	106839	78.02%
Other quality controls	21013	15.35%
Total	136935	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	15738	10.66%
Skin irritation/corrosion	123	0.08%
Skin sensitisation	2040	1.38%
Eye irritation/corrosion	40	0.03%
Repeated dose toxicity	38892	26.34%
Carcinogenicity	10349	7.01%
Genotoxicity	4333	2.93%
Reproductive toxicity	32612	22.09%
Developmental toxicity	15150	10.26%
Neurotoxicity	248	0.17%
Kinetics	4604	3.12%
Pharmaco-dynamics (incl safety pharmacology)	4885	3.31%
Ecotoxicity	11733	7.95%
Safety testing in food and feed area	289	0.2%
Target animal safety	512	0.35%
Other toxicity/safety testing	6088	4.12%
Total	147636	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	10252	65.14%
Other lethal methods	23	0.15%
Non lethal methods	5463	34.71%
Total	15738	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	20109	51.7%
29 - 90 days	12063	31.02%
> 90 days	6720	17.28%
Total	38892	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	2894	24.67%
Chronic toxicity	6568	55.98%
Endocrine activity	1313	11.19%
Bioaccumulation	955	8.14%
Other ecotoxicity	3	0.03%
Total	11733	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	201850	64.59%
Legislation on medicinal products for veterinary use and their residues	38777	12.41%
Medical devices legislation	948	0.3%
Industrial chemicals legislation	37869	12.12%

Plant protection product legislation	15772	5.05%
Biocides legislation	322	0.1%
Food legislation including food contact material	2619	0.84%
Feed legislation including legislation for the safety of target animals, workers and environment	9981	3.19%
Other legislation	4355	1.39%
Total	312493	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	285929	91.5%
Legislation satisfying national requirements only [within EU]	2224	0.71%
Legislation satisfying Non-EU requirements only	24340	7.79%
Total	312493	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	83961	45.91%
Other product types	98924	54.09%
Total	182885	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1749901	95.84%
Yes	75872	4.16%
Total	1825773	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	90329	4.95%
Mild [up to and including]	1157902	63.42%
Moderate	489062	26.79%
Severe	88480	4.85%
Total	1825773	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1089973	59.7%
Genetically altered without a harmful phenotype	617725	33.83%
Genetically altered with a harmful phenotype	118075	6.47%
Total	1825773	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	171778	523	172301
Rats	63		63
Pigs	211		211
Sheep	167		167
Domestic fowl	460		460
Xenopus	1328		1328
Zebra fish	34992	4	34996
Other fish	187		187
Total	209186	527	209713

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	485	0.23%
Mild [up to and including]	191197	91.17%
Moderate	16824	8.02%
Severe	1207	0.58%
Total	209713	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	38119	18.18%
Genetically altered without a harmful phenotype	160689	76.62%
Genetically altered with a harmful phenotype	10905	5.2%
Total	209713	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	40240	20.11%
Cardiovascular Blood and Lymphatic System	11225	5.61%
Nervous System	26267	13.13%
Respiratory System	284	0.14%
Gastrointestinal System including Liver	3664	1.83%
Musculoskeletal System	3744	1.87%
Immune System	29944	14.97%
Urogenital/Reproductive System	7597	3.8%
Sensory Organs (skin, eyes and ears)	5751	2.87%
Endocrine System/Metabolism	1661	0.83%
Multisystemic	53825	26.9%
Ethology / Animal Behaviour /Animal Biology	438	0.22%
Other basic research	15419	7.71%
Total	200059	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Human Cancer	5817	60.25%
Human Infectious Disorders	2636	27.3%
Human Cardiovascular Disorders	376	3.89%

Human Nervous and Mental Disorders	374	3.87%
Human Musculoskeletal Disorders	15	0.16%
Human Immune Disorders	35	0.36%
Human Urogenital/Reproductive Disorders	229	2.37%
Other Human Disorders	155	1.61%
Animal Diseases and Disorders	17	0.18%
Total	9654	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	307839	279	308118
Rats	2769		2769
Sheep	6		6
Domestic fowl	278		278
Xenopus	336	55	391
Zebra fish	90242		90242
Other fish	191		191
Total	401661	334	401995

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	20	0%
Mild [up to and including]	340902	84.8%
Moderate	24332	6.05%
Severe	36741	9.14%
Total	401995	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Not genetically altered	18231	4.54%
Genetically altered without a harmful phenotype	330940	82.32%
Genetically altered with a harmful phenotype	52824	13.14%
Total	401995	100.00%

Norway

Norway: Narrative 2018

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

2018 is the first EU reporting period for Norway, so no comparison with previous EU reports can be made.

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

2018 is the first EU reporting period for Norway, so no comparison with previous EU reports can be made.

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

2018 is the first EU reporting period for Norway, so no comparison with previous EU reports can be made

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

We have an extensive dialog with the applicant while evaluating the application, often resulting in refinements and sometimes also reductions. This is however hard to show in statistics.

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

Of other species of fish around 59,3 % were salmon, followed by cod (23%), other marine fish (15,9%), other salmonides (1,6%) and other fresh water species (0,1%).

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.

We have no cases where 'severe' classification is exceeded.

Norway: Statistical Data 2018

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	52300	3.17%
Rats	5104	0.31%
Guinea-Pigs	378	0.02%
Other rodents	2251	0.14%
Rabbits	18	0%
Cats	4	0%
Dogs	139	0.01%
Other carnivores	204	0.01%
Horses, donkeys and cross-breeds	2	0%
Pigs	669	0.04%
Goats	25	0%
Sheep	3174	0.19%
Cattle	1305	0.08%
Other mammals	1918	0.12%
Domestic fowl	1762	0.11%
Other birds	13053	0.79%
Reptiles	20	0%
Rana	2	0%
Other amphibians	186	0.01%
Zebra fish	33660	2.04%
Other fish	1534373	92.96%
Total	1650547	100.00%

Place of birth of animals other than non-human primates

Place of birth	Number of animals	Percentage
Animals born in the EU at a registered breeder	1420323	86.05%
Animals born in the EU but not at a registered breeder	166452	10.08%
Animals born in rest of Europe	60091	3.64%
Animals born in rest of world	3681	0.22%
Total	1650547	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage

No data reported

Generation of non-human primates

NHP Generation	Number of animals	Percentage

No data reported

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	52300	3378	55678
Rats	5104	2	5106
Guinea-Pigs	378		378
Other rodents	2251		2251
Rabbits	18		18
Cats	4		4
Dogs	139	6	145
Other carnivores	204		204
Horses, donkeys and cross-breeds	2	1	3
Pigs	669	7	676
Goats	25		25
Sheep	3174	15	3189
Cattle	1305	52	1357
Other mammals	1918	65	1983
Domestic fowl	1762		1762
Other birds	13053	38	13091
Reptiles	20		20
Rana	2		2
Other amphibians	186		186
Zebra fish	33660	4500	38160
Other fish	1534373	8800	1543173
Total	1650547	16864	1667411

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

Purpose Category	Number of uses	Percentage
Basic Research	852927	51.15%
Translational and applied research	751124	45.05%
Regulatory use and Routine production	34728	2.08%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	17858	1.07%
Preservation of species	9497	0.57%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1026	0.06%
Forensic enquiries	251	0.02%
Total	1667411	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	17340	2.03%
Cardiovascular Blood and Lymphatic System	11563	1.36%
Nervous System	31905	3.74%
Respiratory System	507	0.06%
Gastrointestinal System including Liver	5003	0.59%

Basic research	Number of uses	Percentage
Musculoskeletal System	181	0.02%
Immune System	30969	3.63%
Urogenital/Reproductive System	1171	0.14%
Sensory Organs (skin, eyes and ears)	470	0.06%
Endocrine System/Metabolism	6510	0.76%
Multisystemic	113495	13.31%
Ethology / Animal Behaviour /Animal Biology	596267	69.91%
Other basic research	37546	4.4%
Total	852927	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	8760	1.17%
Human Infectious Disorders	472	0.06%
Human Cardiovascular Disorders	238	0.03%
Human Nervous and Mental Disorders	1985	0.26%
Human Gastrointestinal Disorders including Liver	35	0%
Human Immune Disorders	326	0.04%
Human Endocrine/Metabolism Disorders	350	0.05%
Other Human Disorders	121	0.02%
Animal Diseases and Disorders	671497	89.4%
Animal Welfare	67283	8.96%
Diagnosis of diseases	39	0.01%
Non-regulatory toxicology and ecotoxicology	18	0%
Total	751124	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	23562	67.85%
Other efficacy and tolerance testing	895	2.58%
Toxicity and other safety testing including pharmacology	2288	6.59%
Routine production	7983	22.99%
Total	34728	100.00%

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

Regulatory uses - Quality control (including batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	1746	7.41%
Batch potency testing	20283	86.08%
Other quality controls	1533	6.51%
Total	23562	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	40	1.75%
Kinetics	180	7.87%
Ecotoxicity	60	2.62%
Target animal safety	2008	87.76%
Total	2288	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	40	100%
Total	40	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotoxicity	Number of uses	Percentage
Acute toxicity	60	100%
Total	60	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	20115	75.21%
Legislation on medicinal products for veterinary use and their residues	6530	24.42%
Other legislation	100	0.37%
Total	26745	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	26065	97.46%
Legislation satisfying national requirements only [within EU]	580	2.17%
Legislation satisfying Non-EU requirements only	100	0.37%
Total	26745	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	12	0.15%
Other product types	7971	99.85%
Total	7983	100.00%

Uses of animals in research, testing, routine production and education (including training) by first use and reuses

Reuse	Number of uses	Percentage
No	1650547	98.99%
Yes	16864	1.01%
Total	1667411	100.00%

Uses of animals in research, testing, routine production and education (including training) by severity

Severity	Number of uses	Percentage
Non-recovery	77095	4.62%
Mild [up to and including]	946467	56.76%
Moderate	562161	33.71%
Severe	81688	4.9%
Total	1667411	100.00%

Uses of animals in research, testing, routine production and education (including training) by genetic status of animals

Genetic status	Number of uses	Percentage
Not genetically altered	1637243	98.19%
Genetically altered without a harmful phenotype	27008	1.62%
Genetically altered with a harmful phenotype	3160	0.19%
Total	1667411	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

All uses of animals for the creation of new genetically altered animal lines by species, first uses and reuses

Animal species	First uses	Reuses	Total
Mice	2282	900	3182
Zebra fish	49		49
Other fish	11800		11800
Total	14131	900	15031

Uses of animals for the creation of new genetically altered animal lines by severity

Severity	Number of uses	Percentage
Non-recovery	2760	18.36%
Mild [up to and including]	12269	81.62%
Moderate	2	0.01%
Total	15031	100.00%

Uses of animals for the creation of new genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	14987	99.71%
Genetically altered with a harmful phenotype	44	0.29%
Total	15031	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of basic research purposes

Basic research	Number of uses	Percentage
Oncology	490	7.86%
Nervous System	2053	32.95%
Gastrointestinal System including Liver	412	6.61%
Urogenital/Reproductive System	3000	48.15%
Multisystemic	276	4.43%
Total	6231	100.00%

Uses of animals for the creation of new genetically altered animal lines by type of translational and applied research purposes

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	8800	100%
Total	8800	100.00%

All uses of animals for the maintenance of established genetically altered animal lines by species

Animal species	First uses	Reuses	Total uses
Mice	4177		4177
Zebra fish	9		9
Total	4186		4186

Uses of animals for the maintenance of established genetically altered animal lines by severity

Severity	Number of uses	Percentage
Mild [up to and including]	4186	100%
Total	4186	100.00%

Uses of animals for the maintenance of established genetically altered animal lines by genetic status of the animals

Genetic status	Number of uses	Percentage
Genetically altered without a harmful phenotype	4155	99.26%
Genetically altered with a harmful phenotype	31	0.74%
Total	4186	100.00%

VII Member State comparative tables for 2018

Introduction

Based on the recalculated Member State data, three comparative tables are provided for 2018 covering:

- **Numbers of animals**, by species, used for purposes of research, testing, routine production and education (including training)
- **Numbers of all uses** (first and any subsequent reuse) of animals, by species, for the purposes of research, testing, routine production and education (including training)
- Numbers and uses of animals, by species, for the **creation and maintenance of genetically altered animals**

All comparative tables include the 28 Member States of the Union in 2018, and Norway.

Table 1.1: Numbers of animals used for the first time for research, testing, routine production and educational purposes by species and Member State (Part 1) (2018)

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals															
Rodents															
Mice	161,338	290,477	1,176	1,461	67,527	1,104,144	172,248	1,333	23,768	411,189	47,444	1,073,232	18,295	52,116	149,256
Rats	3,805	18,902	1,861	0	21,270	214,039	36,360	295	1,769	51,183	10,890	150,225	6,873	22,951	21,595
Guinea-Pigs	484	14,006	1,800	0	1,188	13,946	2,659	0	16	9,289	1	41,678	12	4,850	589
Hamsters (Syrian)	162	772	0	0	24	932	292	0	0	669	72	5,193	0	0	0
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0
Mongolian gerbil	0	105	0	0	49	3,283	0	0	0	0	0	596	0	0	0
Other rodents	842	55	0	0	717	2,895	13	0	0	539	2,539	2,311	0	0	0
Rabbits															
Rabbits	3,111	61,504	293	0	2,555	81,185	3,116	12	402	18,932	186	129,357	250	1,957	171
Carnivores															
Cats	6	19	0	0	78	556	3	0	0	89	218	437	0	15	0
Dogs	77	367	25	0	425	2,108	357	0	9	856	6,180	2,569	0	369	0
Ferrets	0	0	0	0	80	69	0	0	0	130	0	28	0	0	288
Other carnivores	0	0	0	0	38	389	3,077	0	0	3	35	29	0	0	0
Farm animals															
Horses, donkeys and cross-breeds	13	233	0	0	201	431	178	0	0	112	144	122	0	10	54
Pigs	1,546	5,256	104	0	1,719	17,595	6,977	4	375	11,828	958	14,714	20	2,103	1,662
Goats	42	58	0	0	24	475	13	0	0	198	0	158	0	0	19
Sheep	42	520	0	0	499	4,613	75	0	8	2,024	1,348	3,137	10	0	644
Cattle	467	680	0	0	1,565	6,828	1,997	163	0	1,349	165	1,173	0	33	2,957
Non-human primates															
Prosimians	0	0	0	0	0	11	0	0	0	0	0	159	0	0	0
Marmoset and tamarins	0	0	0	0	0	188	0	0	0	0	0	59	0	0	0
Squirrel monkey	0	0	0	0	0	25	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	0	2	0	0	0	2,314	0	0	0	271	0	2,285	0	0	0
Rhesus monkey	0	5	0	0	0	51	0	0	1	0	0	34	0	0	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	16	0	0	0
Baboons	0	0	0	0	0	10	0	0	0	3	0	17	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	22	0	0	0
Other mammals															
Other mammals	80	102	0	0	130	1,423	28	0	0	179	319	89	0	0	1
Birds															
Domestic fowl	2,302	39,184	60	0	20,333	22,596	2,283	67	656	79,631	5,468	45,210	275	28,326	30
Other birds	323	6,163	0	0	1,364	6,909	559	72	0	2,446	1,063	28,798	0	786	654
Reptiles															
Reptiles	0	54	0	0	263	146	155	0	0	192	30	18	0	0	0
Amphibians															
Rana	0	0	1,420	0	0	834	809	0	0	0	0	256	0	0	0
Xenopus	448	810	0	0	20	1,464	429	0	0	1,246	0	8,844	0	0	42
Other amphibians	1,085	12	270	0	0	1,459	94	0	0	266	77	458	0	0	0
Fish															
Zebra fish	7,370	20,380	0	0	7,215	58,144	2,028	0	63	30,174	7,339	20,457	0	781	3,054
Other fish	13,881	28,177	0	0	89,251	80,107	11,888	411	8,932	86,687	20,700	221,002	0	2,585	17,854
Cephalopods															
Cephalopods	0	0	0	0	0	59	0	0	33	3,919	0	203	0	0	0
Totals															
Total	**197,424**	**487,843**	**7,009**	**1,461**	**216,535**	**1,629,228**	**245,638**	**2,357**	**36,032**	**713,404**	**105,176**	**1,752,906**	**25,735**	**116,882**	**198,870**
%	**1.9**	**4.6**	**0.1**	**0**	**2**	**15.4**	**2.3**	**0**	**0.3**	**6.7**	**1**	**16.6**	**0.2**	**1.1**	**1.9**

Table 1.2: Numbers of animals used for the first time for research, testing, routine production and educational purposes by species and Member State (Part2) (2018)

	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals																
Rodents																
Mice	330,716	1,573	7,019	2,975	0	142,687	52,300	81,028	41,745	6,758	158,425	3,841	6,666	1,094,432	**5,505,169**	**52.1**
Rats	111,057	311	111	1,093	0	90,275	5,104	27,787	5,361	3,642	14,034	235	8,878	169,340	**999,246**	**9.5**
Guinea-Pigs	13,852	15	0	0	0	11,372	378	5,596	0	380	623	0	752	6,445	**129,931**	**1.2**
Hamsters (Syrian)	288	0	0	0	0	911	0	25	0	18	39	0	0	1,416	**10,813**	**0.1**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**20**	**0**
Mongolian gerbil	0	0	0	0	0	105	0	122	0	0	0	0	9	492	**4,761**	**0**
Other rodents	698	0	0	0	0	668	2,251	5,928	37	0	41	0	0	839	**20,373**	**0.2**
Rabbits																
Rabbits	12,141	31	0	36	0	13,622	18	812	55	371	1,730	6	244	10,691	**342,788**	**3.2**
Carnivores																
Cats	0	0	0	0	0	69	4	7	0	0	4	0	12	37	**1,554**	**0**
Dogs	365	0	0	0	0	542	139	5	0	0	409	0	0	2,909	**17,711**	**0.2**
Ferrets	9	0	0	0	0	437	0	0	0	0	0	0	0	466	**1,507**	**0**
Other carnivores	0	0	0	0	0	84	204	216	0	0	192	0	0	308	**4,575**	**0**
Farm animals																
Horses, donkeys and cross-breeds	0	0	0	0	0	84	2	18	0	0	24	0	0	86	**1,712**	**0**
Pigs	1,457	4	0	24	0	10,502	669	601	175	48	1,308	48	2	4,298	**83,997**	**0.8**
Goats	16	0	0	0	0	114	25	52	0	0	249	0	0	58	**1,501**	**0**
Sheep	96	0	0	0	0	543	3,174	447	18	109	46	45	0	4,973	**22,371**	**0.2**
Cattle	638	0	0	0	0	1,634	1,305	198	0	0	1,426	2	0	5,073	**27,653**	**0.3**
Non-human primates																
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**170**	**0**
Marmoset and tamarins	0	0	0	0	0	42	0	0	0	0	0	0	0	92	**381**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**25**	**0**
Cynomolgus monkey	473	0	0	0	0	0	0	0	0	0	4	0	0	2,270	**7,619**	**0.1**
Rhesus monkey	0	0	0	0	0	109	0	0	0	0	10	0	0	110	**320**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**16**	**0**
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**30**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**22**	**0**
Other mammals																
Other mammals	25	0	0	0	0	225	1,918	388	2	0	174	0	0	861	**5,944**	**0.1**
Birds																
Domestic fowl	40,382	0	0	0	0	49,131	1,762	2,352	0	114	1,153	211	237	140,049	**481,812**	**4.6**
Other birds	409	0	0	49	0	13,514	13,053	7,818	0	0	10,550	0	23	6,481	**101,034**	**1**
Reptiles																
Reptiles	0	0	0	0	0	125	20	12	0	0	529	0	0	104	**1,648**	**0**
Amphibians																
Rana	0	0	0	0	0	0	2	0	0	240	2	0	0	675	**4,238**	**0**
Xenopus	222	0	0	0	0	273	0	0	0	0	276	0	0	1,742	**15,816**	**0.1**
Other amphibians	0	0	0	0	0	0	186	330	0	0	2,538	0	0	768	**7,543**	**0.1**
Fish																
Zebra fish	12,115	0	6,621	0	0	19,881	33,660	10,262	2,448	0	17,476	0	0	202,053	**461,521**	**4.4**
Other fish	22,124	1,352	0	240	119	25,206	1,534,373	8,781	12,474	0	25,189	50	0	92,833	**2,304,216**	**21.8**
Cephalopods																
Cephalopods	46	0	0	0	0	0	0	0	8	0	0	0	0	0	**4,268**	**0**
Total	**547,129**	**3,286**	**13,751**	**4,417**	**119**	**382,155**	**1,650,547**	**152,785**	**62,323**	**11,680**	**236,451**	**4,438**	**16,823**	**1,749,901**	**10,572,305**	**100**
%	**5.2**	**0**	**0.1**	**0**	**0**	**3.6**	**15.6**	**1.4**	**0.6**	**0.1**	**2.2**	**0**	**0.2**	**16.6**	**100**	

Table 2.1: All uses (first use and all subsequent reuses) of animals for research, testing, routine production and educational purposes by species and Member State (Part 1) (2018)

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals															
Rodents															
Mice	161,703	291,118	1,176	1,810	68,988	1,125,564	174,511	1,333	23,768	417,440	47,499	1,087,505	18,295	52,163	149,256
Rats	3,805	19,553	1,877	0	21,476	220,340	37,280	295	1,769	51,543	10,951	155,438	6,885	22,975	21,595
Guinea-Pigs	484	14,029	1,801	0	1,188	14,229	2,659	0	16	9,519	1	41,727	17	4,867	589
Hamsters (Syrian)	178	772	0	0	24	940	292	0	0	766	72	5,193	0	0	0
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0
Mongolian gerbil	0	105	0	0	49	3,366	0	0	0	0	0	596	0	0	0
Other rodents	842	55	0	0	717	2,942	13	0	0	539	2,539	2,913	0	0	0
Rabbits															
Rabbits	3,129	61,575	425	0	2,614	85,177	3,116	12	402	22,466	186	131,329	250	1,985	171
Carnivores															
Cats	6	34	0	0	78	765	3	0	0	276	218	1,185	0	15	0
Dogs	113	1,684	25	0	750	3,979	370	0	21	1,132	6,297	4,214	0	428	0
Ferrets	0	0	0	0	80	91	0	0	0	130	0	28	0	0	288
Other carnivores	0	0	0	0	38	389	3,347	0	0	3	35	29	0	0	0
Farm animals															
Horses, donkeys and cross-breeds	68	302	0	0	217	792	181	0	0	169	236	482	18	15	54
Pigs	1,548	5,429	104	0	2,294	18,850	7,643	4	375	11,983	958	14,969	20	2,248	1,662
Goats	42	59	0	0	28	499	13	0	0	405	0	710	0	0	19
Sheep	50	528	0	0	885	4,751	78	0	8	2,188	1,348	4,304	22	0	644
Cattle	495	850	0	0	2,886	7,307	1,999	163	0	1,572	190	2,256	0	33	3,137
Non-human primates															
Prosimians	0	0	0	0	0	63	0	0	0	0	0	159	0	0	0
Marmoset and tamarins	0	0	0	0	0	219	0	0	0	0	0	206	0	0	0
Squirrel monkey	0	0	0	0	0	25	0	0	0	0	0	0	0	0	0
Cynomolgus monkey	0	2	0	0	0	2,875	0	0	0	400	0	3,009	0	0	0
Rhesus monkey	0	41	0	0	0	65	0	0	1	0	0	62	0	5	0
Vervets (Chlorocebus spp.)	0	0	0	0	0	14	0	0	0	0	0	16	0	0	0
Baboons	0	0	0	0	0	10	0	0	0	3	0	36	0	0	0
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	7	0	0	0	0	0	22	0	0	0
Other mammals															
Other mammals	80	171	0	0	137	1,439	29	0	0	184	319	104	0	0	1
Birds															
Domestic fowl	2,302	39,203	60	0	20,390	22,843	2,283	67	656	79,663	5,468	46,029	275	28,328	30
Other birds	323	6,209	0	0	1,390	7,331	559	72	0	2,494	1,063	29,095	0	786	654
Reptiles															
Reptiles	0	324	0	0	263	152	155	0	0	192	30	2,120	0	0	0
Amphibians															
Rana	0	0	1,420	0	0	834	809	0	0	0	0	256	0	0	0
Xenopus	449	839	0	0	20	2,434	1,389	0	0	1,246	0	9,289	0	0	42
Other amphibians	1,085	277	270	0	0	1,459	94	0	0	266	77	458	0	0	0
Fish															
Zebra fish	7,370	20,381	0	0	7,215	58,144	2,028	0	63	30,909	7,339	20,661	0	2,409	3,054
Other fish	13,881	28,939	0	0	89,718	80,522	11,888	411	9,020	87,842	20,700	230,992	0	2,737	17,854
Cephalopods															
Cephalopods	0	0	0	0	0	59	0	0	33	3,919	0	219	0	0	0
Total	**197,953**	**492,479**	**7,158**	**1,810**	**221,445**	**1,668,476**	**250,739**	**2,357**	**36,132**	**727,249**	**105,526**	**1,795,631**	**25,782**	**118,994**	**199,050**
%	**1.8**	**4.6**	**0.1**	**0**	**2**	**15.4**	**2.3**	**0**	**0.3**	**6.7**	**1**	**16.6**	**0.2**	**1.1**	**1.8**

Table 2.2: All uses (first use and all subsequent reuses) of animals for research, testing, routine production and educational purposes by species and Member State (Part2) (2018)

	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals																
Rodents																
Mice	331,233	1,573	7,669	2,975	0	146,358	55,678	81,095	41,805	6,758	159,117	4,440	6,666	1,095,420	**5,562,916**	**51.5**
Rats	111,266	311	111	1,093	0	91,579	5,106	27,826	5,361	3,642	14,806	235	8,878	171,402	**1,017,398**	**9.4**
Guinea-Pigs	14,078	15	0	0	0	11,443	378	5,596	0	446	623	0	752	6,445	**130,902**	**1.2**
Hamsters (Syrian)	288	0	0	0	0	911	0	25	0	18	39	0	0	1,416	**10,934**	**0.1**
Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**20**	**0**
Mongolian gerbil	0	0	0	0	0	105	0	122	0	0	0	0	9	510	**4,862**	**0**
Other rodents	698	0	0	0	0	668	2,251	6,165	37	0	181	0	0	839	**21,399**	**0.2**
Rabbits																
Rabbits	13,000	31	0	36	0	13,788	18	940	55	619	1,738	70	275	11,159	**354,566**	**3.3**
Carnivores																
Cats	0	0	0	0	0	120	4	7	2	0	4	0	12	230	**2,959**	**0**
Dogs	441	0	0	0	0	1,016	145	8	18	0	531	0	0	4,545	**25,717**	**0.2**
Ferrets	9	0	0	0	0	475	0	0	0	0	0	0	0	466	**1,567**	**0**
Other carnivores	0	0	0	0	0	84	204	216	0	0	237	0	0	308	**4,890**	**0**
Farm animals																
Horses, donkeys and cross-breeds	15	0	0	0	0	146	3	47	9	2	146	2	0	10,442	**13,346**	**0.1**
Pigs	1,526	4	0	24	0	10,594	676	603	175	48	1,579	48	2	4,403	**87,769**	**0.8**
Goats	36	0	0	0	0	125	25	59	88	0	261	0	0	58	**2,427**	**0**
Sheep	156	0	0	0	0	643	3,189	594	40	249	46	46	0	54,311	**74,080**	**0.7**
Cattle	693	0	0	0	0	3,607	1,357	202	20	3	2,394	2	0	6,128	**35,294**	**0.3**
Non-human primates																
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**222**	**0**
Marmoset and tamarins	1	0	0	0	0	45	0	0	0	0	0	0	0	113	**584**	**0**
Squirrel monkey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**25**	**0**
Cynomolgus monkey	511	0	0	0	0	0	0	0	0	0	10	0	0	2,934	**9,741**	**0.1**
Rhesus monkey	0	0	0	0	0	160	0	0	0	0	10	0	0	160	**504**	**0**
Vervets (Chlorocebus spp.)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**30**	**0**
Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**49**	**0**
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**29**	**0**
Other mammals																
Other mammals	25	0	0	0	0	225	1,983	388	2	0	260	0	0	889	**6,236**	**0.1**
Birds																
Domestic fowl	42,153	0	0	0	0	51,006	1,762	2,662	0	170	1,153	211	243	140,117	**487,074**	**4.5**
Other birds	409	0	0	49	0	13,884	13,091	7,991	66	0	10,625	0	23	6,978	**103,092**	**1**
Reptiles																
Reptiles	0	0	0	0	0	125	20	12	0	0	529	0	0	104	**4,026**	**0**
Amphibians																
Rana	0	0	0	0	0	0	2	0	0	240	2	0	0	675	**4,238**	**0**
Xenopus	245	0	0	0	0	401	0	0	15	0	298	0	0	5,384	**22,051**	**0.2**
Other amphibians	0	0	0	0	0	0	186	330	0	0	2,538	0	0	777	**7,817**	**0.1**
Fish																
Zebra fish	12,115	0	6,621	0	0	19,881	38,160	10,262	2,448	0	21,265	0	0	205,183	**475,508**	**4.4**
Other fish	22,403	1,352	0	240	119	25,286	1,543,173	8,781	12,474	0	25,539	50	0	94,377	**2,328,298**	**21.5**
Cephalopods																
Cephalopods	46	0	0	0	0	0	0	0	8	0	0	0	0	0	**4,284**	**0**
Total	**551,347**	**3,286**	**14,401**	**4,417**	**119**	**392,675**	**1,667,411**	**153,931**	**62,623**	**12,195**	**243,931**	**5,104**	**16,860**	**1,825,773**	**10,804,854**	**100**
%	**5.1**	**0**	**0.1**	**0**	**0**	**3.6**	**15.4**	**1.4**	**0.6**	**0.1**	**2.3**	**0**	**0.2**	**16.9**	**100**	

Table 3.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species, reuse and Member State[1]) (2018)

	Reuse[2)]	AT	BE	CY	CZ	DE	DK	EL	ES	FI	FR	HR	HU	IE	IT	LU	NL	NO	PL	PT	SE	UK	Total	%
Mice	No	20,525	29,382	68	9,464	103,224	3,281	7,724	31,915	3,773	31,965	0	157	253	4,426	148	7,978	2,282	99	1,038	14,629	171,778	**444,109**	**99.4**
	Yes	0	21	0	0	1,014	0	0	86	0	0	0	0	0	0	0	2	900	0	0	0	523	**2,546**	**0.6**
	Total	**20,525**	**29,403**	**68**	**9,464**	**104,238**	**3,281**	**7,724**	**32,001**	**3,773**	**31,965**	**0**	**157**	**253**	**4,426**	**148**	**7,980**	**3,182**	**99**	**1,038**	**14,629**	**172,301**	**446,655**	**100.0**
Rats	No	0	239	0	141	979	0	0	1,605	0	2,489	0	0	40	18	0	0	0	21	0	632	63	**6,227**	**99.9**
	Yes	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	**4**	**0.1**
	Total	**0**	**239**	**0**	**141**	**979**	**0**	**0**	**1,605**	**0**	**2,493**	**0**	**0**	**40**	**18**	**0**	**0**	**0**	**21**	**0**	**632**	**63**	**6,231**	**100.0**
Hamsters (Syrian)	No	0	0	0	89	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**89**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**89**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	89	**100.0**
Rabbits	No	14	0	0	0	16	0	0	0	0	258	0	36	0	0	0	0	0	0	0	0	0	**324**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**14**	**0**	**0**	**0**	**16**	**0**	**0**	**0**	**0**	**258**	**0**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	324	**100.0**
Ferrets	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Yes	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**4**	**100.0**
	Total	**0**	**0**	**0**	**0**	**4**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	4	**100.0**
Pigs	No	0	0	0	0	29	0	0	4	0	0	0	0	0	25	0	0	0	0	0	0	211	**269**	**98.5**
	Yes	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**4**	**1.5**
	Total	**0**	**0**	**0**	**0**	**33**	**0**	**0**	**4**	**0**	**0**	**0**	**0**	**0**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**211**	273	**100.0**
Sheep	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	167	**167**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**167**	167	**100.0**
Marmoset and tamarins	No	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**10**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	10	**100.0**
Other mammals	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	70	0	0	0	**70**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**70**	**0**	**0**	**0**	70	**100.0**
Domestic fowl	No	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	460	**560**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**100**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**460**	560	**100.0**
Xenopus	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1,328	**1,328**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1,328**	1,328	**100.0**
Other amphibians	No	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**100**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**100**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	100	**100.0**
Zebra fish	No	7,064	5,523	0	0	46,203	649	0	2,257	1,139	3,746	34	0	0	556	0	0	49	0	1,230	15,093	34,992	**118,535**	**98.8**
	Yes	0	0	0	0	0	0	0	0	0	0	0	1,335	0	0	0	0	0	0	0	118	4	**1,457**	**1.2**
	Total	**7,064**	**5,523**	**0**	**0**	**46,203**	**649**	**0**	**2,257**	**1,139**	**3,746**	**34**	**1,335**	**0**	**556**	**0**	**0**	**49**	**0**	**1,230**	**15,211**	**34,996**	119,992	**100.0**
Other fish	No	126	0	0	0	2,809	0	0	1,126	0	0	0	0	0	226	0	0	11,800	0	0	0	187	**16,274**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**126**	**0**	**0**	**0**	**2,809**	**0**	**0**	**1,126**	**0**	**0**	**0**	**0**	**0**	**226**	**0**	**0**	**11,800**	**0**	**0**	**0**	**187**	16,274	**100.0**
All Species	**No**	**27,729**	**35,144**	**68**	**9,794**	**153,370**	**3,930**	**7,724**	**36,907**	**4,912**	**38,458**	**34**	**193**	**293**	**5,251**	**148**	**7,978**	**14,131**	**190**	**2,268**	**30,354**	**209,186**	**588,062**	**99.3**
	Yes	**0**	**21**	**0**	**0**	**1,022**	**0**	**0**	**86**	**0**	**4**	**0**	**1,335**	**0**	**0**	**0**	**2**	**900**	**0**	**0**	**118**	**527**	**4,015**	**0.7**
	Total	**27,729**	**35,165**	**68**	**9,794**	**154,392**	**3,930**	**7,724**	**36,993**	**4,912**	**38,462**	**34**	**1,528**	**293**	**5,251**	**148**	**7,980**	**15,031**	**190**	**2,268**	**30,472**	**209,713**	**592,077**	**100.0**

Table notes:

1) Table includes only those Member States that have reported data for this purpose

2) Reuse “No” = numbers of animals used for the first time;
Reuse “Yes” = all subsequent reuses;
Total = numbers of all uses.

Table 3.2: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and Member State[1]) (2018)

	Reuse[2]	AT	BE	CZ	DE	DK	EE	EL	ES	FI	FR	IE	IT	LU	NL	NO	PL	PT	SE	SK	UK	Total	%
	No	12,045	28,403	626	309,563	179	643	831	68,801	285	73,036	457	828	0	1,186	4,177	136	16,177	69	473	307,839	**825,754**	**99.9**
Mice	Yes	0	13	0	210	0	0	0	0	0	42	0	0	0	0	0	0	0	0	0	279	**544**	**0.1**
	Total	**12,045**	**28,416**	**626**	**309,773**	**179**	**643**	**831**	**68,801**	**285**	**73,078**	**457**	**828**	**0**	**1,186**	**4,177**	**136**	**16,177**	**69**	**473**	**308,118**	**826,298**	**100.0**
	No	0	211	0	1,492	0	0	0	1	0	1,855	0	0	0	0	0	0	9	0	259	2,769	**6,596**	**100.0**
RRats	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**211**	**0**	**1,492**	**0**	**0**	**0**	**1**	**0**	**1,855**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**0**	**259**	**2,769**	**6,596**	**100.0**
	No	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	**0**	**5**	**100.0**
Dogs	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**100.0**
	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**6**	**6**	**100.0**
Sheep	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**6**	**6**	**100.0**
	No	0	0	0	219	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**278**	**497**	**100.0**
Domestic fowl	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**219**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**278**	**497**	**100.0**
	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**336**	**336**	**85.9**
Xenopus	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**55**	**55**	**14.1**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**391**	**391**	**100.0**
	No	0	0	0	3,868	0	0	0	3,052	0	720	0	0	107	54	9	0	30	0	0	**90,242**	**98,082**	**100.0**
Zebra fish	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**3,868**	**0**	**0**	**0**	**3,052**	**0**	**720**	**0**	**0**	**107**	**54**	**9**	**0**	**30**	**0**	**0**	**90,242**	**98,082**	**100.0**
	No	0	0	0	494	0	0	0	0	0	768	0	0	0	0	0	0	0	0	0	**191**	**1,453**	**100.0**
Other fish	**Yes**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0.0**
	Total	**0**	**0**	**0**	**494**	**0**	**0**	**0**	**0**	**0**	**768**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**191**	**1,453**	**100.0**
	No	**12,045**	**28,614**	**626**	**315,636**	**179**	**643**	**831**	**71,854**	**285**	**76,384**	**457**	**828**	**107**	**1,240**	**4,186**	**136**	**16,216**	**69**	**732**	**401,661**	**932,729**	**99.9**
All Species	**Yes**	**0**	**13**	**0**	**210**	**0**	**0**	**0**	**0**	**0**	**42**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**334**	**599**	**0.1**
	Total	**12,045**	**28,627**	**626**	**315,846**	**179**	**643**	**831**	**71,854**	**285**	**76,426**	**457**	**828**	**107**	**1,240**	**4,186**	**136**	**16,216**	**69**	**732**	**401,995**	**933,328**	**100.0**

Table notes:

1) Table includes only those Member States that have reported data for this purpose

2) Reuse "No" = numbers of animals used for the first time;
Reuse "Yes" = all subsequent reuses;
Total = numbers of all uses.