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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 2019

PART C:

MEMBER STATE DATA 2019

MEMBER STATE COMPARATIVE TABLES FOR 2019

MEMBER STATE DATA 2019

VI Member State narratives and data submissions 2019

Introduction

Member States submitted 2019 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 2019.

The submissions include data from all 28 Member States of the EU in 2019, and Norway.

The Member State data tables in the following pages are presented respecting the same three-way division as the EU 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 EU - 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 2012/707/EU were submitted for publication in this EU report.

Austria

Austria: Narrative 2019

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 2019 is 246.315 (2018: 237.727), which is an increase of approx. 3,6 % or in absolute numbers 8.588 animals. In comparison with the previous three 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 of animals in any of the specific areas and analysis of the reasons thereof.

The total number of mice used for scientific purposes in 2019 is 205.858 (2018: 194.273). An increase in the use of mice is especially observed for the purposes “Translational and applied research, Human infectious disorders”, “Basic research, Multisystemic” and “Basic Research, Ethology/Animal Behaviour/ Animal Biology”.

With regards to the categories of purposes, a decrease is observed for “Maintenance of colonies of established genetically altered animals, not used in procedures” (from 29.361 in 2017, 12.045 in 2018 to 8.327 animals in 2019) and “basic research, Endocrine System/Metabolism” (from 6.576 in 2018 to 2.530 animals in 2019). In 2019 no animals were used for the purpose “Regulatory use and routine production type, Quality control (incl batch safety and potency testing), Pyrogenicity testing” (2018: 1.923 animals, 2017: 9.125 animals).

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

No significant changes are observed.

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

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

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

“Other mammals” include i.a. Cervus, Sus scrofa and Vicugna pacos, “Other birds” i.a. Columbidae, Anser anser and Corvus corax; “Other fish” include i.a. Onchorhynchus mykiss, Chondrostoma nasus, Rutilus rutilus, Salmo trutta and Squalius cephalus; “Other amphibian” include i.a. Ambystoma mexicanum.

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 2019

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	180737	82.78%
Rats	4748	2.17%
Guinea-Pigs	118	0.05%
Hamsters (Syrian)	291	0.13%
Mongolian gerbil	113	0.05%
Other rodents	14	0.01%
Rabbits	960	0.44%
Cats	35	0.02%
Dogs	138	0.06%
Horses, donkeys and cross-breeds	14	0.01%
Pigs	1836	0.84%
Goats	10	0%
Sheep	91	0.04%
Cattle	559	0.26%
Other mammals	73	0.03%
Domestic fowl	2087	0.96%
Other birds	154	0.07%
Xenopus	673	0.31%
Other amphibians	3587	1.64%
Zebra fish	6538	2.99%
Other fish	15549	7.12%
Total	218325	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	198955	91.13%
Animals born in the EU but not at a registered breeder	17204	7.88%
Animals born in rest of Europe	3	0%
Animals born in rest of world	2163	0.99%
Total	218325	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	180737	653	181390
Rats	4748		4748
Guinea-Pigs	118		118
Hamsters (Syrian)	291		291
Mongolian gerbil	113		113
Other rodents	14		14
Rabbits	960	26	986
Cats	35		35
Dogs	138	17	155
Horses, donkeys and cross-breeds	14	76	90
Pigs	1836	4	1840
Goats	10		10
Sheep	91	6	97
Cattle	559	25	584
Other mammals	73		73
Domestic fowl	2087		2087
Other birds	154	1	155
Xenopus	673		673
Other amphibians	3587	11	3598
Zebra fish	6538		6538
Other fish	15549	34	15583
Total	218325	853	219178

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	103423	47.19%
Translational and applied research	90468	41.28%
Regulatory use and Routine production	17867	8.15%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4196	1.91%
Preservation of species	55	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3169	1.45%
Total	219178	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	19858	19.2%
Cardiovascular Blood and Lymphatic System	5938	5.74%
Nervous System	11817	11.43%
Respiratory System	240	0.23%
Gastrointestinal System including Liver	2421	2.34%
Musculoskeletal System	6618	6.4%
Immune System	21969	21.24%
Urogenital/Reproductive System	1731	1.67%
Sensory Organs (skin, eyes and ears)	258	0.25%
Endocrine System/Metabolism	2038	1.97%

Multisystemic	11749	11.36%
Ethology / Animal Behaviour /Animal Biology	11872	11.48%
Other basic research	6914	6.69%
Total	103423	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18119	20.03%
Human Infectious Disorders	56601	62.56%
Human Cardiovascular Disorders	777	0.86%
Human Nervous and Mental Disorders	3999	4.42%
Human Respiratory Disorders	219	0.24%
Human Gastrointestinal Disorders including Liver	246	0.27%
Human Musculoskeletal Disorders	337	0.37%
Human Immune Disorders	536	0.59%
Human Urogenital/Reproductive Disorders	200	0.22%
Human Sensory Organ Disorders (skin, eyes and ears)	405	0.45%
Human Endocrine/Metabolism Disorders	1024	1.13%
Other Human Disorders	3618	4%
Animal Diseases and Disorders	3629	4.01%
Animal Welfare	113	0.12%
Diagnosis of diseases	645	0.71%
Total	90468	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	17697	99.05%
Toxicity and other safety testing including pharmacology	34	0.19%
Routine production	136	0.76%
Total	17867	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	28	0.16%
Batch potency testing	16839	95.15%
Other quality controls	830	4.69%
Total	17697	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Neurotoxicity	34	100%
Total	34	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	17697	99.81%
Other legislation	34	0.19%
Total	17731	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	17027	96.03%
Legislation satisfying Non-EU requirements only	704	3.97%
Total	17731	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	136	100%
Total	136	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	218325	99.61%
Yes	853	0.39%
Total	219178	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	6147	2.8%
Mild [up to and including]	123140	56.18%
Moderate	69646	31.78%
Severe	20245	9.24%
Total	219178	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	146142	66.68%
Genetically altered without a harmful phenotype	61504	28.06%
Genetically altered with a harmful phenotype	11532	5.26%
Total	219178	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	16141		16141
Zebra fish	2443		2443
Other fish	226		226
Total	18810		18810

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

Severity	Number of uses	Percentage
Mild [up to and including]	17121	91.02%
Moderate	1501	7.98%
Severe	188	1%
Total	18810	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	2255	11.99%
Genetically altered without a harmful phenotype	13303	70.72%
Genetically altered with a harmful phenotype	3252	17.29%
Total	18810	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	8851	47.08%
Cardiovascular Blood and Lymphatic System	62	0.33%
Nervous System	171	0.91%
Gastrointestinal System including Liver	781	4.15%
Immune System	1714	9.12%
Endocrine System/Metabolism	492	2.62%
Multisystemic	4929	26.22%
Other basic research	1801	9.58%
Total	18801	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	9	100%
Total	9	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	8327		8327
Total	8327		8327

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

Severity	Number of uses	Percentage
Mild [up to and including]	7998	96.05%
Moderate	324	3.89%
Severe	5	0.06%
Total	8327	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	423	5.08%
Genetically altered without a harmful phenotype	6352	76.28%
Genetically altered with a harmful phenotype	1552	18.64%
Total	8327	100.00%

Belgium

Belgium: Narrative 2019

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

Compared to 2018 (556,271 uses), there is a decrease of 11.20% in the number of uses for scientific purposes in 2019 (493,982 uses).

Number of use in 2017	Number of use in 2018	Number of use in 2019
543074	556271	493982

Since 2015, the number of re-use continues to decline. Compared to 2018 there is a decrease of 10.75% and even a decrease of 17.15% compared to the numbers of 2017.

Re-Use	Number of use in 2017	Number of use in 2018	Number of use in 2019
No	538043	551601	489814
Yes	5031	4670	4168
Total uses	**543074**	**556271**	**493982**

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

Species	Number of use in 2017	Number of use in 2018	Number of use in 2019
Mammals	442398	454576	401065
Birds	46812	45412	41703
Fish	52462	54843	49807
Amphibians	1241	1116	1106
Reptiles	181	324	301
Cephalopods	0	0	0
Total uses	**543094**	**556271**	**493982**

Within the mammals category we notice that the increasing trend in the use of mice has come to an end in 2019. In 2019 the use of mice dropped (decrease of 10.48% compared to 2017 and 14.30% compared to 2018).

Other interesting trends in this category are the increasing use of cats and the decreasing use of dogs. Regarding the use of cats, it is important to note that the vast majority of projects involve the use of pets under treatment as patients at the veterinary clinic. They have a certain medical condition / disorder / disease or characteristic and are included in a study (after approval of the owner). For the animals, this means that, for example, a blood and / or urine sample is taken that must provide useful information within a study (and is not part of the standard treatment).

The decrease in the use of dogs can mainly be explained by the fact that fewer studies were carried out in 2019 in the field of Alzheimer's research (more specifically less research concerning the distribution in the body of test substances). A small majority of dogs were used in research conducted for the development of human drugs. Another large category includes, once again, pets that are being treated as patients in a veterinary clinic and are involved in scientific research.

Animal Species	Number of use in 2017	Number of use in 2018	Number of use in 2019
Mice	334054	348937	299038
Cats	61	34	227
Dogs	1856	1684	1302

In the birds category, there is a decrease for domestic fowl compared to 2018 (-9.98%). The use of other birds increased slightly (3.25%).

Animal Species	Number of use in 2017	Number of use in 2018	Number of use in 2019
Domestic fowl	39674	39203	35292
Other birds	7138	6209	6411

In the fish category, there was a decrease in the use of zebra fish in 2018 and an increase in 2019. This can partly be explained by efforts to make more use of animals at the larval stage (less than 6 days) in research on human diseases. However, testing showed that the results were less consistent and subsequently the use of zebrafish increased again in 2019.

The use of other fish decreased by 63.05% compared to 2018, due to a decreasing use of other fish in several research domains.

Animal Species	Number of use in 2017	Number of use in 2018	Number of use in 2019
Zebra fish	28435	25904	39115

Other Fish	24027	28939	10692

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

Purpose Category	Number of use in 2017	Number of use in 2018	Number of use in 2019
Basic Research	272795	251704	222946
Translational and applied research	117258	121645	130724
Regulatory use and Routine production	141853	140896	115267
Protection of the natural environment in the interests of the health or welfare of human beings or animals	706	359	798
Preservation of species	151	5598	243
Higher education or training for the acquisition, maintenance or improvement of vocational skills	8051	7442	6287
Forensic enquiries	0	0	0
Maintenance of colonies of established genetically altered animals, not used in other procedures	2260	28627	17717
Non-EU Purpose	0	0	0
Total uses	**543074**	**556271**	**493982**

Between 2018 and 2019, basic research diminished by 11.43%. This was in particular due to decreases in the area of Oncology research and research on the Nervous System.

During the same time period Regulatory use and Routine production decreased by 18.19%. This is mostly explained by a decrease in the category of Other efficacy and tolerance testing (-50,65%) and Quality control (incl. batch safety and potency testing) (-30,32%). This was due to a temporary drop in projects within this category. It is expected that this number will increase again in 2020.

The number of procedures in the area of the Preservation of species went down. This is mainly due to the fact that a certain test, in which the fish safety of axial flow pumps was tested, has been completed in 2018.

The number of procedures concerning Maintenance of colonies of established genetically altered lines increased significantly in 2018 as the institutions were actively contacted at that time to explain the terminology. In 2019 the numbers for Maintenance went down again because several establishments adapted their procedures and now choose to combine identification and genotyping in one step.

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

Severity	Number of use in 2017	% in 2017	Number of use in 2018	% in 2018	Number of use in 2019	% in 2019
Non-recovery	26546	4,89%	20565	3,70%	14074	2,85%
Mild	297189	54,72%	311660	56,03%	284376	57,57%
Moderate	134577	24,78%	154633	27,80%	131963	26,71%
Severe	84762	15,61%	69413	12,48%	63569	12,87%
Total uses	543074	100,00%	556271	100,00%	493982	100,00%

Within the actual severities classification we note almost no changes. The percentages seem to be quite stable. There are no remarkable changes or trends.

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

Continuation of the RE-Place project (creation of a database that brings together expertise on alternative methods for animal testing) and funding of several specific 3R research projects. No impact on the statistics has yet been noted.

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

1. Other fish

21,5% of the fishes are reported under the "other" category.

Taking into account the categories of fish for which at least 5 uses have been registered, the other fishes are mostly Cyprinidae (24%) and Salmonidae (24%), followed by Anguillidae (13%), Cichlidae (12%) and Nothobranchiidae (8%).

Other fish	Number of uses	Other fish	Number of uses
Cyprinus carpio	2561	*Lactoria cornuta*	5
Oncorhynchus mykiss	1658	*Metynnis hypsauchen*	5
Anguilla anguilla	1384	*Piaractus brachypomus*	5
Oreochromis niloticus	1235	*Pygopristis denticulata*	5
Nothobranchius furzeri	868	*Synodontis nigriventris*	5
Salmo salar	590	*Ostracion solorensis*	4
Scortum barcoo	576	*Synodontis soloni*	4
Clarias gariepinus	443	*Dascyllus trimaculatus*	3
Thymallus thymallus	295	*Myloplus rubripinnis*	3
Kryptolebias marmoratus	270	*Schistura denisoni*	3
Gasterosteus aculeatus	212	*Serrasalmus maculatus*	3
Lota lota	135	*Synodontis ilebrevis*	3

Sander lucioperca	85	*Yasuhikotakia morleti*	3
Pleuronectes platessa	54	*Ancistrus dolichopterus*	2
Raja clavata	39	*Epalzeorhynchos bicolor*	2
Dicentrarchus labrax	37	*Helostoma temminkii*	2
Pseudotropheus saulosi	26	*Maylandia zebra*	2
Neogobius melanostomus	23	*Pygocentrus piraya*	2
Raja brachyura	18	*Serrasalmus elongatus*	2
Parophidion vassali	16	*Catoprion mento*	1
Psetta maxima	15	*Colossoma macropomum*	1
Pygocentrus nattereri	14	*Corydoras sp.*	1
Raja undulata	13	*Hyphessobrycon sp.*	1
Raja montagui	12	*Methynnis lippincottianus*	1
Synodontis grandiops	11	*Puntigrus tetrazona*	1
Haplochromis sp. Tomato	10	*Pygocentrus cariba*	1
Microsynodontis batesi	8	*Raja microocellata*	1
Myloplus schomburgkii	6	*Serrasalmus manueli*	1
Alosa fallax	5	*Synodontis victoriae*	1

2. Other amphibians

23.96% of the amphibians are reported under the “other” category.

They are mostly Ranidae (*Lithobates catesbeianus*) (80% of other amphibians), Ceratophrydae (in order of importance: *Ceratophrys cranwelli, Ceratophrys cornuta, Ceratophrys 128 rnate, Lepidobatrachus laevis, Ceratophrys aurita, Chacophrys pierotti* and *Ceratophrys stolzmanni*) (19%) and Microhylidae (*Dyscophus guineti)* (<1%).

Other amphibians	Number of uses
Lithobates catesbeianus larve	200
Ceratophrys cranwelli	12
Lithobates catesbeianus adult	12
Ceratophrys cornuta	9
Ceratophrys ornata	9
Lepidobatrachus laevis	9
Ceratophrys aurita	6
Chacophrys pierotti	4
Ceratophrys stolzmanni	2
Dyscophus guineti	2

3. Other birds

15,37% of the birds are reported under the “other” category.

They are mostly Paridae (*Parus major*) (43% of other birds) and Phasianidae (*Meleagris gallopavo* and *Coturnix japonica*) (41% of other birds).

The other birds are members of Anatidae (14%), Fringillidae (Serinus canaria) (1%), Columbidae (<1%), Estrildidae (*Taeniopygia guttata*) (<1%), Laridae (*Larus fuscus*) (<1%) and Sturnidae (*Sturnus vulgaris*) (<1%).

Other birds	Number of uses
Parus major	2916
Meleagris gallopavo	2562
Anatidae	970
Coturnix japonica	186
Serinus canaria	90
Columbidae	24
Taeniopygia guttata	10
Larus fuscus	5
Sturnus vulgaris	4

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 2019

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	256049	58.11%
Rats	16985	3.86%
Guinea-Pigs	11142	2.53%
Hamsters (Syrian)	806	0.18%
Mongolian gerbil	108	0.02%
Other rodents	166	0.04%
Rabbits	63075	14.32%
Cats	208	0.05%
Dogs	542	0.12%
Horses, donkeys and cross-breeds	46	0.01%
Pigs	5091	1.16%
Goats	63	0.01%
Sheep	527	0.12%
Cattle	1251	0.28%
Rhesus monkey	7	0%
Other mammals	103	0.02%
Domestic fowl	35286	8.01%
Other birds	6186	1.4%
Reptiles	15	0%
Xenopus	267	0.06%

Other amphibians	14	0%
Zebra fish	32364	7.35%
Other fish	10290	2.34%
Total	440591	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	423118	96.04%
Animals born in the EU but not at a registered breeder	14236	3.23%
Animals born in rest of Europe	411	0.09%
Animals born in rest of world	2819	0.64%
Total	440584	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	6	85.71%
Animals born in Asia	1	14.29%
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	256049	991	257040
Rats	16985	90	17075
Guinea-Pigs	11142		11142
Hamsters (Syrian)	806		806
Mongolian gerbil	108		108
Other rodents	166		166
Rabbits	63075	19	63094
Cats	208	19	227
Dogs	542	760	1302
Horses, donkeys and cross-breeds	46	64	110
Pigs	5091	194	5285
Goats	63	1	64
Sheep	527	11	538
Cattle	1251	169	1420
Rhesus monkey	7	30	37
Other mammals	103	74	177
Domestic fowl	35286	6	35292
Other birds	6186	225	6411
Reptiles	15	286	301
Xenopus	267	574	841
Other amphibians	14	251	265
Zebra fish	32364	1	32365
Other fish	10290	402	10692
Total	440591	4167	444758

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	191451	43.05%
Translational and applied research	130712	29.39%
Regulatory use and Routine production	115267	25.92%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	798	0.18%
Preservation of species	243	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6287	1.41%
Total	444758	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	41138	21.49%
Cardiovascular Blood and Lymphatic System	11488	6%
Nervous System	23191	12.11%
Respiratory System	6539	3.42%
Gastrointestinal System including Liver	16792	8.77%
Musculoskeletal System	7655	4%
Immune System	51884	27.1%
Urogenital/Reproductive System	4851	2.53%

Sensory Organs (skin, eyes and ears)	2320	1.21%
Endocrine System/Metabolism	5772	3.01%
Multisystemic	3763	1.97%
Ethology / Animal Behaviour /Animal Biology	7889	4.12%
Other basic research	8169	4.27%
Total	191451	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18993	14.53%
Human Infectious Disorders	16936	12.96%
Human Cardiovascular Disorders	1473	1.13%
Human Nervous and Mental Disorders	30568	23.39%
Human Respiratory Disorders	3384	2.59%
Human Gastrointestinal Disorders including Liver	5397	4.13%
Human Musculoskeletal Disorders	1680	1.29%
Human Immune Disorders	3172	2.43%
Human Urogenital/Reproductive Disorders	1099	0.84%
Human Sensory Organ Disorders (skin, eyes and ears)	4409	3.37%
Human Endocrine/Metabolism Disorders	1756	1.34%
Other Human Disorders	2144	1.64%
Animal Diseases and Disorders	26379	20.18%
Animal Welfare	2986	2.28%
Diagnosis of diseases	5443	4.16%
Non-regulatory toxicology and ecotoxicology	4893	3.74%
Total	130712	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	42666	37.01%
Other efficacy and tolerance testing	9029	7.83%
Toxicity and other safety testing including pharmacology	4938	4.28%
Routine production	58634	50.87%
Total	115267	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	3918	9.18%
Batch potency testing	36928	86.55%
Other quality controls	1820	4.27%
Total	42666	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	604	12.23%
Repeated dose toxicity	1017	20.6%
Genotoxicity	73	1.48%
Kinetics	839	16.99%
Pharmaco-dynamics (incl safety pharmacology)	56	1.13%
Ecotoxicity	443	8.97%
Safety testing in food and feed area	753	15.25%
Target animal safety	1153	23.35%
Total	4938	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	Number of	Percentage

sub-acute toxicity testing methods	uses	
LD50, LC50	290	48.01%
Non lethal methods	314	51.99%
Total	604	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	1010	99.31%
29 - 90 days	7	0.69%
Total	1017	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	443	100%
Total	443	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	38676	68.29%
Legislation on medicinal products for veterinary use and their residues	15263	26.95%
Medical devices legislation	853	1.51%
Food legislation including food contact material	222	0.39%
Feed legislation including legislation for the safety of target animals, workers and environment	1104	1.95%
Other legislation	515	0.91%
Total	56633	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	43477	76.77%
Legislation satisfying Non-EU requirements only	13156	23.23%
Total	56633	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	58479	99.74%
Monoclonal antibody by mouse ascites method	17	0.03%
Other product types	138	0.24%
Total	58634	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	440591	99.06%
Yes	4167	0.94%
Total	444758	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	13910	3.13%
Mild [up to and including]	244584	54.99%
Moderate	123130	27.68%
Severe	63134	14.2%
Total	444758	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	328788	73.93%
Genetically altered without a harmful phenotype	100355	22.56%
Genetically altered with a harmful phenotype	15615	3.51%
Total	444758	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	24281		24281
Rats	396		396
Hamsters (Syrian)	80		80
Zebra fish	6750		6750
Total	31507		31507

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

Severity	Number of uses	Percentage
Non-recovery	164	0.52%
Mild [up to and including]	22373	71.01%
Moderate	8569	27.2%
Severe	401	1.27%
Total	31507	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	5310	16.85%
Genetically altered without a harmful phenotype	20648	65.53%
Genetically altered with a harmful phenotype	5549	17.61%
Total	31507	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	8689	27.59%
Cardiovascular Blood and Lymphatic System	3402	10.8%
Nervous System	3782	12.01%
Gastrointestinal System including Liver	6349	20.16%
Musculoskeletal System	1428	4.53%
Immune System	1473	4.68%
Urogenital/Reproductive System	703	2.23%
Sensory Organs (skin, eyes and ears)	9	0.03%
Endocrine System/Metabolism	3862	12.26%
Multisystemic	1764	5.6%
Other basic research	34	0.11%
Total	31495	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	12	100%
Total	12	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	17716	1	17717
Total	17716	1	17717

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

Severity	Number of uses	Percentage
Mild [up to and including]	17419	98.32%
Moderate	264	1.49%
Severe	34	0.19%
Total	17717	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	764	4.31%
Genetically altered without a harmful phenotype	15256	86.11%
Genetically altered with a harmful phenotype	1697	9.58%
Total	17717	100.00%

Bulgaria

Bulgaria: Narrative 2019

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

The total number of animals, used for 2019, compared to 2018 is increased. The number of re-used animals is increased too. The used animals are only animals born in the EU at register breeder. The number of used rodents and mice is slightly increased.

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

The total number of animals, used for 2019, compared to 2018 is increased. In some cases, this is due to the fact, that the most applications were from universities and the high number of animals were for training of students. In another part of the cases, the applications are from Animal Husbandry Institutes, researching nutrition-related processes. This is the reason, that the number of sheep, other fish and equidae is increased.

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

The procedures with non-recovery severity are decreased. The number of procedures with moderate severity is slightly increased. The reason for minimizing the procedures with severe severity in 2019 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.

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 authorized, the details of the use and the reasons why 'severe' classification was exceeded.

No.

Bulgaria: Statistical Data 2019

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	2145	14.37%
Rats	2310	15.48%
Guinea-Pigs	2657	17.81%
Hamsters (Syrian)	20	0.13%
Rabbits	1158	7.76%
Pigs	27	0.18%
Domestic fowl	505	3.38%
Other birds	115	0.77%
Rana	4840	32.44%
Other amphibians	305	2.04%
Other fish	840	5.63%
Total	14922	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	14922	100%
Total	14922	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	2145		2145
Rats	2310		2310
Guinea-Pigs	2657	30	2687
Hamsters (Syrian)	20		20
Rabbits	1158		1158
Cats		54	54
Dogs		8	8
Horses, donkeys and cross-breeds		10	10
Pigs	27	9	36
Goats		12	12
Sheep		283	283
Cattle		9	9
Domestic fowl	505	100	605
Other birds	115		115
Rana	4840		4840
Other amphibians	305		305
Other fish	840		840
Total	14922	515	15437

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	2244	14.54%
Translational and applied research	250	1.62%
Regulatory use and Routine production	4954	32.09%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	7989	51.75%
Total	15437	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Nervous System	820	36.54%
Gastrointestinal System including Liver	293	13.06%
Musculoskeletal System	105	4.68%
Sensory Organs (skin, eyes and ears)	17	0.76%
Endocrine System/Metabolism	154	6.86%
Multisystemic	337	15.02%
Other basic research	518	23.08%
Total	2244	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	30	12%
Animal Diseases and Disorders	150	60%
Non-regulatory toxicology and ecotoxicology	70	28%
Total	250	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4600	92.85%
Toxicity and other safety testing including pharmacology	354	7.15%
Total	4954	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	4300	93.48%
Pyrogenicity testing	300	6.52%
Total	4600	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Pharmaco-dynamics (incl safety pharmacology)	234	66.1%
Ecotoxicity	120	33.9%
Total	354	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	100	83.33%
Chronic toxicity	20	16.67%
Total	120	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	4790	96.69%
Legislation on medicinal products for veterinary use and their residues	164	3.31%
Total	4954	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4954	100%
Total	4954	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	14922	96.66%
Yes	515	3.34%

Total	15437	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1644	10.65%
Mild [up to and including]	12518	81.09%
Moderate	1275	8.26%
Total	15437	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	15437	100%
Total	15437	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 2019

Report has been prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

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

Animal Species used for scientific procedures

Data for 2019, 2018 and 2017:

Animal Species	2019		2018		2017	
	number	%	number	%	number	%
Mice	19,216	66.99	18,295	70.87	19,806	69.41
Rats	6,446	22.47	6,885	26.67	7,700	26.99
Guinea Pigs	107	0.37	17	0.07	21	0.07
Rabbits	12	0.04	250	0.97	426	1,49
Horses, donkeys & cross-breeds	18	0.06	18	0.07	25	0.09
Pigs	2	0.01	20	0.08	2	0.01
Sheep	15	0.05	22	0.09	39	0.14
Cattle	-	-	-	-	30	0.11
Domestic fowl	2,840	9.90	275	1.07	255	0.89
Zebra fish	28	0.10	34	0.13	230	0.81
Summary	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows:

- an overall slightly increase in the total number of animals used for scientific purposes and most in mice, guinea pigs and domestic fowl
- a decrease in the number of pigs, sheep and zebra fish and
- the trend of no usage of cattle for scientific purposes continues.

Re-use vs first use

Data for 2019, 2018 and 2017:

Re-Use	2019		2018		2017	
	number	%	number	%	number	%
No	28,650	99.88	25,769	99.82	28,431	99.64
Yes	34	0.12	47	0.18	103	0.36
Total uses	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows slightly decrease in the proportion of Re-use vs first use.

Genetically altered animals

Data for 2019, 2018 and 2017:

Genetic Status	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Not genetically altered	25,463	88.77	24,711	95.72	26,027	91.21
Genetically altered without a harmful phenotype	2,882	10,05	968	3.75	2,452	8.59
Genetically altered with a harmful phenotype	339	1,18	137	0.53	55	0.19
Summary	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows:

- number of not genetically altered animals slightly increased than in 2018 but still is lower than in 2017
- an overall decrease of the number of genetically altered animals without a harmful phenotype in the three years period and
- an overall increase of the number of genetically altered animals with a harmful phenotype in the three years period.

The proportion of animals used for scientific purposes within three types of genetically status increased significantly during three years period.

Creation of New Genetically altered lines

Data for 2019, 2018 and 2017:

Creation of New GL	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
No	28,656	99,90	25,782	99.87	28,304	99.19
Yes	28	0,10	34	0.13	230	0.81
Summary	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows the decrease of number of animals used for creation of new genetically altered lines.

Origins of animals

Data for 2019, 2018 and 2017:

Place of Birth	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Animals born in the EU at a registered breeder	28,618	99.89	25,739	99.88	28,292	99.51
Animals born in the	32	0.11	30	0.12	60	0.21

EU but not at a registered breeder						
Animals born in the rest of Europe	-	-	0	0	0	0
Animals born in the rest of world	-	-	0	0	79	0.28
Summary	28,650	100	28,431	100	21,790	100

Compared to the data for 2017 and 2018, the data for 2019 shows there are no significant changes regarding the place of birth of animals.

Legislative Requirement

Data for 2019, 2018 and 2017:

Legislative Requirement	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Legislation satisfying EU requirements	4,244	14.80	2,461	9.53	2,182	7.65
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 2017 and 2018, the data for 2019 shows that there is a significant 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 2019, 2018 and 2017:

Purpose Category	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Basic Research	10,195	35.54	18,865	73.07	22,067	77.34
Translational and applied research	12,664	44.15	3,169	12.28	2,761	9.68
Regulatory use and	4,244	14.80	2,461	9.53	2,182	7.65

Routine production						
Higher education or training for the acquisition, maintenance or improvement of vocational skills	849	2.96	1,321	5.12	1,428	5.00
Maintenance of colonies of established genetically altered animals, not used in other procedures	732	2.55	0	0	96	0.34
Summary	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows:

- significant and continuous decrease in number of animals used for basic research
- significant increase in number of animals used for translational and applied research
- continuous increase in number of animals used for regulatory use and routine production
- significant decrease in number of animals used for higher education
- significant increase in number of animals 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 2019, 2018 and 2017:

Severity of procedures	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Non-recovery	1,321	4.61	1,250	4.84	3,005	10.53
Mild (up to and including)	6,844	23.86	7,693	29.80	8,338	29.22
Moderate	18,266	63.68	16,170	62.64	11,593	40.63
Severe	2,253	7.85	703	2.72	5,598	19.62
Total number	28,684	100	25,816	100	28,534	100

Compared to the data for 2017 and 2018, the data for 2019 shows no significant changes in number of animals used in non-recovery procedures, a slightly decrease in number of animals used in mild and moderate procedures and significant increase in number of animals used in severe procedures.

The numbers of animals used in severe procedures increased even though high 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.

During 2019 a lot of communication between Competent Authority and Croatian National Committee (Ethical committee for the protection of animals used for scientific purposes) was ensured on the need for improvement of implementation of the principle of replacement, reduction and refinement. This resulted in more often communication among all what ensure better understanding by the users of the requirements of the legislation and therefore resulted in better quality of submissions for project evaluation and approval.

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 2019, 2018 and 2017:

Purpose Category	**2019**		**2018**		**2017**	
	number	**%**	**number**	**%**	**number**	**%**
Regulatory use and routine production – Quality control (incl batch safety and potency testing) - Other quality controls	720	-	900	76.60	1,195	75.39

For regulatory use and routine production - Quality control (incl batch safety and potency testing) - Other quality controls in 2017, 2018 and 2019 tests performed have been required by EU Pharmacopeia and animals used in tests were mice.
In 2019 there is a slightly decrease in number of animals used

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

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

Croatia: Statistical Data 2019

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	18484	66.27%
Rats	6446	23.11%
Guinea-Pigs	106	0.38%
Rabbits	12	0.04%
Pigs	2	0.01%
Domestic fowl	2840	10.18%
Total	27890	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	27858	99.89%
Animals born in the EU but not at a registered breeder	32	0.11%
Total	27890	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	18484		18484
Rats	6446		6446
Guinea-Pigs	106	1	107
Rabbits	12		12
Horses, donkeys and cross-breeds		18	18
Pigs	2		2
Sheep		15	15
Domestic fowl	2840		2840
Total	27890	34	27924

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	10195	36.51%
Translational and applied research	12636	45.25%
Regulatory use and Routine production	4244	15.2%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	849	3.04%
Total	27924	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	298	2.92%
Cardiovascular Blood and Lymphatic System	681	6.68%
Nervous System	1761	17.27%
Gastrointestinal System including Liver	24	0.24%
Musculoskeletal System	806	7.91%
Immune System	3137	30.77%
Sensory Organs (skin, eyes and ears)	100	0.98%
Endocrine System/Metabolism	61	0.6%
Multisystemic	1843	18.08%
Other basic research	1484	14.56%
Total	10195	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	4035	31.93%
Human Nervous and Mental Disorders	87	0.69%
Human Respiratory Disorders	3221	25.49%
Human Gastrointestinal Disorders including Liver	1953	15.46%
Human Musculoskeletal Disorders	800	6.33%
Human Immune Disorders	1025	8.11%
Human Urogenital/Reproductive Disorders	522	4.13%
Human Sensory Organ Disorders (skin, eyes and ears)	234	1.85%
Human Endocrine/Metabolism Disorders	153	1.21%
Diagnosis of diseases	141	1.12%
Non-regulatory toxicology and ecotoxicology	465	3.68%
Total	12636	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	720	16.97%
Toxicity and other safety testing including pharmacology	3038	71.58%
Routine production	486	11.45%
Total	4244	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	720	100%
Total	720	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	198	6.52%
Target animal safety	320	10.53%
Other toxicity/safety testing	2520	82.95%
Total	3038	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	198	100%
Total	198	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	918	24.43%
Legislation on medicinal products for veterinary use and their residues	2840	75.57%
Total	3758	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3758	100%
Total	3758	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	486	100%
Total	486	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	27890	99.88%
Yes	34	0.12%

Total	27924	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1293	4.63%
Mild [up to and including]	6112	21.89%
Moderate	18266	65.41%
Severe	2253	8.07%
Total	27924	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	25435	91.09%
Genetically altered without a harmful phenotype	2286	8.19%
Genetically altered with a harmful phenotype	203	0.73%
Total	27924	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	28		28
Total	28		28

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

Severity	Number of uses	Percentage
Non-recovery	28	100%
Total	28	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	28	100%
Total	28	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	28	100%
Total	28	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	732		732
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
Genetically altered without a harmful phenotype	596	81.42%
Genetically altered with a harmful phenotype	136	18.58%
Total	732	100.00%

Cyprus

Cyprus: Narrative 2019

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

On this reporting year (2019) also Zebra fish and their larvae were used. Also, in 2019 no animals were classified in severe procedures.

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

In general, there were significant changes in the numbers of animals used since the previous reporting year. The number of projects that animals were used was clearly increased, by 66.6% (from 15 in 2018 to 25 in 2019), which led to a rise of the number of animals used by 16.4% since last year.

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

In 2019, animals were not used in severe procedures, in comparison to 2018 that 5.32% of the animals were classified as such.

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.

No proportion of animal use was reported under the category "other".

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

There were no such cases for the year 2019.

Cyprus: Statistical Data 2019

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	2156	99.77%
Zebra fish	5	0.23%
Total	2161	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	2161	100%
Total	2161	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	2156		2156
Zebra fish	5		5
Total	2161		2161

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	2038	94.31%
Translational and applied research	123	5.69%
Total	2161	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	503	24.68%
Nervous System	794	38.96%
Musculoskeletal System	138	6.77%
Urogenital/Reproductive System	29	1.42%
Sensory Organs (skin, eyes and ears)	180	8.83%
Endocrine System/Metabolism	203	9.96%
Other basic research	191	9.37%
Total	2038	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Urogenital/Reproductive Disorders	91	73.98%
Non-regulatory toxicology and ecotoxicology	32	26.02%
Total	123	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	2161	100%
Total	2161	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	20	0.93%
Mild [up to and including]	2051	94.91%
Moderate	90	4.16%
Total	2161	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	841	38.92%
Genetically altered without a harmful phenotype	1252	57.94%
Genetically altered with a harmful phenotype	68	3.15%
Total	2161	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	25		25
Total	25		25

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

Severity	Number of uses	Percentage
Mild [up to and including]	25	100%
Total	25	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	25	100%
Total	25	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	25	100%
Total	25	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 2019

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 2019 number of animals used for preservation of species continue to increase since 2015.

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

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

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

There are no significant 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 2019 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” was not exceeded in 2019.

Czechia: Statistical Data 2019

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	62536	26.95%
Rats	19925	8.59%
Guinea-Pigs	2041	0.88%
Hamsters (Syrian)	20	0.01%
Mongolian gerbil	12	0.01%
Other rodents	168	0.07%
Rabbits	4189	1.8%
Cats	25	0.01%
Dogs	259	0.11%
Ferrets	40	0.02%
Horses, donkeys and cross-breeds	110	0.05%
Pigs	2044	0.88%
Goats	30	0.01%
Sheep	545	0.23%
Cattle	848	0.37%
Other mammals	120	0.05%
Domestic fowl	23145	9.97%
Other birds	2538	1.09%
Reptiles	424	0.18%
Xenopus	75	0.03%
Zebra fish	6219	2.68%
Other fish	106774	46.01%
Total	232087	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	194407	83.76%
Animals born in the EU but not at a registered breeder	37096	15.98%
Animals born in rest of world	584	0.25%
Total	232087	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	62536	591	63127
Rats	19925	146	20071
Guinea-Pigs	2041	12	2053
Hamsters (Syrian)	20		20
Mongolian gerbil	12		12
Other rodents	168		168
Rabbits	4189	76	4265
Cats	25		25
Dogs	259	183	442
Ferrets	40		40
Horses, donkeys and cross-breeds	110	15	125
Pigs	2044	548	2592
Goats	30	5	35
Sheep	545	380	925
Cattle	848	1331	2179
Other mammals	120	34	154
Domestic fowl	23145	50	23195
Other birds	2538	24	2562
Reptiles	424		424
Xenopus	75		75
Zebra fish	6219		6219
Other fish	106774	619	107393
Total	232087	4014	236101

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	57446	24.33%
Translational and applied research	44039	18.65%
Regulatory use and Routine production	71870	30.44%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	55634	23.56%
Preservation of species	286	0.12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6826	2.89%
Total	236101	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	8904	15.5%
Cardiovascular Blood and Lymphatic System	5775	10.05%
Nervous System	8828	15.37%
Respiratory System	56	0.1%
Gastrointestinal System including Liver	1615	2.81%
Musculoskeletal System	455	0.79%
Immune System	10357	18.03%
Urogenital/Reproductive System	4833	8.41%
Sensory Organs (skin, eyes and ears)	129	0.22%

Endocrine System/Metabolism	1879	3.27%
Multisystemic	3766	6.56%
Ethology / Animal Behaviour /Animal Biology	5035	8.76%
Other basic research	5814	10.12%
Total	57446	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	4202	9.54%
Human Infectious Disorders	2035	4.62%
Human Cardiovascular Disorders	1463	3.32%
Human Nervous and Mental Disorders	1526	3.47%
Human Gastrointestinal Disorders including Liver	554	1.26%
Human Musculoskeletal Disorders	208	0.47%
Human Immune Disorders	184	0.42%
Human Urogenital/Reproductive Disorders	877	1.99%
Human Sensory Organ Disorders (skin, eyes and ears)	309	0.7%
Human Endocrine/Metabolism Disorders	707	1.61%
Other Human Disorders	122	0.28%
Animal Diseases and Disorders	2235	5.08%
Animal Welfare	22647	51.42%
Diagnosis of diseases	6541	14.85%
Non-regulatory toxicology and ecotoxicology	429	0.97%
Total	44039	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	15369	21.38%
Other efficacy and tolerance testing	463	0.64%
Toxicity and other safety testing including pharmacology	38167	53.11%
Routine production	17871	24.87%
Total	71870	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	737	4.8%
Pyrogenicity testing	51	0.33%
Batch potency testing	14497	94.33%
Other quality controls	84	0.55%
Total	15369	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	746	1.95%
Skin sensitisation	603	1.58%
Repeated dose toxicity	1531	4.01%
Reproductive toxicity	344	0.9%
Developmental toxicity	500	1.31%
Kinetics	220	0.58%
Pharmaco-dynamics (incl safety pharmacology)	62	0.16%
Ecotoxicity	33834	88.65%
Target animal safety	32	0.08%
Other toxicity/safety testing	295	0.77%
Total	38167	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	291	39.01%
Other lethal methods	55	7.37%
Non lethal methods	400	53.62%
Total	746	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	443	28.94%
29 - 90 days	772	50.42%
> 90 days	316	20.64%
Total	1531	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	32194	95.15%
Other ecotoxicity	1640	4.85%
Total	33834	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	1421	2.63%
Legislation on medicinal products for veterinary use and their residues	15920	29.48%
Medical devices legislation	914	1.69%
Industrial chemicals legislation	1693	3.14%
Other legislation	34051	63.06%
Total	53999	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	28824	53.38%
Legislation satisfying national requirements only [within EU]	25175	46.62%
Total	53999	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	359	2.01%
Monoclonal antibody by mouse ascites method	76	0.43%
Other product types	17436	97.57%
Total	17871	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	232087	98.3%
Yes	4014	1.7%
Total	236101	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	10269	4.35%
Mild [up to and including]	92668	39.25%
Moderate	102511	43.42%

Severe	30653	12.98%
Total	236101	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	216853	91.85%
Genetically altered without a harmful phenotype	15234	6.45%
Genetically altered with a harmful phenotype	4014	1.7%
Total	236101	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	14737		14737
Rats	319		319
Hamsters (Syrian)	36		36
Domestic fowl	90		90
Total	15182		15182

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

Severity	Number of uses	Percentage
Non-recovery	6146	40.48%
Mild [up to and including]	405	2.67%
Moderate	8591	56.59%
Severe	40	0.26%
Total	15182	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	90	0.59%
Genetically altered without a harmful phenotype	14976	98.64%
Genetically altered with a harmful phenotype	116	0.76%
Total	15182	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	393	2.6%
Cardiovascular Blood and Lymphatic System	79	0.52%
Nervous System	110	0.73%
Immune System	814	5.38%
Urogenital/Reproductive System	4305	28.44%
Sensory Organs (skin, eyes and ears)	116	0.77%
Endocrine System/Metabolism	165	1.09%
Multisystemic	40	0.26%
Other basic research	9115	60.22%
Total	15137	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	45	100%
Total	45	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

Denmark

Denmark: Narrative 2019

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

In 2019, the overall number of animals used for experimental procedures in Denmark was 252,987. The number is slightly higher than in 2018, where the total number of animals was 249,747 resulting in a 1.3 % increase. The increase can be explained by a significant rise in the use of both zebrafish and other fish compared to 2018.

The majority of experimental procedures used mice (65 %), rats (14 %) and fish (12 %). Together these species were used in approx. 91 % of all experimental procedures in 2019. 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 mainly used for experimental procedures involving Ethology / Animal behavior / Animal biology (basic research purposes) and animal diseases and disorders (translational and applied research purposes).

The overall distribution in purposes of procedures for all animal species are 36 % Basic research, 49 % Translational and applied research and 8 % Regulatory testing for 2019.

The severity assessment for 2019 shows that 50 % of experimental procedures in animals were mild and 44 % were moderate. This is a decrease in “mild” from 61 % in 2018 and an increase in “moderate” from 32 % in 2018. Only about 1,6 % of the animals used for experimental procedures experienced severe suffering in 2019 and this confirms the trend from the previous years.

2. Information on significant increase or decrease in use of 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 2019 the number of mice is 165.923 which is very similar compared to 2017 (163.281 mice), returning from a higher number in 2018 (175.708 mice). The obvious explanation is still that in a small country like Denmark, a changed focus from a few research groups can have a large impact on the statistics.

The use of 3.603 mink in 2019 is similar to the number in 2018 and is still due to research groups, both studying animal welfare and animal 166ehavior in mink for farming. The research focus is especially on nutrition/metabolism and weaning of cubs and the vast majority of these experiments are within mild severity. Due to the actions taken towards COVID-19 infections in mink, the number will probably decrease significantly in the next years.

There is some variations in the numbers of guinea pigs, rabbits, pigs, cattle and domestic fowls. However, the total numbers are still relatively low, and changed focus from few research groups can quickly affect the statistics.

The primary increase in the use of animals in 2019 is the significant rise in the numbers of "other fish". As there is an increasing focus on the development of aqua culture for food production, research into infections, vaccines and production issues will also increase. Denmark has a very strong environment for this kind of research.

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

There has been a decrease in the percentage of mild severity from 61 % in 2018 to 50 % in 2019 and a rise in the percentage of moderate severity from 32 % in 2018 to 44 % in 2019. There is no apparent explanation for this change, sending the level of "mild" back to the 2017 level, 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 1.14 % in 2018 to 1.6 % in 2019. Compared to the number from previous years, 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 sharing best practice and dissemination of guidelines.

An updated website for the National Committee has been launched, having a strong focus on disseminating best practice, primarily towards animal technicians and animal caretakers.

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-center's annual symposium, which is open to all interested. 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 provide great opportunities 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.

In two cases the use of the category "other" is relatively high in Denmark – this concerns "other carnivores" and "other fish".

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" is due to a large research focus on farming especially rainbow trout, seabass, cod and salmon. The number of "other carnivores" is due to a large research focus on improving animal welfare for farming mink in mink farms. Changes due to action taken towards mink production in relation to COVID-19 are expected.

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 Denmark, the **"severe"** classification was not exceeded in any cases in 2019.

Denmark: Statistical Data 2019

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	157301	64.34%
Rats	36407	14.89%
Guinea-Pigs	3905	1.6%
Hamsters (Syrian)	6	0%
Other rodents	23	0.01%
Rabbits	2297	0.94%
Cats	1	0%
Dogs	365	0.15%
Other carnivores	3603	1.47%
Horses, donkeys and cross-breeds	47	0.02%
Pigs	8478	3.47%
Goats	51	0.02%
Sheep	18	0.01%
Cattle	980	0.4%
Other mammals	23	0.01%
Domestic fowl	1230	0.5%
Other birds	439	0.18%
Reptiles	45	0.02%
Rana	448	0.18%
Xenopus	91	0.04%
Other amphibians	59	0.02%
Zebra fish	3935	1.61%
Other fish	24740	10.12%
Total	244492	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	197325	80.71%
Animals born in the EU but not at a registered breeder	39643	16.21%
Animals born in rest of Europe	1283	0.52%
Animals born in rest of world	6241	2.55%
Total	244492	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	157301	2676	159977
Rats	36407	1319	37726
Guinea-Pigs	3905	8	3913
Hamsters (Syrian)	6		6
Other rodents	23	10	33
Rabbits	2297	7	2304
Cats	1		1
Dogs	365	14	379
Other carnivores	3603	240	3843
Horses, donkeys and cross-breeds	47	4	51
Pigs	8478	165	8643
Goats	51		51
Sheep	18		18
Cattle	980	205	1185
Other mammals	23	19	42
Domestic fowl	1230	39	1269
Other birds	439		439
Reptiles	45	8	53
Rana	448	4	452
Xenopus	91	300	391
Other amphibians	59	13	72
Zebra fish	3935		3935
Other fish	24740	2	24742
Total	244492	5033	249525

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	91539	36.69%
Translational and applied research	127123	50.95%
Regulatory use and Routine production	20841	8.35%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4930	1.98%
Preservation of species	948	0.38%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	4144	1.66%
Total	249525	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	18505	20.22%
Cardiovascular Blood and Lymphatic System	3719	4.06%
Nervous System	17260	18.86%
Respiratory System	279	0.3%
Gastrointestinal System including Liver	6345	6.93%
Musculoskeletal System	1447	1.58%
Immune System	21078	23.03%
Urogenital/Reproductive System	1631	1.78%

Sensory Organs (skin, eyes and ears)	386	0.42%
Endocrine System/Metabolism	12212	13.34%
Multisystemic	2309	2.52%
Ethology / Animal Behaviour /Animal Biology	3669	4.01%
Other basic research	2699	2.95%
Total	91539	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	10162	7.99%
Human Infectious Disorders	9524	7.49%
Human Cardiovascular Disorders	4897	3.85%
Human Nervous and Mental Disorders	25481	20.04%
Human Respiratory Disorders	324	0.25%
Human Gastrointestinal Disorders including Liver	3081	2.42%
Human Musculoskeletal Disorders	736	0.58%
Human Immune Disorders	3583	2.82%
Human Urogenital/Reproductive Disorders	2531	1.99%
Human Sensory Organ Disorders (skin, eyes and ears)	288	0.23%
Human Endocrine/Metabolism Disorders	40466	31.83%
Other Human Disorders	2641	2.08%
Animal Diseases and Disorders	20308	15.98%
Animal Welfare	2203	1.73%
Diagnosis of diseases	772	0.61%
Non-regulatory toxicology and ecotoxicology	126	0.1%
Total	127123	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	13681	65.64%
Other efficacy and tolerance testing	1375	6.6%
Toxicity and other safety testing including pharmacology	5064	24.3%
Routine production	721	3.46%
Total	20841	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	2470	18.05%
Batch potency testing	10272	75.08%
Other quality controls	939	6.86%
Total	13681	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	120	2.37%
Skin irritation/corrosion	4	0.08%
Skin sensitisation	74	1.46%
Repeated dose toxicity	1612	31.83%
Genotoxicity	22	0.43%
Reproductive toxicity	35	0.69%
Kinetics	510	10.07%
Pharmaco-dynamics (incl safety pharmacology)	1386	27.37%
Ecotoxicity	1292	25.51%
Safety testing in food and feed area	9	0.18%
Total	5064	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	120	100%
Total	120	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	657	40.76%
29 - 90 days	651	40.38%
> 90 days	304	18.86%
Total	1612	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	182	14.09%
Chronic toxicity	1110	85.91%
Total	1292	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	19183	95.34%
Medical devices legislation	24	0.12%
Industrial chemicals legislation	844	4.19%
Food legislation including food contact material	9	0.04%
Other legislation	60	0.3%
Total	20120	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	20116	99.98%
Legislation satisfying Non-EU requirements only	4	0.02%
Total	20120	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	687	95.28%
Other product types	34	4.72%
Total	721	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	244492	97.98%
Yes	5033	2.02%
Total	249525	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	10994	4.41%
Mild [up to and including]	121012	48.5%
Moderate	113407	45.45%
Severe	4112	1.65%
Total	249525	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	216774	86.87%
Genetically altered without a harmful phenotype	27295	10.94%
Genetically altered with a harmful phenotype	5456	2.19%
Total	249525	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	1679		1679
Rats	51		51
Zebra fish	722		722
Total	2452		2452

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

Severity	Number of uses	Percentage
Non-recovery	37	1.51%
Mild [up to and including]	2088	85.15%
Moderate	327	13.34%
Total	2452	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	1410	57.5%
Genetically altered without a harmful phenotype	1042	42.5%
Total	2452	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	131	5.34%
Nervous System	143	5.83%
Gastrointestinal System including Liver	50	2.04%
Musculoskeletal System	37	1.51%
Endocrine System/Metabolism	184	7.5%
Multisystemic	174	7.1%
Other basic research	1733	70.68%
Total	2452	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	6043		6043
Total	6043		6043

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

Severity	Number of uses	Percentage
Non-recovery	178	2.95%
Mild [up to and including]	5855	96.89%
Moderate	4	0.07%
Severe	6	0.1%
Total	6043	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	6039	99.93%
Genetically altered with a harmful phenotype	4	0.07%
Total	6043	100.00%

Estonia

Estonia: Narrative 2019

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

The number of project applications submitted and authorisations granted increased from 14 in 2018 to 20 in 2019. This however had a small impact on the number of animals used in 2019 because many authorised projects were inactive or had not yet started during 2019. This lead to an increase of 55 animals compared to the previous year (3000 animals in 2018, 3055 in 2019). Use of GA animals decreased from 48% in 2018 to 21,11% in 2019. All GA animals used were without a harmful phenotype. Mice were still the most commonly used species (46,32% of all uses), however their use dropped from 1976 animals in 2018 to 1415 in 2019. Decrease occurred also in the use of rats, domestic fowl and other fish. An increase compared to 2018 was seen in the use of rabbits, other birds and most of all cattle (from 162 animals in 2018 to 866 in 2019). All animals used were born in the EU. In 2018 83,9 % of all animals were born at a registered breeder, in 2019 it dropped to 59,19%. This comes mainly from the increased use of cattle.

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

The most uses as in previous years were in basic research which accounted for 65,04% with 1987 animals used in 2019 (72,1% with 2165 animals in 2018). In 2018 animal biology was the area of basic research with the highest numbers of animals used (22,3%) but in 2019 it was nervous system (28,79%). This change was due to new authorisations granted for nervous system research in 2019. No uses in 2019 for the maintenance of GA animals. Use of animals increased significantly in translational and applied research – from 5,13% (154 animals) in 2018 to 30,02% (917 animals) in 2019. This is mostly due to increased use for research on animal diseases and disorders.

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

Of all uses in 2018 29,87% were classified as mild, 48,27% moderate, 5,83% severe and 16,03% non-recovery. In 2019 the proportions were 64,75% mild, 27,69% moderate, 0% severe and 7,56% non-recovery. Very small amount of projects authorised before and during 2019 include procedures with severe estimated severity. Some of those projects had not yet started in 2019, others already ended in 2018, which explains the change in severities.

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

We 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 11,85% of all animals. This accounted for 204 birds (6,68% of all uses) and 158 fish (5,17% of all uses).

Category “Other birds” included 104 greenfinches (*Chloris chloris*), 12 reed warblers (*Acrocephalus scirpaceus*) and 88 pied flycatchers (*Ficedula hypoleuca*). This made up 77,86% of all birds used. In “Other fish” category were 158 northern pikes (*Esox 176ucius*) which made up 100% of all fish used in 2019.

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 where severity exceeded the “severe” classification. No projects exceeding severe classification were authorised.

Estonia: Statistical Data 2019

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	1379	45.68%
Rats	285	9.44%
Rabbits	65	2.15%
Pigs	4	0.13%
Cattle	866	28.68%
Domestic fowl	58	1.92%
Other birds	204	6.76%
Other fish	158	5.23%
Total	3019	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	1787	59.19%
Animals born in the EU but not at a registered breeder	1232	40.81%
Total	3019	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	1379	36	1415
Rats	285		285
Rabbits	65		65
Pigs	4		4
Cattle	866		866
Domestic fowl	58		58
Other birds	204		204
Other fish	158		158
Total	3019	36	3055

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	1987	65.04%
Translational and applied research	917	30.02%
Regulatory use and Routine production	123	4.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	28	0.92%
Total	3055	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	351	17.66%
Cardiovascular Blood and Lymphatic System	188	9.46%
Nervous System	572	28.79%
Gastrointestinal System including Liver	32	1.61%
Musculoskeletal System	80	4.03%
Immune System	440	22.14%
Urogenital/Reproductive System	6	0.3%
Endocrine System/Metabolism	48	2.42%
Multisystemic	12	0.6%
Ethology / Animal Behaviour /Animal Biology	258	12.98%
Total	1987	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Respiratory Disorders	57	6.22%
Animal Diseases and Disorders	860	93.78%
Total	917	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Routine production	123	100%
Total	123	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

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
Other product types	123	100%
Total	123	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	3019	98.82%
Yes	36	1.18%
Total	3055	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	231	7.56%
Mild [up to and including]	1978	64.75%
Moderate	846	27.69%
Total	3055	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	2410	78.89%
Genetically altered without a harmful phenotype	645	21.11%
Total	3055	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

Finland

Finland: Narrative 2019

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

In Finland, 98 457 procedures were done in 2019, which was 11 % less than in 2018 (110 723 procedures). The overall picture was quite similar as in previous years, the species most used in procedures being mice, rats, zebra fish and other fish.

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

The reduction in numbers were mainly due to the reduced use of dogs (2 196 vs 6 297 in 2018) with blood sampling for disease genes, reduced use of domestic fowls (2 785 vs 5 468, respectively) in batch safety testing and reduced use of other fish (13 492 vs 20 700, respectively) in areas of basic research. The users of these species are single research groups whose activities may vary greatly from year to year.

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

The severity of procedures divided similarly between severity classes: 58 % of animals were used with mild, 31 % with moderate, 6,5 % with severe and 4,5 % with non-recovery severity. No changes in trends were observed. The severe procedures involved 5 187 mice (4 857 in 2018) and 1 127 rats (1 940 in 2018). As in previous years, the severe procedures were done mainly in the purpose of Human nervous and mental disorders in translational research (4957 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 the Protection of Animals Used for Scientific and Educational Purposes in Finland has promoted 3R information sharing in Finland via 3R working group. The group organized the 2-day course for scientists: *Modern methods in basic research and drug discovery.* The 3R group prepared further the Finnish 3R Consortium organizing meetings with various participants. The Consortium aims to act as a national focal point on 3Rs. It will organize education, share information and promote co-research projects. Net pages for the Consortium and web-courses for competencies are also in construction.

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 2019

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	48767	52.75%
Rats	9904	10.71%
Guinea-Pigs	2	0%
Hamsters (Syrian)	180	0.19%
Other rodents	2315	2.5%
Rabbits	160	0.17%
Cats	178	0.19%
Dogs	2037	2.2%
Other carnivores	91	0.1%
Horses, donkeys and cross-breeds	36	0.04%
Pigs	919	0.99%
Sheep	1243	1.34%
Cattle	147	0.16%
Other mammals	119	0.13%
Domestic fowl	2785	3.01%
Other birds	1296	1.4%
Zebra fish	8784	9.5%
Other fish	13492	14.59%
Total	92455	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	68277	73.85%
Animals born in the EU but not at a registered breeder	20588	22.27%
Animals born in rest of world	3590	3.88%
Total	92455	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	48767	88	48855
Rats	9904	56	9960
Guinea-Pigs	2		2
Hamsters (Syrian)	180		180
Other rodents	2315		2315
Rabbits	160		160
Cats	178		178
Dogs	2037	159	2196
Other carnivores	91		91
Horses, donkeys and cross-breeds	36	9	45
Pigs	919		919
Sheep	1243		1243
Cattle	147	125	272
Other mammals	119		119
Domestic fowl	2785		2785
Other birds	1296		1296
Zebra fish	8784		8784
Other fish	13492		13492
Total	92455	437	92892

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	54268	58.42%
Translational and applied research	32823	35.33%
Regulatory use and Routine production	3754	4.04%
Preservation of species	76	0.08%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1971	2.12%
Total	92892	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	5932	10.93%
Cardiovascular Blood and Lymphatic System	2896	5.34%
Nervous System	9768	18%
Respiratory System	872	1.61%
Gastrointestinal System including Liver	1632	3.01%
Musculoskeletal System	54	0.1%
Immune System	5120	9.43%
Urogenital/Reproductive System	6815	12.56%
Sensory Organs (skin, eyes and ears)	1497	2.76%
Endocrine System/Metabolism	2588	4.77%
Multisystemic	7701	14.19%
Ethology / Animal Behaviour /Animal Biology	8948	16.49%
Other basic research	445	0.82%
Total	54268	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3243	9.88%
Human Infectious Disorders	907	2.76%
Human Cardiovascular Disorders	648	1.97%
Human Nervous and Mental Disorders	17893	54.51%
Human Gastrointestinal Disorders including Liver	59	0.18%
Human Musculoskeletal Disorders	876	2.67%
Human Immune Disorders	390	1.19%
Human Urogenital/Reproductive Disorders	2	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	2243	6.83%
Human Endocrine/Metabolism Disorders	621	1.89%
Other Human Disorders	1226	3.74%
Animal Diseases and Disorders	3818	11.63%
Animal Welfare	302	0.92%
Diagnosis of diseases	318	0.97%
Non-regulatory toxicology and ecotoxicology	277	0.84%
Total	32823	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1425	37.96%
Other efficacy and tolerance testing	70	1.86%
Toxicity and other safety testing including pharmacology	1063	28.32%
Routine production	1196	31.86%
Total	3754	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	1425	100%
Total	1425	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	10	0.94%
Repeated dose toxicity	26	2.45%
Kinetics	396	37.25%
Pharmaco-dynamics (incl safety pharmacology)	631	59.36%
Total	1063	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
Other lethal methods	10	100%
Total	10	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	26	100%
Total	26	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	2542	99.37%
Legislation on medicinal products for veterinary use and their residues	16	0.63%
Total	2558	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2558	100%
Total	2558	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1196	100%
Total	1196	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	92455	99.53%
Yes	437	0.47%
Total	92892	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	4066	4.38%
Mild [up to and including]	52840	56.88%
Moderate	29618	31.88%
Severe	6368	6.86%
Total	92892	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	66596	71.69%
Genetically altered without a harmful phenotype	21149	22.77%
Genetically altered with a harmful phenotype	5147	5.54%
Total	92892	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	3993		3993
Zebra fish	1296		1296
Total	5289		5289

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

Severity	Number of uses	Percentage
Non-recovery	59	1.12%
Mild [up to and including]	4367	82.57%
Moderate	860	16.26%
Severe	3	0.06%
Total	5289	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	2031	38.4%
Genetically altered without a harmful phenotype	2937	55.53%
Genetically altered with a harmful phenotype	321	6.07%
Total	5289	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	337	7.29%
Cardiovascular Blood and Lymphatic System	10	0.22%
Nervous System	1025	22.18%
Gastrointestinal System including Liver	147	3.18%
Musculoskeletal System	3	0.06%
Immune System	1905	41.22%
Urogenital/Reproductive System	353	7.64%
Endocrine System/Metabolism	170	3.68%
Multisystemic	672	14.54%
Total	4622	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	353	52.92%
Human Endocrine/Metabolism Disorders	314	47.08%
Total	667	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	276		276
Total	276		276

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

Severity	Number of uses	Percentage
Mild [up to and including]	91	32.97%
Moderate	185	67.03%

Total	276	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	1	0.36%
Genetically altered without a harmful phenotype	96	34.78%
Genetically altered with a harmful phenotype	179	64.86%
Total	276	100.00%

France

France: Narrative 2018

1. General information on any changes in trends observed since the previous reporting period (2018).

The 2019 survey comprises responses from the 621 establishments approved for the use of laboratory animals (user establishments). Of these 621 establishments, 64 stated that they had not used any animals in experimental procedures requiring project authorisation under the Directive in 2019.

The number of times animals were used decreased for the fourth consecutive year, with 1 865 403 uses in 2019 compared to 1 910 519 in 2018, i.e. a decrease of 2.4%. The distribution of the species used remains fairly close to that of the previous year, but the number of uses classified as 'severe' is significantly lower. The number of uses of genetically modified animals is also lower.

Species used

The 2019 figures confirm the dominance of the mouse model in experimental procedures (61% of uses, as compared to 62% in 2018). Rats (9%) and rabbits (7%) remain the two next most popular species. Fish represent 12% of uses of all species combined, a percentage similar to that of 2018.

The number of cat uses, largely for regulatory tests of tolerance for veterinary medicines or studies regarding cat nutrition, decreased from 1 185 to 1 007 in 2019. Conversely, dog uses increased from 4 219 to 4 898. These are mainly regulatory toxicology tests in human or veterinary medicine.

The use of primates decreased by 5%, from 3 510 to 3 339, i.e. a decrease of just under 5% compared with 2018. In 66% of cases, primates used for the first time were individuals of generation F2, a very similar percentage to that of 2018. The proportion of primates being re-used was 38% in 2019, as compared with 26% in 2018 and in 2017.

Re-uses

All species combined, the total number of re-uses was 37 816 in 2019 compared with 42 771 in 2018. The proportion of re-uses is stable, at around 2.0%.

Genetically modified animals

The number of uses of genetically modified animals is decreasing: 22% of uses in 2019 compared with 25% in 2018. As in 2018, the vast majority of these genetically modified animals were mice (89.2%). The proportion of phenotypes identified as harmful increased but remained low (3.3% in 2019 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.

As in previous years, the vast majority of animal uses (92%) fall into three main areas: basic research, translational research and regulatory uses or production of organic products for therapeutic use.

Basic research remains the main use, accounting for 41% of uses in 2019, compared with 36% in 2018. A more detailed examination shows that research on the nervous system uses the most animals.

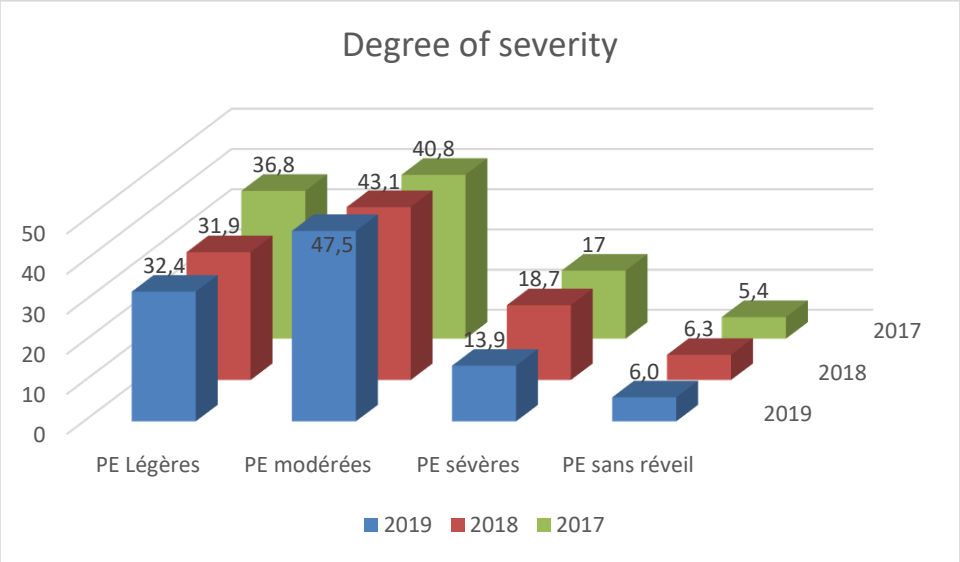
The amount of animals used in translational research has declined, with this sector accounting for 22% of uses, as compared with 28% in 2018. Within this varied set, projects relating to animal welfare are steadily increasing. The significant decrease in the category 'diagnostic tests for diseases' is linked to improvements in the classification of uses.

In 2019, by contrast, animal uses in regulatory toxicology research, development, production or quality and safety testing of medicines and food moved into second place, with 29% of uses as opposed to 27% the previous year.

Among the other areas of use, which are less significant in terms of number, maintenance of colonies of genetically altered animals decreased by 17% (representing 3% of uses), teaching and professional development by 12% (representing 2% of uses), species conservation by 5% (2% of 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 (80%). 'Severe' and 'non-recovery' procedures represented 14% and 6% of all procedures respectively.



PE = Experimental Procedure (EP)

Mild EP Moderate EP Severe EP Non-recovery EP

The trend from 2018 on shows a slight increase in the number of uses of animals in moderate procedures and a significant decrease in severe procedures, which has dropped from 18.7% in 2018 to 13.9% in 2019.

The decrease in the number of uses classified as severe is partly due to a better assessment of the degree of severity of a procedure for the production of reagents for diagnostic tests for diseases. The French authorities have also asked the establishment concerned to explore all possibilities for refining the production techniques in order to reduce the harm for the animals concerned.

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

France continues to actively promote the principles of replacement, refinement and reduction (the 'three Rs'). This commitment is shown in particular through the robust application of the project authorisation process, with two levels of verification: firstly, the collegial examination by the animal testing ethics committee, then validation by the ministry responsible for research, which issues the authorisations. It also translates into more stringent training requirements for staff responsible for caring for animals or for carrying out and designing scientific projects.

In addition, all stakeholders benefit from the sharing of good practices promoted for years by the French national committee for the protection of animals used for scientific purposes, the professional associations concerned with animal experimentation (AFSTAL, GIRCOR and OPAL) or at national meetings such as the colloquium of chairpersons of animal testing ethics committees. The latest colloquium, with 120 participants, was organised on 7 October 2019 by the ministry responsible for research. Finally, in 2020, two new national networks will help further progress to be made in implementating the 'three Rs', more rapidly integrating technological developments or new recommendations on the most refined practices in terms of animal welfare. These are the national network of animal testing ethics committees (*'Réseau national des comités d'éthique en expérimentation animale'*) and the national network of bodies responsible for animal welfare (*'Réseau national des structures chargées du bien-être animal'*).

The national platform for the development of alternative methods, FRANCOPA, which is a member of the European network ECOPA, brings together all stakeholders and also works actively to promote the 'three Rs'. This platform is set to evolve in 2021 since a plan for a national centre for the promotion of the 'three Rs' with expanded responsibilities is being finalised and has already been presented to Parliament.

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

A particular effort has been made to assign specific categories to the uses declared as 'other'. Hence, for basic research, this year the 'other' category represents just 0.38% of uses, mainly for research on embryonic development.

As in 2018, the 'other fish' category remains sizeable, accounting for 9% of uses (177 188). This category includes fish for human consumption, such as European seabass (10 500), rainbow trout (13 500), salmon (19 000) and shad (12 000), the reproduction, physiology and diet of which are the subject of numerous studies by public research bodies such as the French national institute for agricultural research (*Institut national de recherche pour l'agriculture - INRA*) and the national institute for ocean science (*Institut français de recherche pour l'exploitation de la mer- Ifremer*).

The 'other birds' category accounts for 2% of uses (37 982). It includes a project to produce vaccines for turkeys which alone uses 28 000 turkeys. This category also includes other domestic species, such as geese or ducks, and some wild species such as king penguins or albatrosses involved in ethology studies.

The routine production of products other than blood products or monoclonal antibodies (such as PR53) accounts for 117 259 uses. The two main projects in this category concern the production of proteins for therapeutic use and the production of a vaccine 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 this classification was exceeded.

No authorisation was issued in 2019 for applications exceeding the 'severe' classification with intense pain which is likely to be long-lasting and cannot be ameliorated.

Two applications for authorisation in this category are currently being examined.

France: Statistical Data 2019

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	1040279	59.83%
Rats	157486	9.06%
Guinea-Pigs	37360	2.15%
Hamsters (Syrian)	5907	0.34%
Hamsters (Chinese)	17	0%
Mongolian gerbil	428	0.02%
Other rodents	1374	0.08%
Rabbits	133789	7.69%
Cats	448	0.03%
Dogs	3011	0.17%
Ferrets	150	0.01%
Other carnivores	24	0%
Horses, donkeys and cross-breeds	88	0.01%
Pigs	12478	0.72%
Goats	112	0.01%
Sheep	3946	0.23%
Cattle	1483	0.09%
Prosimians	109	0.01%
Marmoset and tamarins	50	0%
Cynomolgus monkey	1842	0.11%
Rhesus monkey	22	0%
Vervets (Chlorocebus spp.)	25	0%
Baboons	24	0%
Other species of Old World Monkeys (Cercopithecoidea)	2	0%
Other mammals	179	0.01%
Domestic fowl	76303	4.39%
Other birds	37789	2.17%
Reptiles	218	0.01%

Rana	260	0.01%
Xenopus	3950	0.23%
Other amphibians	253	0.01%
Zebra fish	42385	2.44%
Other fish	176891	10.17%
Cephalopods	74	0%
Total	1738756	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	1443573	83.12%
Animals born in the EU but not at a registered breeder	220684	12.71%
Animals born in rest of Europe	57305	3.3%
Animals born in rest of world	15120	0.87%
Total	1736682	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	215	10.37%
Animals born in Asia	259	12.49%
Animals born in America	18	0.87%
Animals born in Africa	1300	62.68%
Animals born elsewhere	282	13.6%
Total	2074	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	605	29.17%
F2 or greater	1370	66.06%
Self-sustaining colony	99	4.77%
Total	2074	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	1040279	15669	1055948
Rats	157486	4634	162120
Guinea-Pigs	37360	63	37423
Hamsters (Syrian)	5907	5	5912
Hamsters (Chinese)	17		17
Mongolian gerbil	428		428
Other rodents	1374	208	1582
Rabbits	133789	1551	135340
Cats	448	559	1007
Dogs	3011	1877	4888
Ferrets	150		150
Other carnivores	24		24
Horses, donkeys and cross-breeds	88	607	695
Pigs	12478	125	12603
Goats	112	695	807
Sheep	3946	949	4895
Cattle	1483	712	2195
Prosimians	109		109
Marmoset and tamarins	50	122	172
Cynomolgus monkey	1842	1081	2923
Rhesus monkey	22	41	63
Vervets (Chlorocebus spp.)	25	3	28
Baboons	24		24
Other species of Old World Monkeys (Cercopithecoidea)	2	18	20
Other mammals	179		179
Domestic fowl	76303	321	76624
Other birds	37789	193	37982
Reptiles	218	5933	6151
Rana	260		260
Xenopus	3950	1727	5677
Other amphibians	253	320	573
Zebra fish	42385	79	42464
Other fish	176891	297	177188
Cephalopods	74	22	96
Total	1738756	37811	1776567

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	738901	41.59%
Translational and applied research	421314	23.72%
Regulatory use and Routine production	538993	30.34%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5635	0.32%
Preservation of species	35084	1.97%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	36632	2.06%
Forensic enquiries	8	0%

Total	1776567	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	81914	11.09%
Cardiovascular Blood and Lymphatic System	38224	5.17%
Nervous System	172048	23.28%
Respiratory System	12149	1.64%
Gastrointestinal System including Liver	40106	5.43%
Musculoskeletal System	32893	4.45%
Immune System	110679	14.98%
Urogenital/Reproductive System	28046	3.8%
Sensory Organs (skin, eyes and ears)	13022	1.76%
Endocrine System/Metabolism	56529	7.65%
Multisystemic	6871	0.93%
Ethology / Animal Behaviour /Animal Biology	139573	18.89%
Other basic research	6847	0.93%
Total	738901	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	135204	32.09%
Human Infectious Disorders	42604	10.11%
Human Cardiovascular Disorders	12796	3.04%
Human Nervous and Mental Disorders	49004	11.63%
Human Respiratory Disorders	5859	1.39%
Human Gastrointestinal Disorders including Liver	9797	2.33%
Human Musculoskeletal Disorders	13578	3.22%
Human Immune Disorders	23660	5.62%
Human Urogenital/Reproductive Disorders	3703	0.88%
Human Sensory Organ Disorders (skin, eyes and ears)	5054	1.2%
Human Endocrine/Metabolism Disorders	21530	5.11%
Other Human Disorders	3422	0.81%
Animal Diseases and Disorders	58962	13.99%
Animal Welfare	8007	1.9%
Diagnosis of diseases	9729	2.31%
Non-regulatory toxicology and ecotoxicology	18405	4.37%
Total	421314	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	180572	33.5%
Other efficacy and tolerance testing	11913	2.21%
Toxicity and other safety testing including pharmacology	105447	19.56%
Routine production	241061	44.72%
Total	538993	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	36689	20.32%
Pyrogenicity testing	12007	6.65%
Batch potency testing	120243	66.59%
Other quality controls	11633	6.44%
Total	180572	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	4061	3.85%
Skin irritation/corrosion	1128	1.07%
Skin sensitisation	10613	10.06%
Eye irritation/corrosion	112	0.11%
Repeated dose toxicity	20435	19.38%
Carcinogenicity	1350	1.28%
Genotoxicity	606	0.57%
Reproductive toxicity	9083	8.61%
Developmental toxicity	17158	16.27%
Kinetics	20436	19.38%
Pharmaco-dynamics (incl safety pharmacology)	9431	8.94%
Phototoxicity	396	0.38%
Ecotoxicity	9929	9.42%
Safety testing in food and feed area	226	0.21%
Target animal safety	251	0.24%
Other toxicity/safety testing	232	0.22%
Total	105447	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	1562	38.46%
Other lethal methods	80	1.97%
Non lethal methods	2419	59.57%
Total	4061	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	11857	58.02%
29 - 90 days	5804	28.4%
> 90 days	2774	13.57%
Total	20435	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	7186	72.37%
Chronic toxicity	2671	26.9%
Bioaccumulation	34	0.34%
Other ecotoxicity	38	0.38%
Total	9929	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	213285	71.59%
Legislation on medicinal products for veterinary use and their residues	45621	15.31%
Medical devices legislation	19648	6.59%
Industrial chemicals legislation	11098	3.73%
Plant protection product legislation	3334	1.12%
Biocides legislation	1286	0.43%
Food legislation including food contact material	1135	0.38%
Feed legislation including legislation for the safety of target animals, workers and environment	798	0.27%
Other legislation	1727	0.58%
Total	297932	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	289878	97.3%
Legislation satisfying national requirements only [within EU]	1448	0.49%
Legislation satisfying Non-EU requirements only	6606	2.22%
Total	297932	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	88001	36.51%
Monoclonal antibody by mouse ascites method	35801	14.85%
Other product types	117259	48.64%
Total	241061	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	1738756	97.87%
Yes	37811	2.13%
Total	1776567	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	110512	6.22%
Mild [up to and including]	551634	31.05%
Moderate	855981	48.18%
Severe	258440	14.55%
Total	1776567	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	1426043	80.27%
Genetically altered without a harmful phenotype	294247	16.56%
Genetically altered with a harmful phenotype	56277	3.17%
Total	1776567	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	18382	5	18387
Rats	2534		2534
Rabbits	268		268
Pigs	14		14
Zebra fish	3964		3964
Total	25162	5	25167

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

Severity	Number of uses	Percentage
Non-recovery	3014	11.98%
Mild [up to and including]	7651	30.4%
Moderate	12438	49.42%
Severe	2064	8.2%
Total	25167	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	9470	37.63%
Genetically altered without a harmful phenotype	11910	47.32%
Genetically altered with a harmful phenotype	3787	15.05%
Total	25167	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	1848	8.37%
Cardiovascular Blood and Lymphatic System	1470	6.65%
Nervous System	5577	25.24%
Musculoskeletal System	1341	6.07%
Immune System	2099	9.5%
Urogenital/Reproductive System	116	0.53%
Sensory Organs (skin, eyes and ears)	1365	6.18%
Endocrine System/Metabolism	837	3.79%
Multisystemic	5852	26.49%
Ethology / Animal Behaviour /Animal Biology	1400	6.34%
Other basic research	187	0.85%
Total	22092	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	218	7.09%
Human Infectious Disorders	12	0.39%
Human Nervous and Mental Disorders	5	0.16%
Human Respiratory Disorders	28	0.91%
Human Musculoskeletal Disorders	98	3.19%
Human Immune Disorders	260	8.46%
Human Sensory Organ Disorders (skin, eyes and ears)	14	0.46%
Human Endocrine/Metabolism Disorders	268	8.72%

Other Human Disorders	2152	69.98%
Diagnosis of diseases	20	0.65%
Total	3075	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	57388		57388
Rats	1591		1591
Dogs	10		10
Zebra fish	4680		4680
Total	63669		63669

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

Severity	Number of uses	Percentage
Mild [up to and including]	45202	71%
Moderate	18442	28.97%
Severe	25	0.04%
Total	63669	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	11648	18.29%
Genetically altered without a harmful phenotype	50728	79.67%
Genetically altered with a harmful phenotype	1293	2.03%
Total	63669	100.00%

Germany

Germany: Narrative 2019

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

In 2019, 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 75% of the animals used for testing were rodents, mainly mice and rats, with mice accounting for around 65%. Approximately 16% of the animals were fish, around 4% were rabbits and around 2% were birds. The number of mice used fell compared to the previous year (around 72% in 2018), whereas the number of fish used increased considerably (around 9% 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.

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 699 000 animals were used for this purpose in 2019, which is approximately 13 000 more 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 compared to the previous year. Around 1 309 000 animals of the total number of animals used were genetically modified. These animals thus accounted for approximately 45% (compared to approximately 44% in 2018). This concerned in particular mice (89%) and fish (9%).

Primates

The number of primates used fell slightly. A total of 3 416 primates were used in 2019, which is 92 more than in the previous year.

Dogs and cats

The number of dogs and cats used, in particular for statutory testing and for applied research, was 3 525 and 954, respectively. Compared to the previous year there was an overall decrease in the number of dogs (3 993 in 2018) and an increase in the number of cats (765 in 2018).

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 13% were used for researching human and animal diseases. Around 22% of the animals were used in the production and quality control of medical products or for toxicological safety tests. Around 18% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

Compared to 2018 there was a slight overall decrease in the areas of researching human and animal diseases (around 2%) and maintaining colonies of genetically modified animals (around 6%), and an increase of around 6% in particular in the area of research into species conservation.

- **Basic research**
  In 2019 important areas of basic research included, in particular, research into the nervous system (around 20%) and the immune system (around 18%). These figures are virtually unchanged compared to the previous year.

- **Human and animal diseases**
  In the area of researching human and animal diseases, there was an emphasis on human cancers. Some 40% of the animals used for testing in this area were used for this purpose. This figure is virtually unchanged compared to the previous year (around 39% in 2018).

- **Toxicological safety tests**
  In 2019 there was an increase compared to the previous year, in particular in the area of testing medical products for ecotoxicity. This is an area where alternative methods are increasingly being used, but due to the complex interaction between medicinal products and the organism, testing on animals is still required to demonstrate that products are safe and effective.

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 65%). Around 24% of the tests were classified as ‘moderate’ and 5% were classified as ‘severe’. Compared to the previous year, there was an increase of 4% in tests whose severity was classified as ‘mild’ and a slight decrease 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%, the same level as in the previous year.

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. This includes

launching and supporting various projects aimed at replacing animal testing with alternative methods as quickly as possible, such as 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.

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. trout, common nase, common roach, European perch, barbel) were used for the purposes of basic ethological research and research into species conservation. This partially concerned animals caught in the wild that were re-released after the test was finished. The severity classification was generally 'mild' (around 94%).

Among birds, primarily local wild bird species (e.g. Zebra finch, tern, blue tit, great tit, common buzzard) were used. These animal species were mainly used for the purposes of basic ethological research and researching various animal diseases. This primarily concerned birds caught in the wild that were re-released after the test was finished. The severity classification for the animals involved was generally 'mild' (around 82%).

Moreover, a small number of additional species were used, including 'other rodents' and 'other amphibians'. Rodents, in particular field mice, bank voles and yellow-necked mice, were primarily used in basic ethological research. This partially concerned animals caught in the wild that were re-released after the test was finished. The severity classification was generally 'mild' (around 98%). Amphibians, in particular the common frog, axolotl and the common toad, were mainly used with the aim of protecting the natural environment, and therefore the health or welfare of human beings or animals, and in the context of basic research. Generally the severity classification was 'mild' (around 48%) or the tests were carried out entirely under general anaesthesia from which the animal never regained consciousness (around 44%).

Category 'other uses'

The emphasis in this category is on 'basic research' and tests for '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 aim of refining these methods;

- research in the field of energy homeostasis;
- research in the field of gerontology.

The severity classification for the animals involved was generally 'mild' (around 80%).

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

- testing new diagnostic and therapeutic procedures in the area of human cancers;
- testing the effectiveness and mode of action of feed additives;
- testing the effectiveness and mode of action of substances in the area of respiratory diseases;
- pharmacodynamic tests in the context of developing therapies in the area of human or animal tumour diseases.

The severity classification for the animals involved was generally 'mild' (around 62%) to 'moderate' (around 31%).

Category 'other legal provisions'

The following other legal provisions were of particular relevance 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 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 2019.

Germany: Statistical Data 2019

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	1123358	62.02%
Rats	189538	10.46%
Guinea-Pigs	9655	0.53%
Hamsters (Syrian)	1054	0.06%
Mongolian gerbil	2785	0.15%
Other rodents	13857	0.77%
Rabbits	90860	5.02%
Cats	680	0.04%
Dogs	1678	0.09%
Ferrets	122	0.01%
Other carnivores	301	0.02%
Horses, donkeys and cross-breeds	519	0.03%
Pigs	18701	1.03%

Goats	409	0.02%
Sheep	4695	0.26%
Cattle	5886	0.32%
Prosimians	85	0%
Marmoset and tamarins	92	0.01%
Cynomolgus monkey	2385	0.13%
Rhesus monkey	51	0%
Baboons	6	0%
Other mammals	1919	0.11%
Domestic fowl	24371	1.35%
Other birds	10392	0.57%
Reptiles	85	0%
Rana	381	0.02%
Xenopus	10472	0.58%
Other amphibians	5208	0.29%
Zebra fish	90635	5%
Other fish	201073	11.1%
Cephalopods	17	0%
Total	1811270	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	1704578	94.25%
Animals born in the EU but not at a registered breeder	89931	4.97%
Animals born in rest of Europe	1582	0.09%
Animals born in rest of world	12560	0.69%
Total	1808651	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	324	12.37%
Animals born in Asia	1888	72.09%
Animals born in Africa	407	15.54%
Total	2619	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	135	5.15%
F2 or greater	1576	60.18%
Self-sustaining colony	908	34.67%
Total	2619	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	1123358	27003	1150361
Rats	189538	5048	194586
Guinea-Pigs	9655	216	9871
Hamsters (Syrian)	1054		1054
Mongolian gerbil	2785	8	2793
Other rodents	13857	4	13861
Rabbits	90860	3364	94224
Cats	680	274	954
Dogs	1678	1841	3519
Ferrets	122	2	124
Other carnivores	301		301
Horses, donkeys and cross-breeds	519	254	773
Pigs	18701	1130	19831
Goats	409	20	429
Sheep	4695	150	4845
Cattle	5886	737	6623
Prosimians	85	55	140
Marmoset and tamarins	92	4	96
Cynomolgus monkey	2385	495	2880
Rhesus monkey	51	35	86
Vervets (Chlorocebus spp.)		8	8
Baboons	6		6
Other species of Old World Monkeys (Cercopithecoidea)		13	13
Other mammals	1919	23	1942
Domestic fowl	24371	369	24740
Other birds	10392	380	10772
Reptiles	85	10	95
Rana	381		381
Xenopus	10472	1299	11771
Other amphibians	5208		5208
Zebra fish	90635	153	90788
Other fish	201073	1630	202703
Cephalopods	17		17
Total	1811270	44525	1855795

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	888228	47.86%
Translational and applied research	272358	14.68%
Regulatory use and Routine production	474902	25.59%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	11568	0.62%
Preservation of species	154934	8.35%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	53805	2.9%
Total	1855795	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	93405	10.52%
Cardiovascular Blood and Lymphatic System	84816	9.55%
Nervous System	169692	19.1%
Respiratory System	17892	2.01%
Gastrointestinal System including Liver	31146	3.51%
Musculoskeletal System	15726	1.77%
Immune System	169201	19.05%
Urogenital/Reproductive System	18169	2.05%
Sensory Organs (skin, eyes and ears)	24772	2.79%
Endocrine System/Metabolism	41774	4.7%
Multisystemic	76049	8.56%
Ethology / Animal Behaviour /Animal Biology	33023	3.72%
Other basic research	112563	12.67%
Total	888228	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	109834	40.33%
Human Infectious Disorders	23067	8.47%
Human Cardiovascular Disorders	10908	4.01%
Human Nervous and Mental Disorders	29854	10.96%
Human Respiratory Disorders	8014	2.94%
Human Gastrointestinal Disorders including Liver	7871	2.89%
Human Musculoskeletal Disorders	2444	0.9%
Human Immune Disorders	16481	6.05%
Human Urogenital/Reproductive Disorders	2187	0.8%
Human Sensory Organ Disorders (skin, eyes and ears)	3862	1.42%
Human Endocrine/Metabolism Disorders	18433	6.77%
Other Human Disorders	3759	1.38%
Animal Diseases and Disorders	18408	6.76%
Animal Welfare	8229	3.02%
Diagnosis of diseases	1878	0.69%
Plant diseases	100	0.04%
Non-regulatory toxicology and ecotoxicology	7029	2.58%
Total	272358	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	170524	35.91%
Other efficacy and tolerance testing	20342	4.28%
Toxicity and other safety testing including pharmacology	202391	42.62%
Routine production	81645	17.19%
Total	474902	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	25013	14.67%
Pyrogenicity testing	6457	3.79%
Batch potency testing	139017	81.52%
Other quality controls	37	0.02%
Total	170524	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	6561	3.24%

Skin irritation/corrosion	366	0.18%
Skin sensitisation	6000	2.96%
Eye irritation/corrosion	23	0.01%
Repeated dose toxicity	19787	9.78%
Carcinogenicity	1210	0.6%
Genotoxicity	2531	1.25%
Reproductive toxicity	17354	8.57%
Developmental toxicity	18093	8.94%
Kinetics	21025	10.39%
Pharmaco-dynamics (incl safety pharmacology)	58978	29.14%
Ecotoxicity	36710	18.14%
Safety testing in food and feed area	1683	0.83%
Target animal safety	1871	0.92%
Other toxicity/safety testing	10199	5.04%
Total	202391	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	889	13.55%
Other lethal methods	230	3.51%
Non lethal methods	5442	82.94%
Total	6561	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	12771	64.54%
29 - 90 days	5535	27.97%
> 90 days	1481	7.48%
Total	19787	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	4242	11.56%
Chronic toxicity	19624	53.46%
Reproductive ecotoxicity	224	0.61%
Endocrine activity	8784	23.93%
Bioaccumulation	3471	9.46%
Other ecotoxicity	365	0.99%
Total	36710	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	282051	71.72%
Legislation on medicinal products for veterinary use and their residues	13152	3.34%
Medical devices legislation	6380	1.62%
Industrial chemicals legislation	39600	10.07%
Plant protection product legislation	45183	11.49%
Biocides legislation	412	0.1%
Food legislation including food contact material	206	0.05%
Feed legislation including legislation for the safety of target animals, workers and environment	4412	1.12%
Other legislation	1861	0.47%
Total	393257	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	381288	96.96%
Legislation satisfying national requirements only [within EU]	2255	0.57%
Legislation satisfying Non-EU requirements only	9714	2.47%
Total	393257	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	76646	93.88%
Monoclonal antibody by mouse ascites method	1456	1.78%
Other product types	3543	4.34%
Total	81645	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	1811270	97.6%
Yes	44525	2.4%
Total	1855795	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	131475	7.08%
Mild [up to and including]	1148086	61.86%
Moderate	479210	25.82%
Severe	97024	5.23%
Total	1855795	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	1208909	65.14%
Genetically altered without a harmful phenotype	511454	27.56%
Genetically altered with a harmful phenotype	135432	7.3%
Total	1855795	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	90641	527	91168
Rats	332		332
Rabbits	16		16
Pigs	91	4	95
Marmoset and tamarins	43	4	47
Domestic fowl	196		196
Other birds	10		10
Xenopus	1748		1748
Other amphibians	271		271
Zebra fish	48498		48498
Other fish	1385		1385
Total	143231	535	143766

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

Severity	Number of uses	Percentage
Non-recovery	5386	3.75%
Mild [up to and including]	109316	76.04%
Moderate	28478	19.81%
Severe	586	0.41%
Total	143766	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	37981	26.42%
Genetically altered without a harmful phenotype	86608	60.24%
Genetically altered with a harmful phenotype	19177	13.34%
Total	143766	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	9052	6.48%
Cardiovascular Blood and Lymphatic System	18038	12.9%
Nervous System	33290	23.81%
Respiratory System	9	0.01%
Gastrointestinal System including Liver	3601	2.58%
Musculoskeletal System	1824	1.3%
Immune System	15835	11.33%
Urogenital/Reproductive System	13051	9.34%
Sensory Organs (skin, eyes and ears)	2088	1.49%
Endocrine System/Metabolism	3342	2.39%
Multisystemic	32855	23.5%
Ethology / Animal Behaviour /Animal Biology	10	0.01%
Other basic research	6798	4.86%
Total	139793	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	1334	33.58%
Human Infectious Disorders	24	0.6%
Human Cardiovascular Disorders	1361	34.26%
Human Nervous and Mental Disorders	86	2.16%
Human Gastrointestinal Disorders including Liver	38	0.96%
Human Musculoskeletal Disorders	2	0.05%
Human Immune Disorders	467	11.75%
Human Urogenital/Reproductive Disorders	122	3.07%
Human Sensory Organ Disorders (skin, eyes and ears)	519	13.06%
Human Endocrine/Metabolism Disorders	20	0.5%
Total	3973	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	191080	5727	196807
Rats	2055		2055
Zebra fish	3258		3258
Other fish	911		911
Total	197304	5727	203031

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

Severity	Number of uses	Percentage
Non-recovery	16	0.01%
Mild [up to and including]	177073	87.21%
Moderate	11956	5.89%
Severe	13986	6.89%
Total	203031	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	166895	82.2%
Genetically altered with a harmful phenotype	36136	17.8%
Total	203031	100.00%

Greece

Greece: Narrative 2019

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

An increased use of animals is reported in Greece for 2019 due to the authorisation of more research protocols compared to 2018.

A continuous increased use of animals born in the EU but not by a registered breeder has been reported. This refers to fish of domestic species (other fish) 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 decreased use of genetically altered mice without a harmful phenotype by 10% is noted in Greek statistical data in 2019 compared to 2018. Furthermore a significant decrease by approximately 50% is noted in human cardiovascular studies (Translational and applied research) using mice as well a significant decrease by approximately in human immune disorders (Translational and applied research). This is attributed to the different type of protocols performed in Greek establishments for 2019.

B) A significant use of fish is depicted in Greek statistical data in 2019 again 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. A new fish user establishment has been authorised in 2019 which contributed to the increase of the number of fish used in Greece compared to 2018. *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”. In 2019 a significant number of fish from the Mediterranean Sea (not by a registered breeder) was used in a research protocol.

C) Regarding the use of cephalopods:

The application of the protocol performed in this user establishment had the objective to assess the sensitivity and immune response of *O. vulgaris* against common fish pathogens under different physicochemical water parameters (i.e. different temperatures). Animals are infected either intramuscularly or intravenously, hemolymph is collected for the assessment of immune stimulation and at the end of the experiment, organ samples are collected to assess immune responses and bacteria presence internally. All procedures are carried out under anesthesia, while organ sampling is performed after euthanasia with an overdose of anesthetic. In 2019, the protocol was applied once in 87 animals. From these, 46 individuals either died or used for the collection of samples (severe procedure) and for 41 individuals, the protocol was characterized as mild.

D) 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.

E) It has to be noted that some user establishments do not perform protocols with the use of animals every year. Data from these establishments are only presented when appropriate.

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.

H) A continuous use of genetically altered animals is constantly noted during the last years, due to the type of projects authorised and the research trends of recent years globally.

I) A continuous decreased use of dogs is noted during the years, according to the relevant protocols authorised.

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. However there is a significant increase in "non recovery" severity in fish used in 2019 by a newly authorised fish establishment, where procedures in fish are performed under general anesthesia, are euthanized and then tissue or organ samples are taken.

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) A significant increase in the severity of procedures in mice is depicted, which can be attributed to the increased number of basic research oncology protocols in 2019, similar to 2017. Furthermore, there is a significant increase in the number of fish (gilthead sea bream and European sea bass) used with severe outcome in a user establishment. The application of experimental protocols on teleosts in this particular user establishment had the objective to assess either resistance of fish to fish pathogens or the efficacy of vaccines. These protocols were classified as severe because mortality is caused to 100% of fish. In 2019 all fish used for this protocol died, increasing thus the number of severely affected animals in total.

D) A significant increase in the severity of procedures in other fish is depicted, which can be attributed to the research protocol outcome of a user establishment project which had the objective to assess the sensitivity and immune response of *Dicentrarchus labrax* and *Sparus aurata* against common fish pathogens under different physicochemical water parameters (i.e. different temperatures).

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 si“nific”nt 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 2019.

Greece: Statistical Data 2019

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	25658	53.76%
Rats	1984	4.16%
Guinea-Pigs	8	0.02%
Rabbits	407	0.85%
Cats	12	0.03%
Pigs	332	0.7%
Rhesus monkey	1	0%
Domestic fowl	200	0.42%
Zebra fish	543	1.14%
Other fish	18494	38.75%
Cephalopods	87	0.18%
Total	47726	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	35987	75.4%
Animals born in the EU but not at a registered breeder	11658	24.43%
Animals born in rest of world	80	0.17%
Total	47725	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	25658		25658
Rats	1984	46	2030
Guinea-Pigs	8		8
Rabbits	407		407
Cats	12		12
Dogs		8	8
Pigs	332		332
Rhesus monkey	1		1
Domestic fowl	200		200
Zebra fish	543		543
Other fish	18494	75	18569
Cephalopods	87		87
Total	47726	129	47855

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	26408	55.18%
Translational and applied research	5182	10.83%
Regulatory use and Routine production	6975	14.58%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	8541	17.85%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	749	1.57%
Total	47855	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	4211	15.95%
Cardiovascular Blood and Lymphatic System	1249	4.73%
Nervous System	2419	9.16%
Respiratory System	552	2.09%
Gastrointestinal System including Liver	1569	5.94%
Musculoskeletal System	388	1.47%
Immune System	4594	17.4%
Urogenital/Reproductive System	273	1.03%
Sensory Organs (skin, eyes and ears)	871	3.3%
Endocrine System/Metabolism	171	0.65%
Multisystemic	174	0.66%
Ethology / Animal Behaviour /Animal Biology	9283	35.15%
Other basic research	654	2.48%
Total	26408	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	841	16.23%
Human Infectious Disorders	468	9.03%
Human Cardiovascular Disorders	373	7.2%

Human Nervous and Mental Disorders	640	12.35%
Human Respiratory Disorders	20	0.39%
Human Gastrointestinal Disorders including Liver	165	3.18%
Human Musculoskeletal Disorders	155	2.99%
Human Immune Disorders	1059	20.44%
Human Sensory Organ Disorders (skin, eyes and ears)	108	2.08%
Other Human Disorders	128	2.47%
Animal Diseases and Disorders	360	6.95%
Animal Welfare	756	14.59%
Diagnosis of diseases	29	0.56%
Non-regulatory toxicology and ecotoxicology	80	1.54%
Total	5182	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	0.53%
Toxicity and other safety testing including pharmacology	6938	99.47%
Total	6975	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	54	0.78%
Carcinogenicity	30	0.43%
Genotoxicity	35	0.5%
Safety testing in food and feed area	6819	98.28%
Total	6938	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	91	1.3%
Medical devices legislation	30	0.43%
Food legislation including food contact material	6854	98.27%
Total	6975	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage

Legislation satisfying EU requirements	6975	100%
Total	6975	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	47726	99.73%
Yes	129	0.27%
Total	47855	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	3890	8.13%
Mild [up to and including]	20798	43.46%
Moderate	10350	21.63%
Severe	12817	26.78%
Total	47855	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	35770	74.75%
Genetically altered without a harmful phenotype	9835	20.55%
Genetically altered with a harmful phenotype	2250	4.7%
Total	47855	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	5165		5165
Zebra fish		20	20
Total	5165	20	5185

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

Severity	Number of uses	Percentage
Mild [up to and including]	4817	92.9%
Moderate	368	7.1%
Total	5185	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	368	7.1%
Genetically altered without a harmful phenotype	4797	92.52%
Genetically altered with a harmful phenotype	20	0.39%
Total	5185	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	434	10.93%
Cardiovascular Blood and Lymphatic System	323	8.14%
Nervous System	1393	35.1%
Gastrointestinal System including Liver	325	8.19%
Immune System	1106	27.87%
Endocrine System/Metabolism	20	0.5%
Other basic research	368	9.27%
Total	3969	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	98.68%
Other Human Disorders	16	1.32%
Total	1216	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	1571		1571
Total	1571		1571

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

Severity	Number of uses	Percentage
Mild [up to and including]	269	17.12%
Moderate	1302	82.88%
Total	1571	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	1127	71.74%
Genetically altered with a harmful phenotype	444	28.26%
Total	1571	100.00%

Hungary

Hungary: Narrative 2019

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 2019 was 136.633, which represents 13.36% increase compared to 2018 and 3 % decrease compared to the same figure of 2017. The reason is for the increased use that there was more experiment in 2019, where the use of animal cannot be replaced. The number of re-used animals was 1.001 (0.73% from total uses) which represents 71% decrease compared to 2018 and 86.96 % decrease compared with the data of 2017.

The number of genetically altered animal used without a harmful phenotype in 2019 was 7.949, which represent about 8.39% decrease compared with the previous year and 0.64% increase compared with 2017. In 2019 the percentage of use is 5.82% from total uses. This also shows decrease compare with 2018.

The data of origin of animals do not show significant difference compare with the previous years. In 2019, the percentage of use of animals born in the EU at a registered breeder was 91.72% and the use of animals born in the EU but not at a registered breeder was 7.70 %. This shows 3.86% increase compare with 2018.

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

The vast majority (92.61%) of used animals were warm-blooded vertebrates. There was increase in the proportion of mammals (form 70.47% to 74.06%), while the proportion of birds and fish decreased (the birds from 24.16% to 18.55% and the fish from 5.38% to 2.79%). In 2019 increased the use of amphibians compare with 2018 (from 0% to 4.60%).

The proportion of rodents among mammals increased from 94.39% to 95.97%. There was 15.5% increase in the number of mice and 27.44% in the number of rats. In case of guinea-pigs there was a 27.5% decrease. Hamsters were not use for scientific purposes neither in 2018 nor 2019. The number of rabbits used for scientific purposes decreased by 47.95% in 2018.

The number of cats used in experiments increased slightly (15 compared to 24). The number of dogs decreased by 16%. 1 non-human primate was used in 2019 (compared to the 5 Rhesus monkeys in 2017).

The number of horses, donkeys and cross-breeds used for scientific purpose represents small increase in 2019 compared with the previous year (from 15 to 19).

There was 12% increase on the number of pigs. The use of cattle for scientific purposes increased by 21% in 2019. The number of sheep represents significant increase in 2019 compare with the previous year (from 0 to 47).

The number of domestic fowl decreased by 13.12%, while the number of other birds shows a slight decrease (from 786 to 739).

The proportion of zebra fish decreased from 3.744 to 2.063 and other fish also decreased by 36%.

When analysed by the purposes of the use of animals, the “regulatory use and routine production” is 42 % of the total uses. The proportion of basic research shows a slight decrease, the translational and applied research shows slight increase than in 2018. There was a significant increase on the category of “Protection of the natural environment in the interests of the health or welfare of human beings or animals” (from 0 to 86) and on the category of “Preservation of species” (from 0 to 6280) compare with 2018.

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

The proportion of mild uses was decreased from 54.32% to 46.18% and moderate uses increased from 23.37% to 30.62%. The severe use also shows a slight increase from 13.33% to 14.51%. On the other hand non-recoveries decreased from 8.98% to 8.68%.

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 their proportion is very low in Hungary. The use of non-human primates occurs only if there is not any alternative method.

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

The number of other amphibians dramatically increased from 0 to 6.280, in 2019. The reason for this is an establishment, where in 2019 investigated *Rana dalmatina, Bufo bufo, Hyla arborea*. There was mainly eggs collection at the natural habitat and after incubation juvenils and natural predators have been investigated. These projects were categorized into protection of the natural environment and preservation of species. It explains the dramatic increase in the value of the purpose category.

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

The number of cases where the 'severe' classification exceeded is not show significant difference compared with 2018.

Hungary: Statistical Data 2019

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	61643	45.83%
Rats	31247	23.23%
Guinea-Pigs	3454	2.57%
Rabbits	956	0.71%
Cats	24	0.02%
Dogs	244	0.18%
Pigs	2485	1.85%
Sheep	23	0.02%
Domestic fowl	24550	18.25%
Other birds	739	0.55%
Other amphibians	6280	4.67%
Zebra fish	1103	0.82%
Other fish	1754	1.3%
Total	134502	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	123310	91.68%
Animals born in the EU but not at a registered breeder	10442	7.76%
Animals born in rest of Europe	626	0.47%
Animals born in rest of world	124	0.09%
Total	134502	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	61643	102	61745
Rats	31247	416	31663
Guinea-Pigs	3454	75	3529
Rabbits	956	96	1052
Cats	24		24
Dogs	244	123	367
Horses, donkeys and cross-breeds		19	19
Pigs	2485	43	2528
Sheep	23	24	47
Cattle		40	40
Rhesus monkey		1	1
Domestic fowl	24550	62	24612
Other birds	739		739
Other amphibians	6280		6280
Zebra fish	1103		1103
Other fish	1754		1754
Total	134502	1001	135503

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	36501	26.94%
Translational and applied research	33257	24.54%
Regulatory use and Routine production	57775	42.64%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	86	0.06%
Preservation of species	6280	4.63%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1604	1.18%
Total	135503	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	3635	9.96%
Cardiovascular Blood and Lymphatic System	3883	10.64%
Nervous System	18663	51.13%
Respiratory System	471	1.29%
Gastrointestinal System including Liver	2433	6.67%
Musculoskeletal System	448	1.23%
Immune System	2239	6.13%
Urogenital/Reproductive System	1872	5.13%
Sensory Organs (skin, eyes and ears)	597	1.64%
Endocrine System/Metabolism	1121	3.07%
Multisystemic	781	2.14%
Ethology / Animal Behaviour /Animal Biology	31	0.08%
Other basic research	327	0.9%
Total	36501	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	2972	8.94%
Human Infectious Disorders	58	0.17%
Human Cardiovascular Disorders	177	0.53%
Human Nervous and Mental Disorders	15093	45.38%
Human Respiratory Disorders	63	0.19%
Human Musculoskeletal Disorders	84	0.25%
Human Immune Disorders	1391	4.18%
Human Urogenital/Reproductive Disorders	22	0.07%
Human Sensory Organ Disorders (skin, eyes and ears)	1153	3.47%
Human Endocrine/Metabolism Disorders	142	0.43%
Other Human Disorders	12	0.04%
Animal Diseases and Disorders	9333	28.06%
Animal Welfare	372	1.12%
Diagnosis of diseases	807	2.43%
Non-regulatory toxicology and ecotoxicology	1578	4.74%
Total	33257	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	25986	44.98%
Other efficacy and tolerance testing	615	1.06%
Toxicity and other safety testing including pharmacology	31112	53.85%
Routine production	62	0.11%
Total	57775	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	7331	28.21%
Pyrogenicity testing	37	0.14%
Batch potency testing	17665	67.98%
Other quality controls	953	3.67%
Total	25986	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	13517	43.45%
Skin irritation/corrosion	143	0.46%
Skin sensitisation	3606	11.59%
Eye irritation/corrosion	115	0.37%
Repeated dose toxicity	5004	16.08%
Genotoxicity	638	2.05%
Reproductive toxicity	3086	9.92%
Developmental toxicity	738	2.37%
Kinetics	1129	3.63%
Pharmaco-dynamics (incl safety pharmacology)	1466	4.71%
Ecotoxicity	1432	4.6%
Other toxicity/safety testing	238	0.76%
Total	31112	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	12490	92.4%
Non lethal methods	1027	7.6%

Total	13517	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	1186	23.7%
29 - 90 days	2746	54.88%
> 90 days	1072	21.42%
Total	5004	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	1432	100%
Total	1432	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	21615	37.45%
Legislation on medicinal products for veterinary use and their residues	31179	54.02%
Industrial chemicals legislation	2600	4.51%
Plant protection product legislation	138	0.24%
Biocides legislation	51	0.09%
Food legislation including food contact material	187	0.32%
Feed legislation including legislation for the safety of target animals, workers and environment	558	0.97%
Other legislation	1385	2.4%
Total	57713	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	56743	98.32%
Legislation satisfying national requirements only [within EU]	935	1.62%
Legislation satisfying Non-EU requirements only	35	0.06%
Total	57713	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	62	100%
Total	62	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	134502	99.26%
Yes	1001	0.74%
Total	135503	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	10901	8.04%
Mild [up to and including]	63049	46.53%
Moderate	41722	30.79%
Severe	19831	14.64%
Total	135503	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	127891	94.38%
Genetically altered without a harmful phenotype	6930	5.11%
Genetically altered with a harmful phenotype	682	0.5%
Total	135503	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	170		170
Zebra fish	960		960
Total	1130		1130

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

Severity	Number of uses	Percentage
Non-recovery	960	84.96%
Mild [up to and including]	49	4.34%
Moderate	121	10.71%
Total	1130	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	91	8.05%
Genetically altered without a harmful phenotype	1019	90.18%
Genetically altered with a harmful phenotype	20	1.77%
Total	1130	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	23	2.04%
Nervous System	147	13.01%
Immune System	960	84.96%
Total	1130	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 2019

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

- There was a 30% decrease in animal use from the previous year (2018).
- There was a significant increase in the number of animals reused in 2019 versus 2018 (1164% increase).
- There was a 33% decrease from 2018 in the number of animals used that were reported as not genetically altered. However, there was a 39% increase in the number of animals used reported as being genetically altered with a harmful phenotype.
- The use of mice has dropped by 36% from the previous year but mice remain the most commonly used species at 69% of all animal uses. The use of rabbits has increased by 223% since 2018. The use of ferrets has increased by 40% since 2018. In relation to agricultural species, the use of pigs has decreased by 81% from 2018, whereas the use of sheep has increased by 49%, and that of cattle has increased by 73% from 2018. There was a 71% increase in the use of zebra fish since 2018. There was a 69% decrease in the use of other fish since 2018.
- The number of animals reported as being used for the purpose of Basic research increased by 79%. The number of animals reported as being used for the purpose of Translational and applied research was 42% lower in 2019 versus 2018, whilst the number of animals used for Regulatory use and Routine Production decreased by 33%. The use of animals for Maintenance of colonies of established genetically altered animals, not used in other procedures increased by 60%. Uses of animals for other project purposes remained relatively stable.

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

- This 30% decrease in total animal use (from 2018 to 2019) is mainly accounted for by a 33% decrease in regulatory testing. This follows a decrease in regulatory testing of 26% between 2017 and 2018. The shift downwards seen in 2019 (mirroring that of 2018) is likely due to the ongoing transition from animal tests to non-animal alternatives for a number of biological and other products, further to regulatory approval being granted for the testing of these products using alternative methods.
- The increase in the number of animals being reused is largely due to the reuse of a significant number of cattle. In Ireland, cattle are used only for agricultural research studies (for the benefit of the species, the environment or the agricultural sector).
- The significant decrease in the numbers of non-genetically altered animals used in 2019 relates to the marked reduction in the numbers of animals used for regulatory testing.

The increase in the number of animals used being reported as genetically altered with a harmful phenotype is thought to be due to three main factors:

(ii) increased familiarity of users with the reporting requirements in respect of genetically altered animals,

(ii) increased awareness and recognition of the impacts of genetic alterations on the phenotypes of animals, with lines of animals that may not have been previously recognised as having a harmful phenotype, now being classified as harmful lines, and

(iii) increased selection of genetically altered animals over non-genetically altered lines for scientific studies, in order to more effectively answer particular scientific questions.

- The notable decrease in the use of mice in 2019 is a reflection of the large decrease in the total number of animals used for regulatory testing. The large increase in the numbers of rabbits being used is due to the relocation of a number of rabbit studies to Ireland from elsewhere in the EU in 2019. The increase in the number of ferrets used is a result of increased levels of regulatory testing that require the use of this species (mainly human vaccine testing). The increase in zebra fish numbers relates to the expanding interest in using zebra fish as a model species within the scientific community, and the authorisation of one project that required the use of a large number of fish.

  In relation to agricultural species, no specific knowledge of any significant factor underlying the reduction in the numbers of pigs undergoing procedures in 2019 is available. It should be noted however that the vast majority of pigs used in Ireland are used for agricultural research (e.g. studies investigating porcine nutrition, physiology and welfare). In some instances studies of this nature utilise only techniques that do not reach the threshold of a procedure. The increases in the numbers of cattle and sheep being used in 2019 versus 2018 are due to several agricultural studies requiring large numbers of these species (for example an epidemiological study) being authorised.

  In relation to the reduction in the use of the species category 'other fish', this is as a result of a marked decrease in the number of fish reported as being tagged for wildlife conservation and monitoring studies in 2019 versus 2018. The HPRA is not aware of the factors underlying the decreased number of fish tagged in 2019.

- The HPRA does not know the reasons underlying the increase in the percentage of uses of animals for the project purpose Basic research. The fall in the numbers of animals reported as being used for Translational and Applied research in 2019 may be due to the overall reduction in animal numbers used in this year. The decrease in the numbers of animals reported as being used for Regulatory use and Routine Production is likely due to the ongoing transition from animal tests to non-animal alternatives for a number of biological and other products, further to regulatory approval being granted for the regulatory testing of these products using alternative methods.

  The increased numbers of animals reported as being used for Maintenance of colonies of established genetically altered animals, not used in other procedures is unknown, but is likely to be as result of several factors:

(ii) increased familiarity of users with the reporting requirements in respect of genetically altered animals,

(ii) increased selection of genetically altered animals over non-genetically altered lines in order to more effectively answer particular scientific questions.

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

The percentage of animals reported as experiencing non-recovery severity increased from 0.53% of the total in 2018, to 1.43% of the total in 2019, representing an increase of almost three-fold between the two years. The rationale behind this increase is uncertain, but it may be as a result of improved understanding among the user community of each of the severity categories, and therefore more accurate reporting year-on-year. The percentage of animals reported as experiencing severe severity in 2019 dropped to 13.31% of total, down from 16.89% in 2018. In absolute terms, the number of animals reported as experiencing severe severity reduced from 33,746 in 2018 to 18,550 in 2019. 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 regulatory testing, and this effort is reflected in the numbers of uses of animals for these types of test in 2019. For example, we have noted a reduction of 40% in the numbers of animals used for batch potency testing from 2018 to 2019, and the percentage reduction in 2019 versus 2017 is 60% less animals used for testing of this nature. Where it is necessary to perform this type of testing using animals (for instance if there is no non-animal alternative available for a specific product), we have also mandated the implementation of early humane endpoints for these tests. This has resulted in decreases in the severity that animals experience, which is particularly important in relation to reducing the numbers of animals experiencing severe severity.

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

With regards to species, 'other fish' accounted for 4% of animal use and 'other birds' less than 1%. These relate to studies of wild animals, such as tagging and conservation projects. 'Other mammals' includes small numbers of deer and badgers that were used in studies investigating the health of these species.

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

This was not exceeded during 2019.

Ireland: Statistical Data 2019

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	95596	70.21%
Rats	22994	16.89%
Guinea-Pigs	603	0.44%
Hamsters (Syrian)	6	0%
Rabbits	552	0.41%
Ferrets	403	0.3%
Horses, donkeys and cross-breeds	19	0.01%
Pigs	323	0.24%
Goats	26	0.02%
Sheep	703	0.52%
Cattle	3417	2.51%
Other mammals	28	0.02%
Domestic fowl	80	0.06%
Other birds	673	0.49%
Xenopus	16	0.01%
Zebra fish	5219	3.83%
Other fish	5506	4.04%
Total	136164	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	129395	95.03%
Animals born in the EU but not at a registered breeder	6007	4.41%
Animals born in rest of Europe	10	0.01%
Animals born in rest of world	752	0.55%
Total	136164	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	95596		95596
Rats	22994		22994
Guinea-Pigs	603		603
Hamsters (Syrian)	6		6
Rabbits	552		552
Ferrets	403		403
Horses, donkeys and cross-breeds	19	10	29
Pigs	323		323
Goats	26		26
Sheep	703	259	962
Cattle	3417	2003	5420
Other mammals	28	3	31
Domestic fowl	80		80
Other birds	673		673
Xenopus	16		16
Zebra fish	5219		5219
Other fish	5506		5506
Total	136164	2275	138439

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	13910	10.05%
Translational and applied research	22341	16.14%
Regulatory use and Routine production	96810	69.93%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5043	3.64%
Preservation of species	18	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	317	0.23%
Total	138439	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	193	1.39%
Cardiovascular Blood and Lymphatic System	71	0.51%
Nervous System	4203	30.22%
Respiratory System	338	2.43%
Gastrointestinal System including Liver	433	3.11%
Musculoskeletal System	38	0.27%
Immune System	2724	19.58%
Sensory Organs (skin, eyes and ears)	898	6.46%
Endocrine System/Metabolism	294	2.11%
Multisystemic	429	3.08%
Ethology / Animal Behaviour /Animal Biology	4289	30.83%
Total	13910	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	695	3.11%
Human Infectious Disorders	588	2.63%
Human Cardiovascular Disorders	964	4.31%
Human Nervous and Mental Disorders	6349	28.42%
Human Respiratory Disorders	248	1.11%
Human Gastrointestinal Disorders including Liver	1366	6.11%
Human Musculoskeletal Disorders	2034	9.1%
Human Immune Disorders	587	2.63%
Human Urogenital/Reproductive Disorders	136	0.61%
Human Sensory Organ Disorders (skin, eyes and ears)	5387	24.11%
Human Endocrine/Metabolism Disorders	901	4.03%
Animal Diseases and Disorders	2275	10.18%
Animal Welfare	410	1.84%
Diagnosis of diseases	398	1.78%
Plant diseases	3	0.01%
Total	22341	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	96172	99.34%
Toxicity and other safety testing including pharmacology	200	0.21%
Routine production	438	0.45%
Total	96810	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	2765	2.88%
Pyrogenicity testing	525	0.55%
Batch potency testing	92882	96.58%
Total	96172	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	200	100%
Total	200	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	200	100%
Total	200	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage

Legislation on medicinal products for human use	96062	99.68%
Legislation on medicinal products for veterinary use and their residues	110	0.11%
Other legislation	200	0.21%
Total	96372	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	96372	100%
Total	96372	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	438	100%
Total	438	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	136164	98.36%
Yes	2275	1.64%
Total	138439	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1991	1.44%
Mild [up to and including]	77452	55.95%
Moderate	40453	29.22%
Severe	18543	13.39%
Total	138439	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	126835	91.62%
Genetically altered without a harmful phenotype	6761	4.88%
Genetically altered with a harmful phenotype	4843	3.5%
Total	138439	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	175		175
Total	175		175

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

Severity	Number of uses	Percentage
Mild [up to and including]	175	100%
Total	175	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	175	100%
Total	175	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
Multisystemic	175	100%
Total	175	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	729		729
Total	729		729

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

Severity	Number of uses	Percentage
Mild [up to and including]	576	79.01%
Moderate	146	20.03%
Severe	7	0.96%
Total	729	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	520	71.33%
Genetically altered with a harmful phenotype	209	28.67%
Total	729	100.00%

Italy

Italy: Narrative 2019

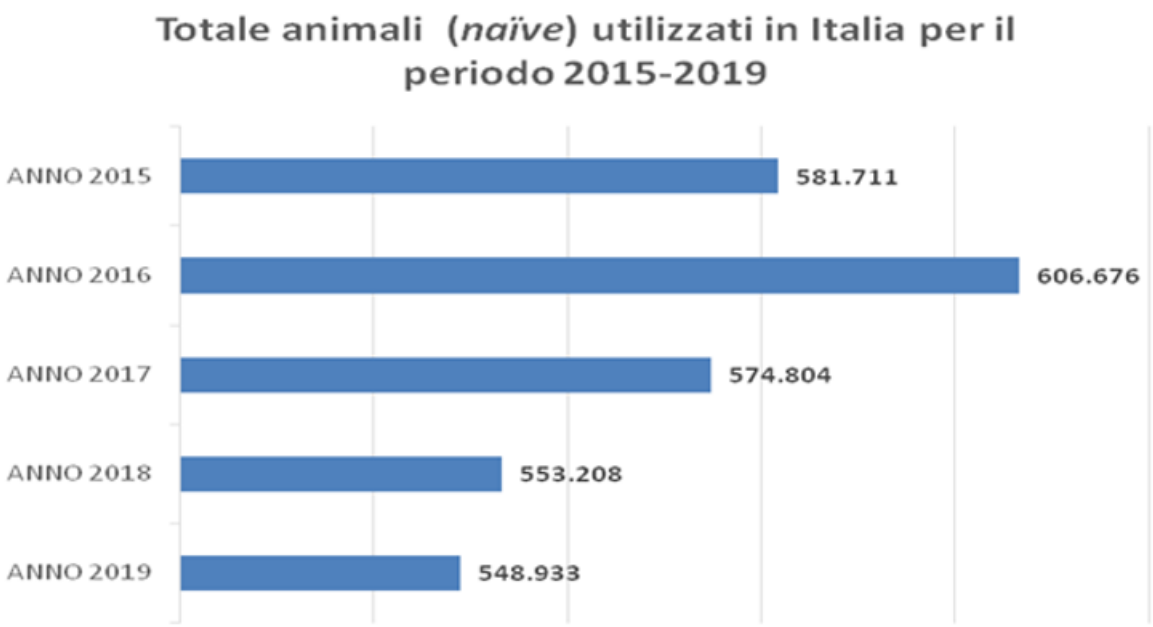
Introduction

The data for Italy for 2019 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

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

The downward trend in the total number of animals used for scientific purposes for the first time ('naive' animals) continued also in 2019. In total, 548 933 animals were used in scientific procedures in 2019, a decline of 0.77% compared to the previous year (see Figure 1).

Figure 1



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

In terms of species, rodents and rabbits accounted for 87% of the animals, including reused animals, used in testing in 2015-2019 (see Table 1). Within these species, the number of rodents fell compared to the previous year.

There was a decrease in the number of primates compared to 2018. Regulatory tests (toxicity and other safety tests) required by European and international law were again the main scientific purpose for which primates were used in 2018 and 2019 (accounting for 99% in 2018 and 2019, up from 86.75% in 2015). The use of primates in basic and translational research thus decreased in percentage terms over the period considered (from 11.67% in 2015 to 1% in 2018 and 2019).

The most frequently used species was Macaca *fascicularis*. In 2019 the use of generation F1 animals dropped to 14%, with F2 animals accounting for 86%.

Table 1

Animal species	% of total, 2015	% of total, 2016	% of total, 2017	% of total, 2018	% of total, 2019	Mean (%) Period 2015-2019	% difference between years 2015-2019
Rodents	89.02%	87.43%	84.73%	83.49%	81.04%	**85.14%**	-7.98%
Rabbits	1.66%	2.49%	3.33%	2.19%	2.01%	**2.32%**	+0.35%
Total rodents + rabbits	**90.68%**	**89.82%**	**88.06%**	**85.68%**	**83.05%**	**87.46%**	-7.63%
Total other animal species	**9.32%**	**10.18%**	**11.94%**	**14.32%**	**16.95%**	**12.54%**	+7.63%
Total (all species)	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	

The breakdown for all animal species was as follows in 2019 (see Table 2):

28.42% of the animals were used in basic biological studies.
33.75% were used in translational or applied research.
36.77% were used for regulatory testing and routine production.
1.06% were used for other purposes.
No animals were used for forensic enquiries.

Table 2

Animal use by purpose of study

Purpose of study	2015	2016	2017	2018	2019
Basic research	37.26%	35.42%	33.55%	29.11%	28.42%
Translational research	24.92%	26.54%	26.48%	32.74%	33.75%
Regulatory testing	36.07%	37.11%	38.96%	37.36%	36.77%
Other	1.75%	0.93%	1.01%	0.79%	1.06%

In 2019 there was again a slight downward trend in the number of animals used for basic research and a slight (1%) increase in animals used for translational or applied research.

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 sixth time in 2019.

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%
2019	5.86%	45.26%	28.57%	20.31%

Comparing the data for 2018 and 2019 shows that:

- there were slight variations in the 'non-recovery' and 'moderate' suffering levels;
- there was a decline in the 'mild' suffering level;
- there was an increase of 3.15% in the 'severe' category.

Mice accounted for 79% 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 impacts 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 2019 the National Committee organised a second national 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.

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 for regulatory purposes in routine production:
Other efficacy and tolerance testing (regarding production of inactivated antigens for animal vaccines);

Other efficacy and tolerance testing (regarding immunogenicity for human vaccines).

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 2019

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	326166	60.08%
Rats	100936	18.59%
Guinea-Pigs	15849	2.92%
Hamsters (Syrian)	434	0.08%
Other rodents	642	0.12%
Rabbits	9703	1.79%
Dogs	542	0.1%
Ferrets	20	0%
Pigs	1382	0.25%
Goats	3	0%
Sheep	169	0.03%
Cattle	395	0.07%
Cynomolgus monkey	302	0.06%
Other mammals	76	0.01%
Domestic fowl	36361	6.7%
Other birds	718	0.13%
Xenopus	786	0.14%
Other amphibians	15	0%
Zebra fish	10232	1.88%
Other fish	38138	7.02%
Cephalopods	34	0.01%
Total	542903	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	452944	83.48%
Animals born in the EU but not at a registered breeder	86439	15.93%
Animals born in rest of Europe	89	0.02%
Animals born in rest of world	3129	0.58%
Total	542601	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	0.33%
Animals born in Asia	158	52.32%
Animals born in Africa	143	47.35%
Total	302	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	42	13.91%
F2 or greater	260	86.09%
Total	302	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	326166	637	326803
Rats	100936	130	101066
Guinea-Pigs	15849	253	16102
Hamsters (Syrian)	434		434
Other rodents	642		642
Rabbits	9703	1453	11156
Dogs	542	115	657
Ferrets	20	2	22
Horses, donkeys and cross-breeds		15	15
Pigs	1382	39	1421
Goats	3	20	23
Sheep	169	125	294
Cattle	395	2	397
Marmoset and tamarins		4	4
Cynomolgus monkey	302	26	328
Rhesus monkey		2	2
Other mammals	76	10	86
Domestic fowl	36361	2217	38578
Other birds	718		718
Xenopus	786	28	814
Other amphibians	15		15
Zebra fish	10232	2143	12375
Other fish	38138	4	38142
Cephalopods	34		34
Total	542903	7225	550128

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	155904	28.34%
Translational and applied research	186140	33.84%
Regulatory use and Routine production	204523	37.18%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1756	0.32%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1805	0.33%
Total	550128	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	32489	20.84%
Cardiovascular Blood and Lymphatic System	8861	5.68%
Nervous System	70742	45.38%
Respiratory System	1347	0.86%
Gastrointestinal System including Liver	3765	2.41%
Musculoskeletal System	8278	5.31%
Immune System	10618	6.81%
Urogenital/Reproductive System	2375	1.52%

Sensory Organs (skin, eyes and ears)	4294	2.75%
Endocrine System/Metabolism	3665	2.35%
Multisystemic	2528	1.62%
Ethology / Animal Behaviour /Animal Biology	2656	1.7%
Other basic research	4286	2.75%
Total	155904	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	49125	26.39%
Human Infectious Disorders	24008	12.9%
Human Cardiovascular Disorders	2283	1.23%
Human Nervous and Mental Disorders	19493	10.47%
Human Respiratory Disorders	15878	8.53%
Human Gastrointestinal Disorders including Liver	2214	1.19%
Human Musculoskeletal Disorders	5206	2.8%
Human Immune Disorders	3730	2%
Human Urogenital/Reproductive Disorders	2451	1.32%
Human Sensory Organ Disorders (skin, eyes and ears)	1354	0.73%
Human Endocrine/Metabolism Disorders	4468	2.4%
Other Human Disorders	2885	1.55%
Animal Diseases and Disorders	39254	21.09%
Animal Welfare	932	0.5%
Diagnosis of diseases	12005	6.45%
Non-regulatory toxicology and ecotoxicology	854	0.46%
Total	186140	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	99870	48.83%
Other efficacy and tolerance testing	39278	19.2%
Toxicity and other safety testing including pharmacology	63110	30.86%
Routine production	2265	1.11%
Total	204523	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	19041	19.07%
Pyrogenicity testing	2177	2.18%
Batch potency testing	75214	75.31%
Other quality controls	3438	3.44%
Total	99870	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	10384	16.45%
Skin irritation/corrosion	887	1.41%
Skin sensitisation	12584	19.94%
Eye irritation/corrosion	165	0.26%
Repeated dose toxicity	6497	10.29%
Genotoxicity	189	0.3%
Reproductive toxicity	1952	3.09%
Developmental toxicity	3859	6.11%
Kinetics	7738	12.26%
Pharmaco-dynamics (incl safety pharmacology)	581	0.92%
Phototoxicity	18	0.03%
Ecotoxicity	5629	8.92%

Safety testing in food and feed area	9326	14.78%
Other toxicity/safety testing	3301	5.23%
Total	63110	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	2034	19.59%
Other lethal methods	85	0.82%
Non lethal methods	8265	79.59%
Total	10384	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	2832	43.59%
29 - 90 days	2486	38.26%
> 90 days	1179	18.15%
Total	6497	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	3966	70.46%
Other ecotoxicity	1663	29.54%
Total	5629	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	121624	60.13%
Legislation on medicinal products for veterinary use and their residues	40140	19.85%
Medical devices legislation	19843	9.81%
Industrial chemicals legislation	6367	3.15%
Plant protection product legislation	63	0.03%
Biocides legislation	64	0.03%
Food legislation including food contact material	9613	4.75%
Feed legislation including legislation for the safety of target animals, workers and environment	102	0.05%
Other legislation	4442	2.2%
Total	202258	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	192608	95.23%
Legislation satisfying national requirements only [within EU]	1842	0.91%
Legislation satisfying Non-EU requirements only	7808	3.86%
Total	202258	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1918	84.68%
Other product types	347	15.32%
Total	2265	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	542903	98.69%
Yes	7225	1.31%
Total	550128	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	32393	5.89%
Mild [up to and including]	249401	45.34%
Moderate	156247	28.4%
Severe	112087	20.37%
Total	550128	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	438190	79.65%
Genetically altered without a harmful phenotype	92956	16.9%
Genetically altered with a harmful phenotype	18982	3.45%
Total	550128	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	3331		3331
Rats	3		3
Pigs	15		15
Cattle	1		1
Zebra fish	354		354
Total	3704		3704

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

Severity	Number of uses	Percentage
Non-recovery	198	5.35%
Mild [up to and including]	533	14.39%
Moderate	2544	68.68%
Severe	429	11.58%
Total	3704	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	841	22.71%
Genetically altered without a harmful phenotype	2344	63.28%
Genetically altered with a harmful phenotype	519	14.01%
Total	3704	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	1023	47.27%
Cardiovascular Blood and Lymphatic System	54	2.5%
Nervous System	688	31.79%
Musculoskeletal System	137	6.33%
Immune System	57	2.63%
Sensory Organs (skin, eyes and ears)	7	0.32%
Endocrine System/Metabolism	173	7.99%
Other basic research	25	1.16%
Total	2164	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	106	6.88%
Human Nervous and Mental Disorders	492	31.95%
Human Musculoskeletal Disorders	117	7.6%
Human Endocrine/Metabolism Disorders	15	0.97%
Other Human Disorders	810	52.6%
Total	1540	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	2326		2326
Total	2326		2326

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

Severity	Number of uses	Percentage
Mild [up to and including]	1774	76.27%
Moderate	93	4%
Severe	459	19.73%
Total	2326	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	1077	46.3%
Genetically altered with a harmful phenotype	1249	53.7%
Total	2326	100.00%

Latvia

Latvia: Narrative 2019

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

In 2017 competent authority has approved 13 projects, in 2018 – 8, but in 2019 - 7. The total number of animals used for scientific purposes has been decreased in recent years - 6289 in 2017, 4417 in 2018 and 4245 –in 2019. During the 2017 active licence had 25 projects, but in 2018 and 2019 –29 projects. However it does not mean that in all projects all procedures were performed and all projects were 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 2016. and 2017 60 genetically altered animals were used per year, however in 2018 -315 (total increase from 1.1% in 2017 to 7.1% in 2018), but in 2019 the number of genetically altered animals dropped to 109 (2.6%). The main reason for this is related to studies concerned specific diseases and their treatment. Year by year depending the type of project genetically altered animals are used more or less. 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 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 less harmful 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).

This year our researchers in some projects started to re-use rodents (n=100), that were previous used in mild procedures as animals from control groups. Using a second time, animals were supposed to undergo non-recovery procedures, where new specific substances were tested and after the procedures the tissue and organs were used for further investigations or stored for using in other procedures thus avoiding unnecessary use of animals for the procurement of organs and tissues.

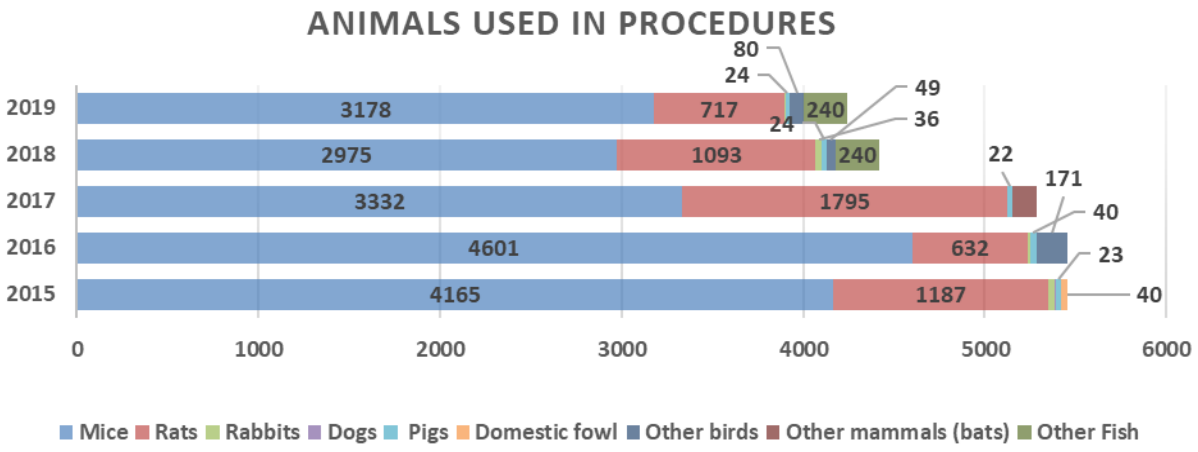
Mostly all animals used in procedures come from EU origin (99.3%), and the biggest part 91.4% from the registered breeder. In 2019 30 mice from USA were used in procedures. Animals were purchased outside Europe because in this region were not available such a specifically genetically altered

animals for research purposes. Also this year slightly increased number of animals born in the EU but not at the registered breeder (from 1.1% 2018 to 7.8% in 2019). This is explained by animal using in field studies and specific circumstances when some species were not available at the registered breeders in nearest neighbour countries, but long distance delivery could affect animals and further research.

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

Comparing last five years the total amount of used mice have decreased from 4165 in 2015 to 3178 in 2019 as well as total amount of rats also decreases from 1187 in 2015 to 717 in 2019 (see Fig.1). However in 2017 there is seen increasing rate of using rats. 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.

Figure 1



This year comparing to previous year (2018 mice – 2975, rats – 1093, 2019 mice – 3178, rats – 717) increased total amount of used mice and decreased a total amount of used rats. It is somehow an answer from the researchers on our request to use smaller and less sensitive animals as possible in procedures. In the same time there is no evident increasing of using other species, except wild birds. The increased rate of wild birds used in this year (80 in 2019 and 49 in 2018) can be explained by progress of specific project, however the total amount of animals planned used in project has not increased and licenses for projects using birds were not required.

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

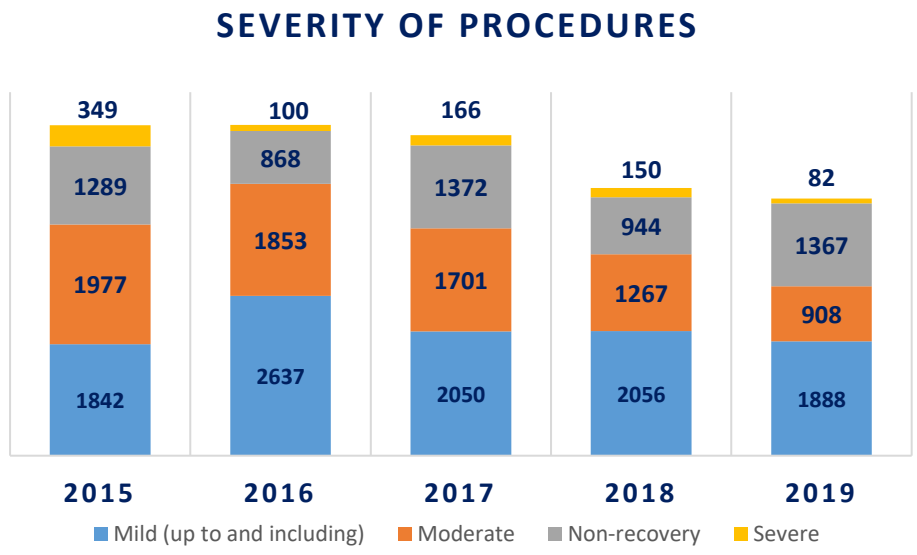
The biggest part of all animals were used in **mild procedures** (see Fig. 2 and Fig. 3) – 46.5.% (n=1888) from which 1627 were used in planned mild procedures, but other animals that were supposed to undergo moderate procedures actually for the following reasons underwent mild procedure.

1. For 84 mice (purpose – Trans/Appl (Human Infectious Disorders)) the severity of the procedure was mild instead of moderate due to the lack of prevalent clinical signs of the infection in this model.

2. 105 mice (purpose – Trans/Appl Research (Human Nervous and Mental Disorders)) were supposed to be used in moderate procedures in control groups where not all planned manipulations were performed or no changes were observed in animals following injection of compounds up till 72 hours.

3. 10 mice (purpose – Trans/Appl Research (Human Musculoskeletal Disorders)) and 10 rats (purpose – Trans/Appl Research (Human Cardiovascular Disorders)) were supposed to be used in moderate procedures in control groups where not all planned manipulations were performed.

Figure 2



In total 82 (1.9%) animals in 2019 were used in **severe procedures** from which 30 rats were used in planned severe procedures for purpose Trans/Appl Research (Human Cardiovascular Disorders) and 25 mice for purpose Trans/Appl Research (Human Nervous and Mental Disorders), but other animals from planned easer procedures reasons mentioned below undergo actually severe procedure.

1. During planned moderate procedure (purpose – Basic Research (Oncology)) 2 mice died 2 minutes after the i.p. injection of D-Luciferin. During the 247athological examination, no

bleeding or injury of the organs was detected. Route of injection changed s.c. for the rest of the experiment.

2. Death of 11 mice (purpose – Trans/Appl (Human Infectious Disorders)) due to unexpected anaphylactic shock-like response following the i.p. injection of a new recombinant protein (related to the strain-related hypersensitivity) in planned mild procedure.

3. Health condition after stroke operation of nine mice in planned moderate procedure was not satisfactory (severe weight lost) therefore they were euthanized and 5 rats in planned mild procedure died during surgical manipulation (purpose – Trans/Appl Research (Human Nervous and Mental Disorders).

In moderate procedures in 2019 were used 908 (21.3%) animals from which 703 mice and 105 rats were exposed to previous planned moderate procedures.

In 2019 in non-recovery procedures were used 1367 (32.2%) animals from which 1347 were used for planned non-recovery procedures with following purposes:

a) Higher education or training for the acquisition, maintenance or improvement of vocational skills – 24 pigs,

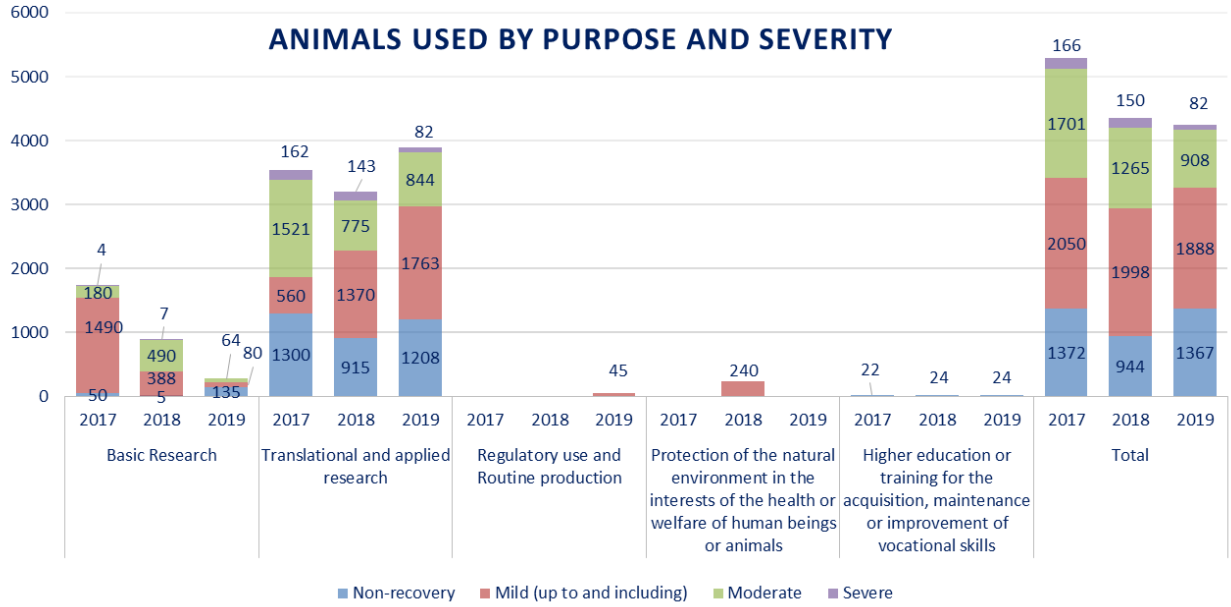
b) Basic Research (Cardiovascular Blood and Lymphatic System) – 50 mice and 85 rats,

c) Trans/Appl Research (Human Cardiovascular Disorders) – 848 mice and 259 rats,

d) Trans/Appl Research (Human Nervous and Mental Disorders) – 80 mice.

21 mice from planned moderate procedure actually underwent non-recovery procedure because of death during surgery manipulations that were the first step for this procedure (Trans/Appl Research (Human Nervous and Mental Disorders).

Figure 3

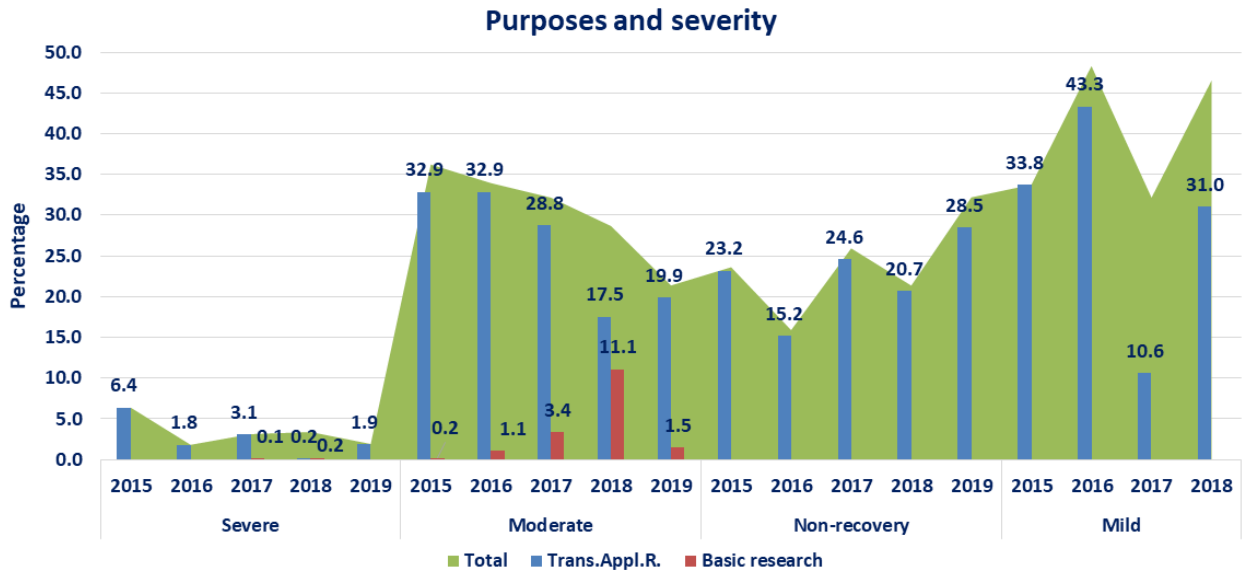


In general observation there are evident changes in severity of procedures. Comparing previous year in 2019 decreased animal using in severe procedures (from 3.4% in 2018 to 1.9% in 2019), in moderate procedures (from 28.7% in 2018 to 21.4% in 2019), in mild procedures (from 46.5% in 2018 to 44.5% in 2019), but increased animal using in non-recovery procedures (from 21.4% in 2018 to 32.2% in 2019). This is explained by starting to use and re-use animals for non-recovery procedures with purpose to get tissue or organs after testing some specific chemical substances while animals are exposed to full anaesthesia to avoid severe suffering. After testing chemical substances tissue and organs are used for further analysis or if possible stored for other experiments were they could be useful.

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 or vaccines with therapeutic effect.

In this research branch (translation and applied research) for the last year increased animal using (see Fig. 3 and Fig.4). 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 in non-recovery procedures. That is because of several studies devoted to basic human cardiovascular and nervous system and basic animal behaviour (birds) research.

Figure 4



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures from 2015 to 2019) 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 2019, as the project was continued from 2014, 24 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 2019 120 *Salmo salar* and 120 *Salmo trutta* were 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 2019 80 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 and 2019 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 2019 there have not been any cases or detected information from users that the 'severe' classification was exceeded in any of procedures.

In 2019 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2019

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	3078	74.26%
Rats	717	17.3%
Rabbits	6	0.14%
Pigs	24	0.58%
Other birds	80	1.93%
Other fish	240	5.79%
Total	4145	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	3789	91.41%
Animals born in the EU but not at a registered breeder	326	7.86%
Animals born in rest of world	30	0.72%
Total	4145	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	3078	100	3178
Rats	717		717
Rabbits	6		6
Pigs	24		24
Other birds	80		80
Other fish	240		240
Total	4145	100	4245

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	279	6.57%
Translational and applied research	3897	91.8%
Regulatory use and Routine production	45	1.06%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	24	0.57%
Total	4245	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Cardiovascular Blood and Lymphatic System	135	48.39%
Nervous System	64	22.94%
Ethology / Animal Behaviour /Animal Biology	80	28.67%
Total	279	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	247	6.34%
Human Infectious Disorders	317	8.13%
Human Cardiovascular Disorders	1211	31.08%
Human Nervous and Mental Disorders	1631	41.85%
Human Musculoskeletal Disorders	40	1.03%
Human Urogenital/Reproductive Disorders	110	2.82%
Animal Diseases and Disorders	341	8.75%
Total	3897	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	45	100%
Total	45	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	45	100%

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

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	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

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	4145	97.64%
Yes	100	2.36%
Total	4245	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1367	32.2%
Mild [up to and including]	1888	44.48%
Moderate	908	21.39%
Severe	82	1.93%
Total	4245	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	4136	97.43%
Genetically altered without a harmful phenotype	109	2.57%
Total	4245	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 2019

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

In 2019, there were 5066 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, 1780 (were 3286) 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 2019 were large increase in the use of Basic Research, Higher education or training for the acquisition, maintenance or improvement of vocational skills, Trans/Appl Research

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

The most common primary purpose for using animals was “Basic Research” (~ 162 %, / 2684 animals was 1024), then Higher education or training for the acquisition, maintenance or improvement of vocational skills (~ 250 % / 1200 animals was 342), for the purpose Trans/Appl Research (~ 122 %, 969 animals was 426).

Decrease was in “Regulatory use” (~ 602 % 213 animals was 1496).

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 2019 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 (~70 %) were used for the procedures classified as mild [up to and including] severity, non-recovery (~ 26 %), moderate (~ 4,6 %)..

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 2019 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 ~9,3% (fish 82) from total fish amount, Salmo trutta ~68% (fish 600) from total fish amount, Acipenser oxyrinchus ~22,7 % (fish 200) from total fish amount) were used during the reporting in 2019.

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 2019.

Lithuania: Statistical Data 2019

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	2790	55.07%
Rats	886	17.49%
Guinea-Pigs	15	0.3%
Rabbits	88	1.74%
Pigs	213	4.2%
Sheep	5	0.1%
Other birds	187	3.69%
Other fish	882	17.41%
Total	5066	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	5066	100%
Total	5066	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	2790		2790
Rats	886		886
Guinea-Pigs	15		15
Rabbits	88		88
Pigs	213		213
Sheep	5		5
Other birds	187		187
Other fish	882		882
Total	5066		5066

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	2684	52.98%
Translational and applied research	1047	20.67%
Regulatory use and Routine production	135	2.66%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1200	23.69%
Total	5066	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	530	19.75%
Nervous System	146	5.44%
Musculoskeletal System	352	13.11%
Immune System	354	13.19%
Urogenital/Reproductive System	15	0.56%
Sensory Organs (skin, eyes and ears)	1287	47.95%
Total	2684	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Infectious Disorders	48	4.58%
Human Cardiovascular Disorders	30	2.87%
Human Nervous and Mental Disorders	418	39.92%
Human Respiratory Disorders	12	1.15%
Human Urogenital/Reproductive Disorders	110	10.51%
Other Human Disorders	16	1.53%
Diagnosis of diseases	107	10.22%
Non-regulatory toxicology and ecotoxicology	306	29.23%
Total	1047	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	100	74.07%
Routine production	35	25.93%
Total	135	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	100	100%
Total	100	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	100	100%
Total	100	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	100	100%
Total	100	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	100	100%
Total	100	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	5066	100%
Total	5066	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1306	25.78%
Mild [up to and including]	3525	69.58%
Moderate	235	4.64%
Total	5066	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	5054	99.76%
Genetically altered without a harmful phenotype	12	0.24%
Total	5066	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 2019

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, 14 656 in 2018 to 11 375 in 2019. 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, 7 817 mammals 2018 and 10 938 mammals in 2019. These figures represent an increase of 27, 52% of the total uses of mammals from 2018 to 2019.

In 2017, 20 173 zebrafishes were used in 2018, 6728 zebrafishes and in 2019, 437 zebrafishes. This represents a massive decrease with a drop of 6 291 uses form 2018 to 2019.

In 2019, mice are the most used species with 10 821.

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 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 2018, which has an impact on the decrease of 28, 84% of the total number of uses in 2019.

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

Comparing the actual severities from 2018 to 2019 no trend was 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 competent authority organised a first 3 R symposium in 2019, where all the members of the animal welfare bodies participated focusing on the replacement, reduction and refinement.

- 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 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 2019 there was no case where the severe-classification has been exceeded.

Luxembourg: Statistical Data 2019

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	10651	95.81%
Rats	117	1.05%
Zebra fish	349	3.14%
Total	11117	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	11117	100%
Total	11117	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	10651	43	10694
Rats	117		117
Zebra fish	349		349
Total	11117	43	11160

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	9374	84%
Translational and applied research	1564	14.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	222	1.99%
Total	11160	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2102	22.42%
Nervous System	941	10.04%
Immune System	6251	66.68%
Endocrine System/Metabolism	80	0.85%
Total	9374	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1382	88.36%
Human Infectious Disorders	33	2.11%
Human Nervous and Mental Disorders	26	1.66%
Human Immune Disorders	123	7.86%
Total	1564	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	11117	99.61%
Yes	43	0.39%
Total	11160	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	4	0.04%
Mild [up to and including]	7281	65.24%
Moderate	3531	31.64%
Severe	344	3.08%
Total	11160	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	3013	27%
Genetically altered without a harmful phenotype	7465	66.89%
Genetically altered with a harmful phenotype	682	6.11%
Total	11160	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	127		127
Zebra fish	88		88
Total	215		215

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

Severity	Number of uses	Percentage
Non-recovery	80	37.21%
Mild [up to and including]	88	40.93%
Moderate	47	21.86%
Total	215	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	95	44.19%
Genetically altered without a harmful phenotype	88	40.93%
Genetically altered with a harmful phenotype	32	14.88%
Total	215	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	32	14.88%
Nervous System	183	85.12%
Total	215	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

Malta

Malta: Narrative 2019

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

Two scientific programs are still ongoing from the previous year. No new applications have been accepted.

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

In relation to the number of animals that should have been used, the projects leader declared that only 265 fish have been used during 2019, which is much below the expected number.

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

The severity is mild.

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

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. The only study ongoing have a severity classified as mild pain.

Malta: Statistical Data 2019

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	265	100%
Total	265	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	265	100%

Total	265	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	265		265
Total	265		265

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	265	100%
Total	265	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	265	100%
Total	265	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	265	100%
Total	265	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]	265	100%
Total	265	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	265	100%
Total	265	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 2019

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

In 2019, the Dutch establishments reported 399,950 animals used in procedures. This is 1,945 less than in 2018. Especially the number zebrafish (-11,088) was reduced. The number 'other fish' (+13,557) has increased.

In 2019 animals were 7,432 times reused, which is 3,090 animals less than in 2018 (10,522). Reuse mainly takes place for the purpose of education and training, and for applied and conversion-oriented research.

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 2019 is within the normal range of fluctuation of previous years. The increase in 'other fish' can largely be attributed to research involved migration patterns and population research.

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

The actual severities reported in 2019 (mild 61.3%, moderate 28.5%, severe 1.2%, and non-recovery: 9%) are generally in line with the actual severities reported in 2018.

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 birds (13,911) : Accipiter gentili, Acipenser baeri, Acrocephalus arundinaceus, Acrocephalus scirpaceus, Anas sinensis, Aythya fuligula, Aythya marila, Branta leucopsis, Bucephala clangula, Calidris canutus, Chroicocephalus ridibundus, Circus aeruginosus, Clangula hyemalis, Columbia livia, Corvus monedula, Cyanistes caeruleus, Cygnus columbianus bewickii, Dryocopus martius, Ficedula hypoleuca, Haematopus ostralegus, Haliaeetus albicilla, Larus fuscus, Limosa limosa, Mareca Penelope, Melanitta nigra, Nymphicus hollandicus, Parus major, Platalea leucorodia, Psittacus erithacus, Sturnus vulgaris, Taeniopygia guttata, Thalasseus sandvicensis, Vanellus vanellus, Irundo rustica, Meleagris Gallopavo.

Other fish (38,843): Abramis brama, Alburnus alburnus, Amblyraja 274rachyu, Ammodytes tobianus, Anguilla Anguilla, Aspius aspius, Barbatula barbatula, Barbus barbus, Blicca bjoerkna, Chelon ramada, Clarias gariepinus, Cobitis taenia, Coregonus oxyrinchus, Cyprinidae hybridae, Cyprinidae sp., Cyprinodon variegatus variegatus, Cyprinus carpio, Dicentrarchus labrax, Erythrophthalmus, Esox Lucius, Gallus gallus, Gasterosteus aculeatus, Gobio gobio, Gymnocephalus cernua, Gymnocephalus cernuus, Hyperoplus lanceolatus, Lampetra fluviatilis, Lepomis gibbosus, Leuciscus idus, Leucoraja naevus, Lota lota, Misgurnus aunguillicaudatus, Mustelus asterias, Neogobius melanostomus, Nothobranchius furzeri, Onchorhyunchus mykiss, Oreochromis niloticus, Osmerus eperlanus, Perca fluviatilis, Phalloptychus Januarius, Pimephales promelas, Platichthys flesus, Ponticola kessleri, Proterorhinus marmoratus, Proterorhinus semilunaris, Pseudorasbora parva, Pundamilia hybrids, Pundamilia nyererei, Pundamilia pundamilia, Pungitius pungitius, Raja brachyura, Raja clavate, Raja montagui, Rhodeus amarus, Romanogobio albipinnatus, Rutilus rutilus, Salmo salar, Salmo sp., Salmo trutta, Salvenilus alpinus x Salvenilus fontinalis, Sander lucioperca, Scardinius, Scardinius erythrophthalmus, Scophthalmus maximus, Scyliorhinus canicular, Siluris glanis, Tinca tinca, Umbra pygmaea, Vimba vimba

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 2019 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2019

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	145260	38.69%
Rats	79937	21.29%
Guinea-Pigs	9108	2.43%
Hamsters (Syrian)	684	0.18%
Mongolian gerbil	54	0.01%
Other rodents	1066	0.28%
Rabbits	12797	3.41%
Cats	52	0.01%
Dogs	235	0.06%
Ferrets	599	0.16%
Other carnivores	68	0.02%
Horses, donkeys and cross-breeds	49	0.01%
Pigs	10773	2.87%
Goats	141	0.04%
Sheep	269	0.07%
Cattle	1814	0.48%
Cynomolgus monkey	37	0.01%
Rhesus monkey	98	0.03%
Other mammals	294	0.08%
Domestic fowl	52287	13.93%
Other birds	13723	3.66%

Reptiles	1	0%
Xenopus	284	0.08%
Other amphibians	720	0.19%
Zebra fish	7587	2.02%
Other fish	37519	9.99%
Total	375456	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	257723	68.67%
Animals born in the EU but not at a registered breeder	107668	28.69%
Animals born in rest of Europe	58	0.02%
Animals born in rest of world	9872	2.63%
Total	375321	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	134	99.26%
Animals born in Asia	1	0.74%
Total	135	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	1	0.74%
Self-sustaining colony	134	99.26%
Total	135	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	145260	1737	146997
Rats	79937	882	80819
Guinea-Pigs	9108		9108
Hamsters (Syrian)	684		684
Mongolian gerbil	54		54
Other rodents	1066		1066
Rabbits	12797	167	12964
Cats	52	119	171
Dogs	235	315	550
Ferrets	599	42	641
Other carnivores	68		68
Horses, donkeys and cross-breeds	49	52	101
Pigs	10773	771	11544
Goats	141	180	321
Sheep	269	124	393
Cattle	1814	2393	4207
Cynomolgus monkey	37	1	38
Rhesus monkey	98	19	117
Other mammals	294		294
Domestic fowl	52287	143	52430
Other birds	13723	141	13864
Reptiles	1		1
Xenopus	284		284
Other amphibians	720		720
Zebra fish	7587		7587
Other fish	37519		37519
Total	375456	7086	382542

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	97550	25.5%
Translational and applied research	110409	28.86%
Regulatory use and Routine production	140646	36.77%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	690	0.18%
Preservation of species	18794	4.91%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	14449	3.78%
Forensic enquiries	4	0%
Total	382542	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	25034	25.66%
Cardiovascular Blood and Lymphatic System	3769	3.86%
Nervous System	19410	19.9%
Respiratory System	569	0.58%

Gastrointestinal System including Liver	3226	3.31%
Musculoskeletal System	1170	1.2%
Immune System	12080	12.38%
Urogenital/Reproductive System	1623	1.66%
Sensory Organs (skin, eyes and ears)	718	0.74%
Endocrine System/Metabolism	6973	7.15%
Multisystemic	4017	4.12%
Ethology / Animal Behaviour /Animal Biology	18886	19.36%
Other basic research	75	0.08%
Total	97550	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	13680	12.39%
Human Infectious Disorders	14743	13.35%
Human Cardiovascular Disorders	5528	5.01%
Human Nervous and Mental Disorders	6549	5.93%
Human Respiratory Disorders	433	0.39%
Human Gastrointestinal Disorders including Liver	921	0.83%
Human Musculoskeletal Disorders	496	0.45%
Human Immune Disorders	2298	2.08%
Human Urogenital/Reproductive Disorders	628	0.57%
Human Sensory Organ Disorders (skin, eyes and ears)	952	0.86%
Human Endocrine/Metabolism Disorders	386	0.35%
Other Human Disorders	203	0.18%
Animal Diseases and Disorders	20512	18.58%
Animal Welfare	39762	36.01%
Diagnosis of diseases	1162	1.05%
Non-regulatory toxicology and ecotoxicology	2156	1.95%
Total	110409	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	36154	25.71%
Other efficacy and tolerance testing	3206	2.28%
Toxicity and other safety testing including pharmacology	70014	49.78%
Routine production	31272	22.23%
Total	140646	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	701	1.94%
Batch potency testing	34438	95.25%
Other quality controls	1015	2.81%
Total	36154	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	932	1.33%
Skin irritation/corrosion	40	0.06%
Skin sensitisation	2345	3.35%
Eye irritation/corrosion	31	0.04%
Repeated dose toxicity	7877	11.25%
Reproductive toxicity	21005	30%
Developmental toxicity	27636	39.47%
Neurotoxicity	415	0.59%
Kinetics	549	0.78%

Pharmaco-dynamics (incl safety pharmacology)	9	0.01%
Ecotoxicity	5593	7.99%
Safety testing in food and feed area	2828	4.04%
Target animal safety	751	1.07%
Other toxicity/safety testing	3	0%
Total	70014	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	932	100%
Total	932	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	4009	50.9%
29 - 90 days	2894	36.74%
> 90 days	974	12.37%
Total	7877	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	505	9.03%
Chronic toxicity	4866	87%
Bioaccumulation	222	3.97%
Total	5593	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	28782	26.32%
Legislation on medicinal products for veterinary use and their residues	23345	21.34%
Medical devices legislation	40	0.04%
Industrial chemicals legislation	51483	47.07%
Plant protection product legislation	1999	1.83%
Biocides legislation	166	0.15%
Food legislation including food contact material	663	0.61%
Feed legislation including legislation for the safety of target animals, workers and environment	2896	2.65%
Total	109374	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	107799	98.56%
Legislation satisfying national requirements only [within EU]	12	0.01%
Legislation satisfying Non-EU requirements only	1563	1.43%
Total	109374	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	31272	100%
Total	31272	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	375456	98.15%
Yes	7086	1.85%
Total	382542	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	35732	9.34%
Mild [up to and including]	233974	61.16%
Moderate	108025	28.24%
Severe	4811	1.26%
Total	382542	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	314280	82.16%
Genetically altered without a harmful phenotype	65036	17%
Genetically altered with a harmful phenotype	3226	0.84%
Total	382542	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	4327		4327
Zebra fish	1243		1243
Total	5570		5570

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

Severity	Number of uses	Percentage
Mild [up to and including]	5188	93.14%
Moderate	382	6.86%
Total	5570	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	3050	54.76%
Genetically altered without a harmful phenotype	2520	45.24%
Total	5570	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	3071	55.31%
Nervous System	1271	22.89%
Respiratory System	186	3.35%
Gastrointestinal System including Liver	9	0.16%
Immune System	321	5.78%
Urogenital/Reproductive System	211	3.8%
Multisystemic	111	2%
Other basic research	372	6.7%
Total	5552	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	12	66.67%
Human Nervous and Mental Disorders	6	33.33%
Total	18	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	1194		1194
Zebra fish	17		17
Total	1211		1211

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

Severity	Number of uses	Percentage
Mild [up to and including]	502	41.45%
Moderate	663	54.75%
Severe	46	3.8%
Total	1211	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	1211	100%
Total	1211	100.00%

Poland

Poland: Narrative 2019

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

In 2019, the downward trend in the number of animals used in Poland continued. Thanks to the training provided, there is a noticeably better understanding among stakeholders of the definition of a 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 in 2019, while the total number of farm animals used decreased significantly, there was a sharp rise in the use of domestic swine and fowl in research.

The established trend of moving away from various species of fish and towards using *Danio rerio* in experiments was also observed. 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 75.62% in 2019.

There is also a clear trend in researchers moving 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 recent years, there has been an 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 3 years. In 2019, there was only a slight increase in moderate procedures, with a marked decrease in severe procedures.

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 (KKE) are to pursue the three Rs and promote alternative research. The KKE supports training courses for persons planning or carrying out experiments in programmes that incorporate this topic. Such information is also provided to local ethics committees on animal experiments (during annual training courses, via the KKE's website and through direct contact). Organisations' welfare teams also use the KKE'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 the specific experiment concerned. To this end, the model application form for authorisation contains a specific field in which the user must enter the method of applying the three Rs in the experiment concerned. In 2018 an additional obligation was added to the application form, as a reminder that procedures must not be carried out, or must be terminated immediately, if alternative methods to the procedures set out in the application are approved in the European Union during the period in which the Committee's authorisation is valid. In 2017, the KKE also took the initiative to set up a cooperation network between organisations and authorities involved in the application of alternative methods.

Furthermore, welfare teams monitor how the three Rs principle is applied. Their activities are monitored by the KKE, 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 purposes, 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 procedures required by law as part of its routine manufacturing process, employs tests not included in the list provided in the report (APIs). This user tests herbal medicinal products.

In 2019, the animal species included in the 'other' category that accounted for over 10% of a given group, were:

- 'Other' species of carnivore (other *Carnivora*): *Neovison vison, Canis lupus.* These species account for 73.42% of all species of carnivore and are used in translational or applied research into animal welfare and research into the protection of the natural environment in the interests of the health or welfare of human beings and animals.

- 'Other' species of mammal (other *Mammalia*): *Nyctalus noctula, Vespertilio murinus, Myotis alcathoe, Myotis brandtii, Myotis mystacinus, Monodelphis domestica, Crocidura suaveolens.* These species account for 18.07% of all species of mammal and are used in basic research into the cardiovascular blood and lymphatic system, the nervous system, multi-systems, ethology/animal behaviour/animal biology, and the determination of differences between species in terms of foraging traits. They are also used in translational or applied research into animal welfare and research aimed at species preservation.

- 'Other' species of bird (other *Aves*): *Calidris pugnax, Gallinago, Calidris ferruginea, Calidris falcinellus, Calidris canutus, Calidris alpine, Haliaeetus albicilla, Ciconia, Actitis hypoleucos, Sylvia borin, Lanius collurio, Columba livia domestica, Meleagris gallopavo var. Domesticus, Arenaria interpres, Sylvia atricapilla, Turdus merula, Corvus corax, Tringa tetanus, Anas platyrhynchos, Tringa nebularia, Cygnus olor, Tringa glareola, Fulica atra, Larus cachinnans, Ichthyaetus melanocephalus, Chroicocephalus ridibundus, hybrids Chroicocephalus*

ridibundus x Ichthyaetus melanocephalus, Ficedula hypoleuca, Calidris alba, Motacilla alba, Motacilla flava, Coturnix japonica, Acrocephalus schoenobaenus, Erithacus rubecula, Chlidonias hybrid, Sterna hirundo, Tringa ochropus, Parus major, Cyanistes caeruleus, Charadrius hiaticula, Charadrius dubius, Acrocephalus scirpaceus, Passer domesticus, Acrocephalus paludicola. These species account for 51.77% of all species of bird used in research. They are mainly used in basic research into the immune system, multi-systems, ethology/animal behaviour/animal biology, ecology, determination of differences between species in terms of foraging traits, and differentiation of blood parasites. In addition, these species are used in research aimed at species preservation. They are also used in manufacturing, including of medicinal products, APIs and herbal starting material, and in regulatory testing, i.e. quality control, in particular batch safety and potency testing, ecotoxicity and acute toxicity.

- 'Other' species of fish (other *Pisces*): *Neogobius melanostomus, Cottus gobio, Poecilia reticulata, Pundamilia nyererei, Acipenser baerii*, *Carassius gibelio, Carassius auratus, Cyprinus carpio, hybrids Cobitis, Cobitis taenia, Perca fluviatilis, Misgurnus fossilis, Oncorhynchus mykiss, Copadichromis borleyi, Sander lucioperca, Anguilla anguill*. These species account for 24.38% of all fish species used in research. They are mainly used in basic research into the immune system, multi-systems, ethology/animal behaviour/animal biology and nano-ecotoxicology. They are also used in translational and applied research into animal welfare and regulatory testing in relation to quality control, in particular batch safety and potency testing, ecotoxicity and acute toxicity.

  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, Bufo bufo*. These species account for 100% of all amphibian species used in research. They are exclusively used in basic research into 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.

No such cases were found.

Poland: Statistical Data 2019

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	148214	52.61%
Rats	46668	16.57%
Guinea-Pigs	11802	4.19%
Hamsters (Syrian)	242	0.09%
Mongolian gerbil	320	0.11%
Other rodents	10972	3.89%

Rabbits	2108	0.75%
Cats	24	0.01%
Dogs	18	0.01%
Other carnivores	116	0.04%
Pigs	2068	0.73%
Sheep	774	0.27%
Cattle	280	0.1%
Other mammals	1020	0.36%
Domestic fowl	12550	4.45%
Other birds	13470	4.78%
Reptiles	80	0.03%
Other amphibians	736	0.26%
Zebra fish	22866	8.12%
Other fish	7394	2.62%
Total	281722	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	249278	88.48%
Animals born in the EU but not at a registered breeder	30692	10.89%
Animals born in rest of world	1752	0.62%
Total	281722	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	148214	42	148256
Rats	46668	288	46956
Guinea-Pigs	11802		11802
Hamsters (Syrian)	242		242
Mongolian gerbil	320		320
Other rodents	10972		10972
Rabbits	2108	336	2444
Cats	24		24
Dogs	18	4	22
Other carnivores	116		116
Horses, donkeys and cross-breeds		42	42
Pigs	2068	4	2072
Goats		26	26
Sheep	774	132	906
Cattle	280	10	290
Other mammals	1020	120	1140
Domestic fowl	12550		12550
Other birds	13470	110	13580
Reptiles	80		80
Other amphibians	736		736
Zebra fish	22866		22866
Other fish	7394		7394
Total	281722	1114	282836

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	207170	73.25%
Translational and applied research	27874	9.86%
Regulatory use and Routine production	44728	15.81%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	60	0.02%
Preservation of species	496	0.18%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2508	0.89%
Total	282836	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	20252	9.78%
Cardiovascular Blood and Lymphatic System	8540	4.12%
Nervous System	107304	51.8%
Respiratory System	478	0.23%
Gastrointestinal System including Liver	7458	3.6%
Musculoskeletal System	1270	0.61%
Immune System	15184	7.33%
Urogenital/Reproductive System	3256	1.57%
Sensory Organs (skin, eyes and ears)	900	0.43%

Endocrine System/Metabolism	3030	1.46%
Multisystemic	8662	4.18%
Ethology / Animal Behaviour /Animal Biology	22856	11.03%
Other basic research	7980	3.85%
Total	207170	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	10880	39.03%
Human Infectious Disorders	30	0.11%
Human Cardiovascular Disorders	866	3.11%
Human Nervous and Mental Disorders	488	1.75%
Human Respiratory Disorders	948	3.4%
Human Gastrointestinal Disorders including Liver	908	3.26%
Human Musculoskeletal Disorders	376	1.35%
Human Immune Disorders	470	1.69%
Human Urogenital/Reproductive Disorders	198	0.71%
Human Sensory Organ Disorders (skin, eyes and ears)	26	0.09%
Human Endocrine/Metabolism Disorders	574	2.06%
Other Human Disorders	80	0.29%
Animal Diseases and Disorders	378	1.36%
Animal Welfare	8362	30%
Diagnosis of diseases	2954	10.6%
Non-regulatory toxicology and ecotoxicology	336	1.21%
Total	27874	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	33648	75.23%
Other efficacy and tolerance testing	130	0.29%
Toxicity and other safety testing including pharmacology	9072	20.28%
Routine production	1878	4.2%
Total	44728	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	7522	22.35%
Pyrogenicity testing	450	1.34%
Batch potency testing	25468	75.69%
Other quality controls	208	0.62%
Total	33648	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	1192	13.14%
Skin irritation/corrosion	470	5.18%
Skin sensitisation	2968	32.72%
Eye irritation/corrosion	12	0.13%
Repeated dose toxicity	560	6.17%
Carcinogenicity	120	1.32%
Kinetics	708	7.8%
Pharmaco-dynamics (incl safety pharmacology)	80	0.88%
Ecotoxicity	2256	24.87%
Safety testing in food and feed area	526	5.8%
Other toxicity/safety testing	180	1.98%
Total	9072	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	104	8.72%
Other lethal methods	124	10.4%
Non lethal methods	964	80.87%
Total	1192	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	200	35.71%
> 90 days	360	64.29%
Total	560	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	2130	94.41%
Chronic toxicity	126	5.59%
Total	2256	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	32240	75.24%
Legislation on medicinal products for veterinary use and their residues	3080	7.19%
Medical devices legislation	4864	11.35%
Industrial chemicals legislation	380	0.89%
Plant protection product legislation	1618	3.78%
Food legislation including food contact material	284	0.66%
Feed legislation including legislation for the safety of target animals, workers and environment	384	0.9%
Total	42850	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	41596	97.07%
Legislation satisfying national requirements only [within EU]	1100	2.57%
Legislation satisfying Non-EU requirements only	154	0.36%
Total	42850	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	120	6.39%
Monoclonal antibody by mouse ascites method	8	0.43%
Other product types	1750	93.18%
Total	1878	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	281722	99.61%
Yes	1114	0.39%
Total	282836	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	13354	4.72%
Mild [up to and including]	59806	21.15%
Moderate	126050	44.57%
Severe	83626	29.57%
Total	282836	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	265970	94.04%
Genetically altered without a harmful phenotype	12930	4.57%
Genetically altered with a harmful phenotype	3936	1.39%
Total	282836	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	404		404
Other mammals	12		12
Zebra fish	72		72
Total	488		488

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

Severity	Number of uses	Percentage
Non-recovery	8	1.64%
Mild [up to and including]	76	15.57%
Moderate	404	82.79%
Total	488	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	158	32.38%
Genetically altered without a harmful phenotype	330	67.62%
Total	488	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	40	8.2%
Nervous System	412	84.43%
Urogenital/Reproductive System	24	4.92%
Multisystemic	12	2.46%
Total	488	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	810		810
Total	810		810

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

Severity	Number of uses	Percentage
Mild [up to and including]	516	63.7%
Moderate	294	36.3%
Total	810	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	90	11.11%
Genetically altered with a harmful phenotype	720	88.89%

Total	810	100.00%

Portugal

Portugal: Narrative 2019

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

In 2019 there was a slight decrease in animal use compared to the previous year (2018). The total number of animals used in 2019 is 79447, which constitutes a 2,09% decrease in animal use, compared to 2018 (total uses: 81107).

Mice continue to be the most used animal species (68,44%), followed by the entry Other fish (15,26%), Rats (7,90%) and Zebra fish (7,06%).

There is a slight increase in the use of Fish (22,32%) compared to 2018 (19,95%) and the use of Mammals dropped 3,11%.

All animal species used in 2019 showed a decrease compared to 2018, except Rats, Rabbits, Pigs, Other birds, Xenopus and Zebra fish that increased. Cephalopods were not used in 2019.

There was an increase on reuse (total reuses: 2026) compared to the previous year (total reuses: 300).

Compared to the previous year, there was a decrease of 4,31% in the use of animals in Basic research and an obvious decrease of 16,72% in the Maintenance of colonies of established genetically altered animals not used in other procedures.

Instead, there was an increase in the use of animals in Translational and applied research, Protection of the natural environment in the interests of the health or welfare of human beings or animals, Preservation of species and Higher education or training for the acquisition, maintenance or improvement of vocational skills.

The use of animals for Regulatory and Routine prodution only represent 0,56% of all uses.

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

The decrease in animal numbers in 2019 is mainly due to an obvious decrease in the Maintenance of colonies of established genetically altered animals, not used in other procedures.

Basic Research continues to represent the majority of all uses (60,42%), followed by Translational and applied research (30,76%), the Protection of the natural environment in the interests of the health or welfare of human beings or animals (3,72%) and Maintenance of colonies of established genetically altered animals, not used in other procedures (3,27%).

The increase in Translational and applied research in 2019 is mainly due to the increase of studies in Human Cancer, Human Infectious Disorders, Human Nervous and Mental Disorders, Human Endocrine/Metabolism Disorders and Animal Welfare.

The increase in the use of Other birds is due to the increase of studies in the Preservation of species (86,97% of all the uses of Other birds) and in Basic research (13,03% of the all uses of Other birds) in the area of Ethology/Animal Behaviour/Animal Biology.

In 2019, Other fish continue to be the second most used animal entry, as in 2018, representing (15,26% of all uses), which is mainly due to studies in the areas of Protection of the Natural environment in the interests of the health or human beings or animals and in Basic and Translational research in the areas of Ethology/Animal Behaviour/Animal Biology and Immune System, Animal Welfare and Nutrition to support the field of Aquaculture.

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

In 2019, the percentages reported for each of the categories of actual severities experienced by the animals were as follows:

- Non-recovery: 3,56%
- Mild: 50,50%
- Moderate: 31,79%
- Severe: 14,15%

The category Mild continues to be the most reported category of severy experienced by animals.

Despite that, compared to the previous year, there was an increase of 12,81% in Moderate procedures and an increase of 4,25% in Severe procedures which is mainly due to the performance of procedures in the areas of Oncology and Immune and Nervous Systems.

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 reflexion on the statistics, somehow, we think it is the case.

The promotion and the implementation of the 3Rs is always present in all the evaluation and 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 2019, the further breakdown on the use of "other" categories is as follows:

On **Animal species**:

- **Other birds** include:
    - Pigeons (*Columba livia*)
    - *Actitis hypoleucus*
    - *Arenaria interpres*
    - *Calidris 294etanu*
    - *Calidris canutus*
    - *Calidris ferruginea*
    - *Charadrius hiaticula*
    - *Limosa laponica*
    - *Numenius phaeopus*
    - *Pluvialis squatarola*
    - *Tringa 294etanus*
- **Other fish** include:
    - Gilthead Sea bream (*Sparus aurata*)
    - Killifish (*Fundulus heteroclitus*)
    - Sea bass (*Dicentrarchus labrax*)
    - *Argyrosomus regius*
    - *Dasyatis pastinaca*
    - *Luciobarbus bocagei*
    - *Myliobatis aquila*
    - *Oreochromis niloticus*
    - *Pseudochondrostoma duriense*
    - P*seudochondrostoma polylepis*
    - *Raja clavata*
    - R*ostroraja alba*
    - *Solea senegalensis*
    - *Squalius alburnoides*
    - *Squalius carolitertii*
    - *Taurulus bubalis*
- **Other mammals** include *Balaenoptera edeni*
- **Other rodents** include *Acomys cahirinus*

On **Purpose**:

- **Other Basic Research** include:
    - Protein biogenesis
    - Embryonic development

- Vector maintenance
- Brain blood barrier translocation
- Bacterial ecosystems
- Cryopreservation
- Stem cell biology

- **Other Translational and Applied Research** include:

  - Malaria
  - Schistosomose
  - Genetic diseases
  - Trypanosomose

- **Other Regulatory use and Routine production** include:

  - Policlonal antibody production

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 2019

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	50555	68.94%
Rats	6273	8.55%
Other rodents	7	0.01%
Rabbits	84	0.11%
Pigs	208	0.28%
Other mammals	3	0%
Other birds	367	0.5%
Xenopus	200	0.27%
Zebra fish	4862	6.63%
Other fish	10775	14.69%
Total	73334	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	66443	90.6%
Animals born in the EU but not at a registered breeder	6578	8.97%
Animals born in rest of Europe	310	0.42%
Animals born in rest of world	3	0%
Total	73334	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	50555	34	50589
Rats	6273	6	6279
Other rodents	7		7
Rabbits	84		84
Pigs	208		208
Goats		84	84
Other mammals	3		3
Other birds	367	55	422
Xenopus	200	47	247
Zebra fish	4862	450	5312
Other fish	10775	1350	12125
Total	73334	2026	75360

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	47086	62.48%
Translational and applied research	23868	31.67%
Regulatory use and Routine production	443	0.59%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2959	3.93%
Preservation of species	382	0.51%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	622	0.83%
Total	75360	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6799	14.44%
Cardiovascular Blood and Lymphatic System	2202	4.68%
Nervous System	8018	17.03%
Respiratory System	297	0.63%
Gastrointestinal System including Liver	530	1.13%
Musculoskeletal System	655	1.39%
Immune System	18313	38.89%
Urogenital/Reproductive System	102	0.22%
Sensory Organs (skin, eyes and ears)	186	0.4%
Endocrine System/Metabolism	1184	2.51%
Multisystemic	1736	3.69%
Ethology / Animal Behaviour /Animal Biology	5888	12.5%
Other basic research	1176	2.5%
Total	47086	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	2757	11.55%
Human Infectious Disorders	11598	48.59%
Human Cardiovascular Disorders	874	3.66%

Human Nervous and Mental Disorders	4863	20.37%
Human Respiratory Disorders	350	1.47%
Human Musculoskeletal Disorders	166	0.7%
Human Immune Disorders	5	0.02%
Human Urogenital/Reproductive Disorders	105	0.44%
Human Sensory Organ Disorders (skin, eyes and ears)	352	1.47%
Human Endocrine/Metabolism Disorders	767	3.21%
Other Human Disorders	310	1.3%
Animal Diseases and Disorders	6	0.03%
Animal Welfare	1244	5.21%
Diagnosis of diseases	71	0.3%
Non-regulatory toxicology and ecotoxicology	400	1.68%
Total	23868	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	359	81.04%
Routine production	84	18.96%
Total	443	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	212	59.05%
Safety testing in food and feed area	147	40.95%
Total	359	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	212	59.05%
Food legislation including food contact material	147	40.95%
Total	359	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	359	100%
Total	359	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	84	100%
Total	84	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	73334	97.31%
Yes	2026	2.69%
Total	75360	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	2826	3.75%
Mild [up to and including]	36574	48.53%
Moderate	24790	32.9%
Severe	11170	14.82%
Total	75360	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	50771	67.37%
Genetically altered without a harmful phenotype	18398	24.41%
Genetically altered with a harmful phenotype	6191	8.22%
Total	75360	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	1217		1217
Zebra fish	269		269
Total	1486		1486

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

Severity	Number of uses	Percentage
Mild [up to and including]	1185	79.74%
Moderate	229	15.41%
Severe	72	4.85%
Total	1486	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	648	43.61%
Genetically altered without a harmful phenotype	663	44.62%
Genetically altered with a harmful phenotype	175	11.78%
Total	1486	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	6	0.65%
Cardiovascular Blood and Lymphatic System	115	12.51%
Nervous System	282	30.69%
Immune System	284	30.9%
Other basic research	232	25.24%
Total	919	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 Infectious Disorders	48	8.47%
Human Nervous and Mental Disorders	404	71.25%
Human Endocrine/Metabolism Disorders	75	13.23%
Other Human Disorders	40	7.05%
Total	567	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	2571		2571
Zebra fish	30		30
Total	2601		2601

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

Severity	Number of uses	Percentage
Mild [up to and including]	2365	90.93%
Moderate	236	9.07%
Total	2601	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	1935	74.39%
Genetically altered with a harmful phenotype	666	25.61%
Total	2601	100.00%

Romania

Romania: Narrative 2019

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

Since the previous reporting year, there was a slight increase in the number of animals used for scientific purposes, from 12195 in 2018 to 13635 in 2019.

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

No animals were used either in projects with the purpose of basic research – gastrointestinal system including liver and respiratory system, or in projects with the purpose of trans./appl. Research – animal diseases and disorders. Other significant drop was seen in pyrogenicity testing within regulatory use/ quality control due to a smaller amount of tests performed for countries using the Russian Pharmacopoeia. On the other hand, there was a significant increase in musculoskeletal system research.

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

There was in increase in the number of animals used in projects classified as severe due to the rise of tests performed with the purpose of oncology within basic research.

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

In order to lower the number of animals used in projects, certain tests were preceded by in vitro studies. The number of animals in the groups were kept to a minimum so as to provide reliable statistical results.

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 2019

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	7481	56.28%
Rats	4551	34.24%
Guinea-Pigs	332	2.5%
Hamsters (Syrian)	50	0.38%
Rabbits	264	1.99%
Pigs	39	0.29%
Sheep	107	0.8%
Domestic fowl	228	1.72%
Rana	240	1.81%
Total	13292	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	13231	99.54%
Animals born in the EU but not at a registered breeder	61	0.46%
Total	13292	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	7481	100	7581
Rats	4551	20	4571
Guinea-Pigs	332		332
Hamsters (Syrian)	50		50
Rabbits	264		264
Horses, donkeys and cross-breeds		2	2
Pigs	39		39
Sheep	107	139	246
Cattle		2	2
Domestic fowl	228	55	283
Other birds		6	6
Rana	240		240
Total	13292	324	13616

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	4741	34.82%
Translational and applied research	5915	43.44%
Regulatory use and Routine production	2067	15.18%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	893	6.56%
Total	13616	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1060	22.36%
Cardiovascular Blood and Lymphatic System	330	6.96%
Nervous System	554	11.69%
Musculoskeletal System	212	4.47%
Immune System	262	5.53%
Urogenital/Reproductive System	84	1.77%
Sensory Organs (skin, eyes and ears)	268	5.65%
Endocrine System/Metabolism	325	6.86%
Multisystemic	1528	32.23%
Ethology / Animal Behaviour /Animal Biology	50	1.05%
Other basic research	68	1.43%
Total	4741	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	259	4.38%
Human Infectious Disorders	78	1.32%
Human Cardiovascular Disorders	1087	18.38%
Human Nervous and Mental Disorders	50	0.85%
Human Gastrointestinal Disorders including Liver	90	1.52%
Human Musculoskeletal Disorders	235	3.97%
Human Immune Disorders	512	8.66%

Human Urogenital/Reproductive Disorders	80	1.35%
Human Sensory Organ Disorders (skin, eyes and ears)	20	0.34%
Human Endocrine/Metabolism Disorders	147	2.49%
Other Human Disorders	74	1.25%
Diagnosis of diseases	2385	40.32%
Non-regulatory toxicology and ecotoxicology	898	15.18%
Total	5915	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1540	74.5%
Toxicity and other safety testing including pharmacology	242	11.71%
Routine production	285	13.79%
Total	2067	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	777	50.45%
Pyrogenicity testing	30	1.95%
Batch potency testing	703	45.65%
Other quality controls	30	1.95%
Total	1540	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	13	5.37%
Skin sensitisation	16	6.61%
Safety testing in food and feed area	213	88.02%
Total	242	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	13	100%
Total	13	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	728	40.85%
Legislation on medicinal products for veterinary use and their residues	841	47.19%
Food legislation including food contact material	213	11.95%
Total	1782	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1131	63.47%
Legislation satisfying Non-EU requirements only	651	36.53%

Total	1782	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	285	100%
Total	285	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	13292	97.62%
Yes	324	2.38%
Total	13616	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	2287	16.8%
Mild [up to and including]	4630	34%
Moderate	5644	41.45%
Severe	1055	7.75%
Total	13616	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	13113	96.31%
Genetically altered without a harmful phenotype	433	3.18%
Genetically altered with a harmful phenotype	70	0.51%
Total	13616	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	19		19
Total	19		19

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

Severity	Number of uses	Percentage
Moderate	19	100%
Total	19	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	19	100%
Total	19	100.00%

Slovakia

Slovakia: Narrative 2019

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

In 2019, almost 700 more animals were used in compariuson with 2018. This is not a significant increase. Approval was renewed for only one user establishment upon his request. Increase in the number of animals used in the projects is related to the fact that the number of establishments carrying out regulated projects has increased by 2 establishments from the original 2 establishments. In 2019, the projects approved for a period of 5 years in 2014 were completed, in which up to 129 projects were approved. /. /The number of animals used in regulated projects carried out to control effectiveness and safety of chemicals and medicines has increased. Several orders for performance of these projects were from the foreign sponsors. In the Slovak Republic, most animals are used in the field of the basic research, the number of which makes up to 64.60% of the total number of animals used in the projects.

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

One approved user establishment included 28 sheep in the approved projects that were not used in 2018. Compared to 2018, no pigs were used but the number of laboratory used mice increased from 40.85% of the total amount to 47.25%. The number of used laboratory rats decreased from the original representation of 51.94% of the total number to 46.56% of the total number. The number of used guinea pigs decreased by 145, as the type of research where the guinea pigs were used decreased. The number of animals used in the regulated projects has increased, specifically in the area of Batsch potency testing in which the number of used animals in total is 41% compared to 18.50% in 2018. /

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

Compared to 2019, the number of projects classified as “mild” decreased to 18.62% of the total number to compared to 2018, when the projects with mild severity used 21.46% of the total number of used animals. At the same time, the percentage of animals used in the projects classified as “moderate” severity increased, which makes up 73.02% of the total number, compared to 2018. As follows from the above, the highest proportion of animals used in the projects experienced a “medium” severity. The proportion of animals with classified “severe” severity has decreased to 5.22% compared to 7.82% in 2018. We have implemented system of control of compliance with 3R principles, description of human end point, based on which few animals experience “severe” severity in the project. Applicants for project approvals modify the projects so that the procedures with classification “severe” severity do not have to be performed. Or minimum of animals will be used in this procedure.

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

Observance of 3R Principles within the use of animals is a legal obligation, as well as the description of compliance with the individual 3R steps in the implementation of the project. Great attention is given to the element of human point what reduces the number of animals that have experienced "severe" severity what has manifested also statistically. Great attention is also paid to 3R principles their observance, analgesia and human end point in the trainings, retrainings of the staff performing functions according to Article 22 and 23 of the Directive.

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

For implementation of the projects in SK, the species for which it is not necessary to fill in category "other" are used. Only one approved establishment uses songbirds, "other" Taeniopygia guttata a Lonchura striata domestica, which is required by the purpose and the objective of the project.

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.

For 2019, in SK no cases of exceeding of classified severity in the project were reported or detected. It is not possible for this case to occur at all. Several projects classified as "severe" have the real severity classified as "moderate" or "mild" according to the retrospective assessment. All projects are approved by the decision in which the exact procedure of performance of the project and classification of severity of each procedure performed on the animals and its consequences are described. If the project is carried out outside the approved procedure without the user requesting a change in the decision approving the project, the user would be punished by the financial penalty, cancellation of the project or other coersive means/sanctions according to the type of violation of the law.

Slovakia: Statistical Data 2019

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	8272	46.19%
Rats	8517	47.56%
Guinea-Pigs	607	3.39%
Mongolian gerbil	12	0.07%
Rabbits	178	0.99%
Cats	13	0.07%
Sheep	28	0.16%
Domestic fowl	249	1.39%
Other birds	31	0.17%
Total	17907	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	17907	100%
Total	17907	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	8272		8272
Rats	8517		8517
Guinea-Pigs	607		607
Mongolian gerbil	12		12
Rabbits	178	12	190
Cats	13		13
Sheep	28		28
Domestic fowl	249		249
Other birds	31		31
Total	17907	12	17919

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	13000	72.55%
Translational and applied research	509	2.84%
Regulatory use and Routine production	4365	24.36%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	45	0.25%
Total	17919	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	707	5.44%
Cardiovascular Blood and Lymphatic System	1068	8.22%
Nervous System	6012	46.25%
Respiratory System	511	3.93%
Gastrointestinal System including Liver	438	3.37%
Musculoskeletal System	160	1.23%
Immune System	563	4.33%
Urogenital/Reproductive System	1816	13.97%
Endocrine System/Metabolism	586	4.51%
Ethology / Animal Behaviour /Animal Biology	415	3.19%
Other basic research	724	5.57%
Total	13000	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	42	8.25%
Human Cardiovascular Disorders	10	1.96%
Human Respiratory Disorders	10	1.96%
Human Musculoskeletal Disorders	35	6.88%
Human Immune Disorders	16	3.14%
Human Urogenital/Reproductive Disorders	150	29.47%
Human Sensory Organ Disorders (skin, eyes and ears)	34	6.68%
Other Human Disorders	80	15.72%
Animal Diseases and Disorders	132	25.93%
Total	509	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	600	13.75%
Toxicity and other safety testing including pharmacology	3732	85.5%
Routine production	33	0.76%
Total	4365	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	354	59%
Batch potency testing	246	41%
Total	600	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	238	6.38%
Skin sensitisation	535	14.34%
Reproductive toxicity	2935	78.64%
Target animal safety	24	0.64%
Total	3732	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	238	100%
Total	238	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	378	8.73%
Legislation on medicinal products for veterinary use and their residues	246	5.68%
Medical devices legislation	25	0.58%
Industrial chemicals legislation	3683	85.02%
Total	4332	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	4332	100%
Total	4332	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	33	100%
Total	33	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	17907	99.93%
Yes	12	0.07%
Total	17919	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	573	3.2%
Mild [up to and including]	2921	16.3%
Moderate	13473	75.19%
Severe	952	5.31%
Total	17919	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	16858	94.08%
Genetically altered without a harmful phenotype	361	2.01%
Genetically altered with a harmful phenotype	700	3.91%
Total	17919	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	353		353
Rats	125		125
Total	478		478

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

Severity	Number of uses	Percentage
Mild [up to and including]	478	100%
Total	478	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	260	54.39%
Genetically altered without a harmful phenotype	98	20.5%
Genetically altered with a harmful phenotype	120	25.1%
Total	478	100.00%

Slovenia

Slovenia: Narrative 2019

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

In 2019, 5.317 animals were used for scientific purposes. More than 93% of all used animals are rodents (mice and rats) and rabbits. Mice is the most commonly used species (approx. 93%). Other species used are pigs, sheep, horses, poultry and fish. No cats, dogs and non-human primates were used for scientific purposes in 2019.

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

Approx. 2.900 animals (94% of them were rodents) was used in basic and translational and applied research, for the purpose of oncology, endocrine, immune and gastrointestinal system including liver and diagnostic of diseases. Among that, the majority of animals was used for the purpose of oncology, which represents almost 34%. Further on, 80 mice was used for the purpose of preservation of species – fat and slim line of mice. 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.

In the field of regulatory use and routine production, approx. 2.300 animals (mainly mice and some rabbits) were used, which is a little higher than in 2018. Animals were used for the purpose of quality control, including batch safety and potency testing.

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

Majority of procedures was classified as mild (over 88%), around 9% were moderate and around 1% severe or non-recovery.

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, regular meetings with animal welfare officers, different workshops.

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 2019. 55 fish (Rainbow trout) were used for the purpose of higher education.

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.

“Severe” classification was never exceeded.

Slovenia: Statistical Data 2019

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	4179	92.87%
Rats	91	2.02%
Pigs	8	0.18%
Sheep	40	0.89%
Domestic fowl	127	2.82%
Other fish	55	1.22%
Total	4500	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	4500	100%
Total	4500	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	4179	753	4932
Rats	91	3	94
Rabbits		51	51
Horses, donkeys and cross-breeds		2	2
Pigs	8		8
Sheep	40	2	42
Domestic fowl	127		127
Other fish	55		55
Total	4500	811	5311

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	770	14.5%
Translational and applied research	2128	40.07%
Regulatory use and Routine production	2268	42.7%
Preservation of species	80	1.51%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	65	1.22%
Total	5311	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	261	33.9%
Nervous System	16	2.08%
Gastrointestinal System including Liver	227	29.48%
Musculoskeletal System	14	1.82%
Immune System	113	14.68%
Endocrine System/Metabolism	130	16.88%
Other basic research	9	1.17%
Total	770	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1797	84.45%
Human Nervous and Mental Disorders	30	1.41%
Human Respiratory Disorders	46	2.16%
Human Endocrine/Metabolism Disorders	95	4.46%
Animal Welfare	40	1.88%
Diagnosis of diseases	120	5.64%
Total	2128	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	2268	100%
Total	2268	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	55	2.43%
Pyrogenicity testing	51	2.25%
Batch potency testing	2162	95.33%
Total	2268	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	2268	100%
Total	2268	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2268	100%
Total	2268	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	4500	84.73%
Yes	811	15.27%
Total	5311	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	40	0.75%
Mild [up to and including]	4717	88.82%
Moderate	497	9.36%
Severe	57	1.07%
Total	5311	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	4947	93.15%
Genetically altered without a harmful phenotype	325	6.12%
Genetically altered with a harmful phenotype	39	0.73%
Total	5311	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	6		6
Total	6		6

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

Severity	Number of uses	Percentage
Mild [up to and including]	6	100%
Total	6	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	6	100%
Total	6	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
Human Endocrine/Metabolism Disorders	6	100%
Total	6	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

Spain

Spain: Narrative 2019

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

This information is collected partly by breeders, suppliers or users of animals used for scientific purposes, and partly by the competent authorities in the Autonomous Communities. Information collected at regional level is submitted to Spain's national authorities, which manage the data in order to comply with the reporting requirements under Article 54(2) of Directive 2010/63/EU.

In 2019 the Autonomous Community of Castile and Leon provided information on the use of animals for scientific and teaching purposes for only some users in its territory, making it difficult to compare data from different reporting years. In 2018 Castile and Leon reported the use of some 37 000 animals, whereas in 2019 this figure had dropped to just over 17 000. The further information contained in this document is based on data submitted by the other Autonomous Communities, and comparisons with previous years are made on that basis.

Other factors to consider are the large amount of data to be recorded, the fact that data is collected both by establishments and by regional authorities (whose systems may also involve different levels of communication), a high rate of staff turnover in the relevant posts, and, in particular, difficulties owing to the strict lockdown imposed across Spain as from the month of March.

This year the number of authorised projects increased slightly as there were various calls for project funding in the field of research, development and innovation. The number of animal used is virtually the same as in 2018, however, most likely because the authorised projects are still at an early stage of implementation.

The use of mammals declined considerably, in particular as regards rodents, by around 10%, and primates, by approximately 50%.

With respect to rodents this concerns in particular mice, partly because mice are used less frequently to determine marine biotoxins and botulinum toxin, but mainly because several centres with a high rate of animal use have changed their animal genotyping protocols. In 2019 a number of centres replaced the genotyping technique involving distal tail cutting with a method based on using surplus tissue samples taken for the purpose of identification. This had a significant impact on the figures for animal use, as set out in more detail in Section 2 (Information on any significant increase or decrease in the use of animals in any of the specific areas and analysis of the reasons for this).

The decline in the use of primates is linked to the area of production regulated by the rules on medicinal products for human use in accordance with EU legislation.

The greatest change in numbers concerns the increased use of fish, specifically 'other fish'. Research in this field is often linked to animal populations, using very early forms of development, meaning

that carrying out (or not carrying out) a few projects can lead to considerable fluctuations in numbers. The situation is similar for cephalopods.

Production animals are, to a large extent, used to study animal diseases in the field of applied research (of particular relevance with regard to farmed fish) and to train students of veterinary medicine. This is true in particular of sheep and equine species.

In any case, as in previous years, it needs to be borne in mind when assessing the figures on animal use that projects linked to animal nutrition (involving small production animals such as broilers, laying hens or fish) normally take place under commercial production conditions and therefore using relatively large groups of animals, which significantly inflates the figures.

A single project involving free-living larvae, in research linked to managing the welfare of the common octopus, explains the major increase in the number of cephalopods used.

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

The variations in the **origin of animals** are due to variations in the types of animal used, not to changes in the origin of any particular type of animal.

Thus, since mice and rats are mainly reared in centres registered for the breeding of animals for scientific purposes, a drop in the number of mice and rats used leads to a lower proportion of animals from registered centres (although the rats and mice that are used continue to come from such centres), and increased use of animals that typically come from non-registered centres leads to a higher proportion of animals not reared in registered centres.

As in previous years, most of the hens (85%), fish other than zebrafish (70%) and, this year, cephalopods (95%) used also come from registered centres, and a large number of hens and 'other fish' bred in registered establishments were used in scientific procedures. In these cases, the animals have been bred in the establishment in which they will be used.

It should be noted that under Spanish animal health legislation, establishments are required to register in order to keep animals. This sometimes leads to errors in the reports, since the persons providing the data sometimes understand that animals from establishments that are listed in the health register (even if they do not have a permit to breed animals for scientific procedures) are to be reported as 'animals from registered centres'.

As regards the animals' **genetic status**, the proportion of animals with no genotype change increased in 2019. This data needs to be put into context, as it is linked to the less frequent use of invasive genotyping in mice. As indicated above, in 2019 several centres replaced the genotyping technique involving distal tail cutting with a method based on using surplus tissue samples taken for the purpose of identification. This has had a significant impact on the figures concerning animal use:

1. As genotyping based on surplus tissue samples, the technique currently used (previously obtained by distant tail cutting) is not considered animal use, there is a drop in:
    a. the number of animals used to maintain genetically modified animal lines;
    b. the number of mice used, since this is the species mainly affected.

2. The uses involving distal tail cutting are mostly classified as ‘mild’, so the change towards tissue sampling also proportionally affects the severity experienced by animals in the procedures.
3. There is also an impact on the level of animal re-use. If the animal genotype is not necessary for it to be used in a given procedure, genotyping is considered to be the first use, and any further use in a subsequent procedure is considered re-use. This means that where there is no invasive genotyping, the subsequent procedure becomes ‘first use’ rather than ‘re-use’, leading to a drop in re-use numbers.

With regard to the **purposes** of use, in addition to the almost 50% decline in animals use to maintain colonies of genetically modified animals not used in any other procedure, as mentioned above, there was also a decline in the use of animals for regulatory testing and animal use in higher education or training for the purposes of acquiring, maintaining or improving professional skills. This is linked to the fact that animal replacement strategies are increasingly widely used in these areas.

The most notable increase has been in translational and applied research, both in percentage terms and in absolute figures. Animal diseases and animal welfare are, once again, the most important fields of research (together these account for more than 40% of uses in applied research). As regards human diseases, significant areas of study include cancers (15%) and endocrine and metabolic diseases (11%).

There was also an increase in use for the purpose of researching animal diseases. As in the previous year, this was linked to the interest of various production sectors in improving and becoming more competitive and, above all, to concerns for the health situation of livestock (in Europe and Africa). In particular,25% of the ‘other fish’ used served this purpose.

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

As regards trends in the severity of tests, the downward trend in the proportion of ‘non-recovery’ uses changed, while the proportion of ‘severe’ uses increased slightly. Correctly assessing the severity of tests as actually experienced by the animals is particularly challenging, especially as regards animals other than mammals, as the means of assessment available to users in this respect are very limited.

Various projects linked to chronic pain, pain receptors, uses of new drugs and debilitating diseases were developed in 2019, leading to an increase in the proportion of uses classified as ‘severe’. Monitoring protocols were another focus of these projects, with particular emphasis on end-point criteria.

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

Work has continued along the same lines as in previous years.

General measures:

- appropriate training of staff, including ongoing training to maintain skills;

- stressing the importance of researchers' carrying out preliminary statistical studies in order to determine the number of animals to be used;
- encouraging 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 in the course of their projects to ensure that any changes in the availability of alternatives are duly considered and used as soon as possible;
- the use of animals has been replaced by other techniques in teaching, and is restricted to the minimum necessary for results to be statistically significant in research;
- sampling is restricted to the minimum necessary for results to be statistically significant;
- active promotion of a culture of ethical evaluation, including review by the Ethics Committee of any activities involving animals or animal samples even if they are outside the scope of Directive 2010/63/EU of 22 September 2010;
- emphasis is placed on the literature review requirement to consider possibilities of replacing, reducing and refining and on thorough assessment of the suitability of the sources consulted when the project is evaluated;
- establishing and reviewing standard operating procedures for the use of animals.

With respect to replacement:

- promoting the use of carcasses in teaching and research, coordinating euthanasia procedures where possible to optimise the use of carcasses, or using organs and parts from slaughterhouses, carcasses from butchers/fishmongers, and remains of samples provided for teaching purposes. At universities, carcasses are used before resorting to using live animals;
- promoting alternatives, such as audio-visual methods and the use of artificial biomodels in teaching;
- promoting and verifying the use of prior in vitro testing where procedures allow.

With regard to reduction:

- thorough checking of sample sizes in prior evaluations of projects;
- promoting the use of pilot studies that can help, for example, to select the correct group sample size;
- reducing the sources of variation: procedural conditions, conditions of the animals and environmental conditions;
- recent emphasis on correctly selecting the sex of animals in studies and aiming for balanced inclusion;
- sequencing of procedures with the aim of using fewer animals.

With regard to refinement:

- improving websites by adding information on refining for the most common procedures;
- monitoring of anaesthetic and analgesic techniques in procedures;
- establishing and checking monitoring protocols and end-point criteria (in the evaluation and execution of projects);
- improvements at facilities, e.g. providing thermal blankets for rodents, both for surgery and post-operatively;
- introducing and maintaining environment-enhancing measures;
- in teaching, the practice has begun of establishing individual records to monitor the involvement of animals in teaching, not only for species such as dogs for which it is a

regulatory requirement, but also for equine species used in teaching. This has allowed the use of animals to be standardised across courses and a maximum age to be set for animals used in teaching, together with efforts to find outcomes such as adoption once the teaching procedures have finished.

These measures are developed at the project authorisation and evaluation stages, during inspections and by means of communication between the parties 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’:

The use of other animal species, which already accounted for more than 11% of all uses in Spain in 2018, increased further to 13% in 2019. The majority of uses again involved ‘other fish’, often as part of research linked to animal populations using very early forms of development. This means that very few projects greatly increase the number of uses, while at the same time causing figures to fluctuate significantly from one year to the next. Much of the research carried out on ‘other fish’ aims to gain a better understanding of their biology and factors affecting their well-being in order to improve fish farming conditions.

Moreover, ‘other animal species’ suitable for livestock farming are used in studies of diseases affecting farm animals and how to treat and prevent them (veterinary medicines and vaccines).

Wild species also continue to be used in the category ‘other animal species’. The research conducted was mainly for the purposes of protecting the environment, preserving bio-diversity or studying the biology and ethology of the species in question (wild terrestrial animals such as red squirrel or lynx, birds including various species of eagle, marine mammals, etc.).

- As regards animals ‘used for other purposes’ the following is worth noting:

Uses for basic research, involving palatability studies, nanoparticles in drug delivery, generation of interspecies chimeras and the development of diagnostic imaging systems are highlighted in the 2019 report.

In the area of other applied research and other human diseases, studies have focused mainly on minimising iatrogenic injury and on diseases of genetic origin.

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 2019

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	405895	54.19%
Rats	48495	6.47%
Guinea-Pigs	7975	1.06%
Hamsters (Syrian)	848	0.11%
Other rodents	1279	0.17%
Rabbits	17231	2.3%
Cats	163	0.02%
Dogs	1091	0.15%
Ferrets	96	0.01%
Other carnivores	5	0%
Horses, donkeys and cross-breeds	265	0.04%
Pigs	9403	1.26%
Goats	252	0.03%
Sheep	2118	0.28%
Cattle	528	0.07%
Cynomolgus monkey	172	0.02%
Rhesus monkey	1	0%
Baboons	3	0%
Other mammals	127	0.02%
Domestic fowl	98231	13.12%
Other birds	3200	0.43%
Reptiles	979	0.13%
Xenopus	401	0.05%
Other amphibians	775	0.1%
Zebra fish	32775	4.38%
Other fish	99897	13.34%
Cephalopods	16756	2.24%
Total	748961	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	686468	91.68%
Animals born in the EU but not at a registered breeder	60344	8.06%
Animals born in rest of Europe	328	0.04%
Animals born in rest of world	1645	0.22%
Total	748785	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	3	1.7%
Animals born in Asia	106	60.23%
Animals born in Africa	67	38.07%
Total	176	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	175	99.43%
Self-sustaining colony	1	0.57%
Total	176	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	405895	3000	408895
Rats	48495	41	48536
Guinea-Pigs	7975	141	8116
Hamsters (Syrian)	848		848
Other rodents	1279		1279
Rabbits	17231	3334	20565
Cats	163	379	542
Dogs	1091	372	1463
Ferrets	96		96
Other carnivores	5		5
Horses, donkeys and cross-breeds	265	16	281
Pigs	9403	7	9410
Goats	252	96	348
Sheep	2118	143	2261
Cattle	528	627	1155
Cynomolgus monkey	172	53	225
Rhesus monkey	1		1
Baboons	3		3
Other mammals	127		127
Domestic fowl	98231	21	98252
Other birds	3200		3200
Reptiles	979		979
Xenopus	401		401
Other amphibians	775		775
Zebra fish	32775	220	32995
Other fish	99897	85	99982
Cephalopods	16756		16756
Total	748961	8535	757496

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	359689	47.48%
Translational and applied research	283257	37.39%
Regulatory use and Routine production	97536	12.88%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	6296	0.83%
Preservation of species	1043	0.14%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	9675	1.28%
Total	757496	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	54152	15.06%
Cardiovascular Blood and Lymphatic System	29357	8.16%
Nervous System	75099	20.88%
Respiratory System	4177	1.16%

Gastrointestinal System including Liver	9533	2.65%
Musculoskeletal System	6107	1.7%
Immune System	23599	6.56%
Urogenital/Reproductive System	5124	1.42%
Sensory Organs (skin, eyes and ears)	4528	1.26%
Endocrine System/Metabolism	21434	5.96%
Multisystemic	35547	9.88%
Ethology / Animal Behaviour /Animal Biology	90465	25.15%
Other basic research	567	0.16%
Total	359689	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	43097	15.21%
Human Infectious Disorders	15009	5.3%
Human Cardiovascular Disorders	7958	2.81%
Human Nervous and Mental Disorders	28851	10.19%
Human Respiratory Disorders	2218	0.78%
Human Gastrointestinal Disorders including Liver	7156	2.53%
Human Musculoskeletal Disorders	4142	1.46%
Human Immune Disorders	7571	2.67%
Human Urogenital/Reproductive Disorders	2333	0.82%
Human Sensory Organ Disorders (skin, eyes and ears)	12108	4.27%
Human Endocrine/Metabolism Disorders	28365	10.01%
Other Human Disorders	382	0.13%
Animal Diseases and Disorders	60238	21.27%
Animal Welfare	54316	19.18%
Diagnosis of diseases	1333	0.47%
Plant diseases	5	0%
Non-regulatory toxicology and ecotoxicology	8175	2.89%
Total	283257	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	66519	68.2%
Other efficacy and tolerance testing	1881	1.93%
Toxicity and other safety testing including pharmacology	28266	28.98%
Routine production	870	0.89%
Total	97536	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	18595	27.95%
Pyrogenicity testing	8827	13.27%
Batch potency testing	39073	58.74%
Other quality controls	24	0.04%
Total	66519	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	4228	14.96%
Skin irritation/corrosion	142	0.5%
Skin sensitisation	895	3.17%
Repeated dose toxicity	5092	18.01%
Developmental toxicity	346	1.22%
Neurotoxicity	180	0.64%
Kinetics	1793	6.34%

Pharmaco-dynamics (incl safety pharmacology)	35	0.12%
Ecotoxicity	14	0.05%
Safety testing in food and feed area	15333	54.25%
Target animal safety	164	0.58%
Other toxicity/safety testing	44	0.16%
Total	28266	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	3000	70.96%
Other lethal methods	40	0.95%
Non lethal methods	1188	28.1%
Total	4228	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	2299	45.15%
29 - 90 days	2246	44.11%
> 90 days	547	10.74%
Total	5092	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	8	57.14%
Bioaccumulation	6	42.86%
Total	14	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	30467	31.52%
Legislation on medicinal products for veterinary use and their residues	49646	51.36%
Medical devices legislation	660	0.68%
Industrial chemicals legislation	309	0.32%
Plant protection product legislation	252	0.26%
Biocides legislation	6	0.01%
Food legislation including food contact material	14861	15.37%
Feed legislation including legislation for the safety of target animals, workers and environment	450	0.47%
Other legislation	15	0.02%
Total	96666	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	85525	88.47%
Legislation satisfying national requirements only [within EU]	6141	6.35%
Legislation satisfying Non-EU requirements only	5000	5.17%
Total	96666	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	678	77.93%
Monoclonal antibody by mouse ascites method	119	13.68%
Other product types	73	8.39%

Total	870	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	748961	98.87%
Yes	8535	1.13%
Total	757496	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	57865	7.64%
Mild [up to and including]	359402	47.45%
Moderate	280110	36.98%
Severe	60119	7.94%
Total	757496	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	527796	69.68%
Genetically altered without a harmful phenotype	201880	26.65%
Genetically altered with a harmful phenotype	27820	3.67%
Total	757496	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	20676	35	20711
Rabbits	21		21
Zebra fish	4097		4097
Other fish	861		861
Total	25655	35	25690

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

Severity	Number of uses	Percentage
Non-recovery	1956	7.61%
Mild [up to and including]	15681	61.04%
Moderate	7736	30.11%
Severe	317	1.23%
Total	25690	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	7624	29.68%
Genetically altered without a harmful phenotype	14885	57.94%
Genetically altered with a harmful phenotype	3181	12.38%
Total	25690	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	4608	19.97%
Cardiovascular Blood and Lymphatic System	1934	8.38%
Nervous System	2923	12.67%
Respiratory System	5	0.02%
Gastrointestinal System including Liver	60	0.26%
Musculoskeletal System	468	2.03%
Immune System	12	0.05%
Urogenital/Reproductive System	1058	4.59%
Sensory Organs (skin, eyes and ears)	4474	19.39%
Endocrine System/Metabolism	492	2.13%
Multisystemic	7035	30.5%
Total	23069	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	210	8.01%
Human Cardiovascular Disorders	17	0.65%
Human Nervous and Mental Disorders	60	2.29%
Human Gastrointestinal Disorders including Liver	306	11.67%
Human Immune Disorders	42	1.6%
Human Endocrine/Metabolism Disorders	1736	66.23%
Animal Diseases and Disorders	250	9.54%
Total	2621	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	31155		31155
Zebra fish	3401		3401
Total	34556		34556

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

Severity	Number of uses	Percentage
Mild [up to and including]	25442	73.63%
Moderate	8899	25.75%
Severe	215	0.62%
Total	34556	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	1020	2.95%
Genetically altered without a harmful phenotype	8313	24.06%
Genetically altered with a harmful phenotype	25223	72.99%
Total	34556	100.00%

Sweden

Sweden: Narrative 2019

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 2019 (260,525 uses) compared to 2018 (274,472 uses) and 2017 (324,771 uses).

Genetic status

The use of genetically altered animals with a harmful phenotype decreased 2019 (25,959 uses) compared to 2018 (27,341 uses); but were proportionally similar (10%). The corresponding use for 2017 was 36,929 uses (11%).

Place of birth

Uses with animals born in the EU but not at a registered breeder was higher in 2019 (32,759 uses) compared to 2018 (29,671 uses), but lower than 2017 (64,675 uses). Much fewer of the animal uses in 2019 were with animals born in the rest of Europe (148 uses) compared to 2018 (15,975 uses) and 2017 (1,608 uses). The 1,361 uses on animals born in the rest of the world is lower than 2018 (2,077) and 2017 (2,714 uses).

Non-human Primate Source

All of the 28 uses on non-human primates in 2019 were of primates born in Asia. This is the same as 2018 where all 20 uses were of primates born in Asia, but it is different from 2017 where most of the 25 uses were of primates born in America.

Species

Mice had 168,194 uses in 2019, which is a decrease compared to 2018 (173,815 uses) and 2017 (220,281 uses). The main purpose for 2019, as well as for 2018 and 2017, was *Basic research,* on *Immune System, Cardiovascular Blood and Lymphatic System, Nervous System, Oncology* and *Endocrine System/Metabolism*. *Basic Research* does however have a lower percentage of all uses of mice in 2019 (76%) compared to 2018 (83%) and 2017 (82%), which had very similar proportions. *Translational and applied research* have instead a higher proportion in 2019 with 22% compared to 2018 (15%) and 2017 (16%).

Rats had 15,502 uses in 2019, which is very similar to 2018 (15,438 uses) and lower than 2017 (19,321 uses). For 2019, as well as for 2018 and 2017, *Basic Research,* especially about the *Nervous System,* was the main purpose. Although another large quantity in *Basic research*, especially compared to 2018 and 2017, was the purpose *Multisystemic* (2,127 uses in 2019, compared to 21 and 37 in 2018 and 2017 respectively).

Syrian hamsters have decreased to 0 uses in 2019 compared to 39 uses in 2018 and 34 uses in 2017.

The amount of uses on rabbits have increased to 2,765 from 1,738 uses in 2018 and 1,574 uses in 2017. In 2019 they are mostly reported as *Basic Research*, the majority divided between *Other basic research* (1,247 uses, 2018: 859 uses, 2017: 819 uses), *Nervous System* (614 uses, 2018: 35 uses, 2017: 114 uses) and *Respiratory System* (662 uses, none in 2017-2018).

Cats had 288 uses in 2019, which is an increase compared to 2018 (4 uses) and 2017 (104 uses). Most uses of cats in 2019 were reported as *Translational and applied research, Animal diseases and disorders* (262 uses) whilst the rest were reported as *Basic Research,* both *Multisystemic* and *Musculoskeletal System*. The former main category had 104 uses in 2017 but none in 2018. The latter categories had no uses in 2017 but 4 uses in 2018 in *Musculoskeletal System*.

Dogs had 364 uses in 2019, which is a decrease compared to 2018 (531 uses) and 2017 (386 uses). The main difference from 2018 and 2017 is the decrease in *Basic Research* to 28 uses (304 and 29 uses in 2018 and 2017 respectively) of which the 28 uses are spread between purposes *Oncology*, *Sensory Organs (skin, eyes and ears)* and *Other basic research*. The largest category for 2019 is however *Translational and applied research* (299 uses, 2018: 198 uses, 2017: 330 uses).

Ferrets increased to 25 uses in 2019 from 0 uses reported in both 2018 and 2017. These 25 uses were reported as *Basic Research* and in subcategory *Nervous System*.

Other carnivores had 115 uses in 2019, which is a decrease compared to 2018 (237 uses) and 2017 (140 uses). In contrast to 2018 and 2017, only 2 uses were recorded as *Preservation of Species* (2018: 201 uses, 2017: 73 uses). This while 48 uses were reported as *Basic Research* (2018: 0 uses, 2017: 28 uses) and 65 uses as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2018: 36 uses, 2017: 39 uses).

Horses, donkeys and cross-breeds had 340 uses in 2019 which is an increase compared to 2018 (146 uses) and a larger increase compared to 2017 (41 uses). The increase compared to 2018 is largest in *Translational and applied research* with 193 uses (2018: 13 uses, 2017: 0 uses). An increase can also be seen in *Higher Education or Training for the Acquisition, Maintenance or Improvement of Vocational Skills* with 126 uses (2018: 100 uses, 2017: 26 uses).

The amount of uses on sheep increased drastically to 442 uses from 46 uses in 2018 and 35 uses in 2017. The majority of uses in 2019 were reported in *Translational and applied research* (395 uses) and mainly in subcategories *Animal Welfare* (296 uses) and *Diagnosis of diseases* (85 uses). A smaller portion were categorized in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (47 uses, 0 uses in 2018 and none in 2017). Most uses in 2018 and 2017 were reported for the purpose of *Basic Research* (2018: 32 uses, 2017: 17 uses) and *Translational and applied research* (2018: 14 uses, 2017: 17 uses).

Goats had 53 uses in 2019, which is a decrease compared to 2018 (261 uses) and an increase from 2017 (30 uses). The main use in 2019 was in *Translational and Applied Research* (25 uses) and a lower number of uses were reported in *Basic research* (12 uses) and *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (16 uses).

Cattle had 1,621 uses in 2019, which is a decrease compared to 2018 (2,394 uses) and an increase from 2017 (1,420 uses). The use of cattle is rather similar for the three years except the 0 uses in *Animal Diseases and Disorders* (*Translational and Applied Research*) in 2019 (2018: 930 uses, 2017: 49 uses). 10 uses in 2019 are however reported in the subcategory *Diagnosis of* diseases. The

number of uses reported in *Basic Research* have increased to 122 uses from 83 uses in 2018 and 56 uses in 2017.

Rhesus monkeys had 8 uses in 2019, which is a decrease compared to both 2018 (10 uses) and 2017 (23 uses). 6 uses in 2019 were reported as *Basic Research* about the *Nervous System* (5 uses in 2018, the other 5 uses in 2018 was for the *Immune system*) while 2 were reported as *Translational and Applied Research, Human Infectious Disorders* which was the only purpose for using rhesus monkeys in 2017 (23 uses).

Another difference in 2019 from 2018 and 2017 is that the largest use group of non-human primates is now Cynomolgus monkey with 20 uses (2018: 10, 2017: 2). Similar to 2018, all uses were reported in *Basic Research*. In 2019, 17 uses were for the purpose *Nervous System* (2018: 4, 2017: 0) and 3 uses in *Cardiovascular Blood and Lymphatic System* (none in 2017-2018). In 2018, 6 uses were reported for the purpose of *Endocrine System/Metabolism*, which was not a purpose reported in 2019 or 2017.

Reptiles have decreased to 139 uses in 2019 from 529 uses in 2018, although it is still an increase from the 0 uses reported in 2017. A difference is that all uses in 2019 are reported as *Basic Research* (*Endocrine System/Metabolism* 110 uses, *Ethology/Animal Behaviour/Animal Biology* 29 uses) compared to 2018 where all 529 uses were reported as *Preservation of species*.

Xenopus frogs have decreased to almost half of the uses compared to previous years (2019: 171 uses, 2018: 298 uses, 2017: 261 uses). The reported purpose categories are the same in 2019 and 2018. The majority are reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2019: 137 uses, 2018: 237 uses). A smaller portion is reported as *Basic Research*, *Nervous System* (2019: 34 uses, 2018: 61 uses), in which a large part of 2017 uses were also reported (145 uses). The rest of the uses in 2017 were instead reported in *Translational and Applied Research*, *Non-regulatory toxicology and ecotoxicology* (116 uses).

The frogs *Rana temporaria* och *Rana pipiens* had 0 uses in 2019, which is a decrease compared to both 2018 (2 uses) and 2017 (308 uses). The 2018 uses were in *Translational and Applied Research, Animal Diseases and Disorders*, specifically testing for prevalence of *Batrachochytrium*. 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).

Zebra fish has increased since 2017 but slightly decreased since 2018. For 2019, 35,089 uses were reported (2018: 36,476 uses, 2017: 29,158 uses). The main uses are within *Basic Research*, in subcategories *Cardiovascular Blood and Lymphatic System* (2019: 16,103 uses, 2018: 16,799 uses and 2017: 7,282 uses), *Multisystemic* (2019: 5,378, 2018: 5,058 and 2017: 7,399) and *Nervous System* (2019: 4,066, 2018: 3,914 and 2017: 1,800). A large quantity of uses are also included in *Translational and applied research* where the most uses are reported as *Human Nervous and Mental Disorders* (2019: 4,426, 2018: 5,960 and 2017: 7,000).

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

The uses in overall are decreasing. One of the changes is the gradual decrease of *Basic Research* to 190,709 uses (73%) in 2019 (2018: 212,334 uses, 77%, 2017: 232,174 uses, 71%), however the proportion of the total is relatively similar to previous years. Another change is that the category *Preservation of species* has decreased to 2,416 uses in 2019 compared to 6,295 uses in 2018 but

increased from 617 uses in 2017. Another change is that *Maintenance of Colonies of Established Genetically Altered Animals, not used in other Procedures* increased to 976 uses in 2019 from 69 uses in 2018 after the decrease from previous 1,679 in 2017.

The spread between purpose categories of uses in 2019 under *Basic Research* is relatively similar to 2018 and 2017. Gradual decreases can be seen in *Nervous* System (2019: 34,646 uses, 2018: 35,775 uses, 2017: 53,425 uses) and *Endocrine System/Metabolism* (2019: 17,894 uses, 2018: 20,334 uses, 2017: 28,055 uses). In *Endocrine System/Metabolism* the largest change is the almost 11,000 fewer uses of mice from 2017. A large decrease is visible in *Other basic research* (2019: 4,763 uses, 2018: 13,397 uses, 2017: 10,528 uses).

Although there are no conclusive data, one could speculate that the decrease in uses under *Other basic research* in part is due to a better understanding of the reporting system, leading to more detailed categorization.

The number of uses in 2019 reported as *Translational and Applied Research* are 55,756, which means that it is back on the same level as 2017 with 55,713 uses (2018: 46,257 uses). However, a change is that *Human Cancer* has returned to a higher number of uses (12,124 uses) after being down on 7,737 uses in 2018 (2017: 10,841). The increase can be seen in the categories *Not genetically altered* and *Genetically altered without a harmful phenotype.* Instead a decrease, from at least 2017, can be seen in *Genetically altered with a harmful phenotype.* Another large change can be seen in the subcategory *Human Endocrine/Metabolism Disorders* with 8,331 uses (2019) from 5,491 uses in 2018 and 5,687 uses in 2017. In addition, *Non-regulatory Toxicology and Ecotoxicology* increased further to 8,423 uses in 2019 from 6,253 uses in 2018 and 1,998 uses in 2017. Furthermore, *Human Nervous and Mental Disorders* decreased to 8,067 uses in 2019 compared to 10,942 uses in 2018 and 9,737 uses in 2017. Furthermore, the subcategory *Human Gastrointestinal Disorders including Liver* decreased to 0 uses again from 56 uses in 2018 and 0 in 2017.

There is also a substantial decrease in the category *Legislation on medicinal products for human use* with 9 uses in 2019 compared to 226 uses in 2018 and 1,651 uses in 2017.

It is not clear what the changes depend on.

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

The actual severities were proportionally quite similar 2019 and 2018, although a larger proportion of uses are reported as *Non-recovery* (2019: 9,370 uses, 3,6%, 2018: 6,128 uses, 2,2%, 2017: 9,324 uses, 2,9%). The uses with severe severity increased to 26,842 uses (10%) in 2019 from 25,492 uses (9%) in 2018. This is however still a smaller proportion of all uses compared to 2017 with 41,058 uses (13%).

Most uses classified as severe in 2019 were reported as *Basic Research* (76%), foremost about the *Immune System* (9,141 uses) and also *Nervous System* (2,863 uses). The number of severe uses in the subcategory *Immune System* increased from 7,306 uses in 2018 and 4,558 uses in 2017. The categories *Multisystemic*, *Oncology* and *Cardiovascular Blood and Lymphatic System* also contain rather large portions of the total (2,122 uses, 1,935 uses and 1,974 uses respectively). The number of severe uses in the subcategory *Nervous System* decreased from 4,398 in 2018 and 12,466 uses in 2017. The number of uses classified as severe have increased for the category *Not genetically altered* (2019: 13,830 uses, 2018: 12,895 uses, 2017: 9,293 uses) but decreased for category *Genetically altered with a harmful phenotype* (2019: 827 uses, 3%, 2018: 1,174 uses, 5%, 2017: 7,999 uses, 19%). *Genetically altered with a harmful phenotype* have instead increased in the severity category mild

(2019: 13,849, 17%, 2018: 1,951, 2%, 2017: 10,005, 9%). The amount of uses for animals without harmful phenotypes but with severe severity have slightly increased from 2018 but decreased substantially from 2017 (2019: 12,185 uses, 2018: 11,423 uses, 2017: 23,766 uses).

A rather large difference for uses classified as moderate severity is that the proportion reported as *Creation of new GL* is lower, 4% 2019 compared to 13% and 7% for 2018 and 2017 respectively. Increase in *Translational and applied research* can be seen for moderate severity in general with 40,823 uses (28%) in 2019 and 31,838 uses (21%) in 2018 and 33,517 uses (20%) in 2017. A decrease is instead visible for *Basic Research* with 93,666 uses (65%) in 2019 and 113,765 uses (74%) in 2018 and 115,372 uses (70%) in 2017.

As with the previous question, it is unclear what the changes depend on in this part.

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

In Sweden our national work with the 3Rs is driven by the Swedish National Committee for the Protection of Animals Used for Scientific Purposes, with the Swedish 3Rs center as its executive body. As the executive body, the main task for the 3Rs center is to carry out the projects decided by the National Committee and to support 3Rs work nationally. The larger projects during the year was the continuation of a project concerning group housing of male mice, mentioned in the 2018 report, as well as a project about marking and tagging fish used for scientific purposes. The latter project has been completed and the former is expected to be completed during 2020.

In the spring of 2019 the composition of the National Committee was altered, anchoring it deeper with all concerned parties, such as those who handle laboratory animals, those who work with animal-free methods and the animal welfare and animal rights organizations. In addition a Group of Experts was put together to assist the National Committee and the 3Rs center where particular expertise is needed. The Group of Experts is composed of a chairman and seven members with great experience in ethics, ethology, refinement and alternative methods.

In addition to employing a Communications officer, the 3Rs center and the National Committee has spent the year working on its visibility both nationally and internationally. This has been achieved by participating in conferences, workshops, seminars and meetings, as well as arranging such activities. For example, the National Committee, with assistance from the 3Rs center, hosted a meeting for the National Committees from 12 European countries in Stockholm early in the year. During the meeting the focus was mainly on planning the orientation for the network's work and to find an understanding in common issues. Amongst other things, it was decided that the Committees will meet once or twice a year and that the cooperation will be called the European NC Network.

Nationally the 3Rs center organized a replace workshop titled: How can we increase the use of modern animal-free methods in regulatory risk assessment? Participants from the academy, the industry and different authorities attended. In connection to the replace workshop the 3Rs center also started a replace network where interested parties around Sweden could sign up to get information about and also be of assistance regarding replace.

Another important step for the visibility and dissemination of information for the 3Rs center was the start of the digital letter Focus on the 3Rs. During 2019 three digital letters were published, each one focused on one of the 3Rs. In future years the goal is to publish four of these letters a year, each with a different 3Rs related topic.

While the National Committee and the 3Rs center is continuously trying to inspire researchers to use replace methods as well as to refine the methods they are using, it is still too early to say whether or not this has reduced the number of animals used in Swedish research.

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

Other carnivores

15% of the carnivores were recorded as other carnivores. These 115 uses consist of brown bear (*Ursus arctos*, 65 uses), raccoon dog (*Nyctereutes procyonoides*, 39 uses), wolf (*Canis lupus,* 6 uses), American mink (*Neovison vison*, 2 uses*)* and lynx (*Lynx lynx*, 3 uses). The uses of other carnivores were reported as *Preservation of Species* (2 uses), *Basic Research* with subcategory *Ethology / Animal Behaviour /Animal Biology* (48 uses) and *Protection of the Natural Environment in the Interests of the Health or Welfare of Human Beings or Animals* (65 uses).

Other birds

84% of the birds were reported as other birds*.* These 10,810 uses consist mostly of collared flycatcher (*Ficedula albicollis*, 3,263 uses), great tit (*Parus major*, 3,161 uses) and Eurasian blue tit (*Cyanistes caeruleus*, 1,966 uses). Most uses of other birds were reported as *Basic research* (9,679 uses, of which all were specified as *Ethology/Animal Behaviour/Animal Biology*).

Other fish

34% of the reported fish constitutes of other fish. Of the 17,873 uses of other fish most are reported as European perch (*Perca fluvialis*, 4,785), Atlantic herring (*Clupea harengus*, 2,754 uses) and guppy (*Poecilia 338eticulate*, 1,840). Most uses of other fish were reported as *Basic Research* (6,010 uses, of which 5,331 were in *Ethology/Animal Behaviour/Animal Biology*) and *Translational and Applied Research* (6,083 uses, of which 5,619 were in *Non-regulatory Toxicology and Ecotoxicology*).

Other amphibians

92% (2,041 uses) of the amphibians are reported as other amphibians, which is lower compared to previous years (2018: 2,538 uses, 2017: 2,694 uses). The species used 2019 are Iberian ribbed newt (*Pleurodeles waltl,* 1,149 uses), moor frog (*Rana arvalis*, 846 uses) and the eastern newt (*Notophthalmus viridescens*, 46 uses). All uses of other amphibians were reported as *Basic Research*, of which 846 uses were in *Ethology/Animal Behaviour/Animal Biology*, 897 uses in *Nervous System* and 298 uses in *Cardiovascular Blood and Lymphatic System*. In 2019 the uses in *Translational and applied research* decreased to 0, compared to 122 uses (2018) and 60 uses (2017).

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

There has been no such case in SE up to this date.

Sweden: Statistical Data 2019

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	159095	69.67%
Rats	15472	6.78%
Guinea-Pigs	428	0.19%
Other rodents	304	0.13%
Rabbits	2745	1.2%
Cats	288	0.13%
Dogs	215	0.09%
Ferrets	25	0.01%
Other carnivores	55	0.02%
Horses, donkeys and cross-breeds	65	0.03%
Pigs	1144	0.5%
Goats	27	0.01%
Sheep	357	0.16%
Cattle	717	0.31%
Cynomolgus monkey	3	0%
Rhesus monkey	2	0%
Other mammals	153	0.07%
Domestic fowl	1958	0.86%
Other birds	10795	4.73%
Reptiles	139	0.06%
Xenopus	171	0.07%
Other amphibians	2041	0.89%
Zebra fish	14373	6.29%
Other fish	17792	7.79%
Total	228364	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	194370	85.12%
Animals born in the EU but not at a registered breeder	32718	14.33%
Animals born in rest of Europe	148	0.06%
Animals born in rest of world	1123	0.49%
Total	228359	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born in Asia	5	100%
Total	5	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	5	100%
Total	5	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	159095	1079	160174
Rats	15472	30	15502
Guinea-Pigs	428	9	437
Other rodents	304		304
Rabbits	2745	20	2765
Cats	288		288
Dogs	215	149	364
Ferrets	25		25
Other carnivores	55	60	115
Horses, donkeys and cross-breeds	65	275	340
Pigs	1144	586	1730
Goats	27	26	53
Sheep	357	85	442
Cattle	717	904	1621
Cynomolgus monkey	3	17	20
Rhesus monkey	2	6	8
Other mammals	153	47	200
Domestic fowl	1958	36	1994
Other birds	10795	15	10810
Reptiles	139		139
Xenopus	171		171
Other amphibians	2041		2041
Zebra fish	14373	3977	18350
Other fish	17792	81	17873
Total	228364	7402	235766

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	167917	71.22%
Translational and applied research	54765	23.23%
Regulatory use and Routine production	1079	0.46%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4457	1.89%
Preservation of species	2416	1.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5132	2.18%
Total	235766	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	21294	12.68%
Cardiovascular Blood and Lymphatic System	23659	14.09%
Nervous System	32534	19.38%
Respiratory System	3045	1.81%
Gastrointestinal System including Liver	1772	1.06%
Musculoskeletal System	2939	1.75%
Immune System	32086	19.11%

Urogenital/Reproductive System	1570	0.93%
Sensory Organs (skin, eyes and ears)	2206	1.31%
Endocrine System/Metabolism	16698	9.94%
Multisystemic	8277	4.93%
Ethology / Animal Behaviour /Animal Biology	17858	10.64%
Other basic research	3979	2.37%
Total	167917	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	11442	20.89%
Human Infectious Disorders	1056	1.93%
Human Cardiovascular Disorders	5786	10.57%
Human Nervous and Mental Disorders	8065	14.73%
Human Respiratory Disorders	5058	9.24%
Human Musculoskeletal Disorders	75	0.14%
Human Immune Disorders	1910	3.49%
Human Urogenital/Reproductive Disorders	99	0.18%
Human Sensory Organ Disorders (skin, eyes and ears)	54	0.1%
Human Endocrine/Metabolism Disorders	8331	15.21%
Other Human Disorders	1559	2.85%
Animal Diseases and Disorders	1796	3.28%
Animal Welfare	611	1.12%
Diagnosis of diseases	500	0.91%
Non-regulatory toxicology and ecotoxicology	8423	15.38%
Total	54765	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1070	99.17%
Toxicity and other safety testing including pharmacology	9	0.83%
Total	1079	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	1070	100%
Total	1070	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Kinetics	9	100%
Total	9	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	9	0.83%
Legislation on medicinal products for veterinary use and their residues	1070	99.17%
Total	1079	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1079	100%
Total	1079	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	228364	96.86%
Yes	7402	3.14%
Total	235766	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	9370	3.97%
Mild [up to and including]	61398	26.04%
Moderate	138156	58.6%
Severe	26842	11.39%
Total	235766	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	126116	53.49%
Genetically altered without a harmful phenotype	94148	39.93%
Genetically altered with a harmful phenotype	15502	6.58%
Total	235766	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	6929	115	7044
Zebra fish	16022	717	16739
Total	22951	832	23783

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

Severity	Number of uses	Percentage
Mild [up to and including]	17498	73.57%
Moderate	6285	26.43%
Total	23783	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	1798	7.56%
Genetically altered without a harmful phenotype	12156	51.11%
Genetically altered with a harmful phenotype	9829	41.33%
Total	23783	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	439	1.93%
Cardiovascular Blood and Lymphatic System	15217	66.76%
Nervous System	2112	9.27%
Musculoskeletal System	1021	4.48%
Immune System	214	0.94%
Urogenital/Reproductive System	397	1.74%
Endocrine System/Metabolism	1196	5.25%
Multisystemic	1412	6.2%
Other basic research	784	3.44%
Total	22792	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	682	68.82%
Human Cardiovascular Disorders	104	10.49%
Human Nervous and Mental Disorders	2	0.2%
Human Respiratory Disorders	7	0.71%
Human Sensory Organ Disorders (skin, eyes and ears)	196	19.78%
Total	991	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	976		976
Total	976		976

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

Severity	Number of uses	Percentage
Mild [up to and including]	500	51.23%

Moderate	476	48.77%
Total	976	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	156	15.98%
Genetically altered without a harmful phenotype	192	19.67%
Genetically altered with a harmful phenotype	628	64.34%
Total	976	100.00%

United Kingdom

United Kingdom: Narrative 2019

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2019 data for Great Britain on the 16 July 2020 and the statistical release can be accessed online here: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2019

The Northern Ireland Department for Health (NIDH) published their 2019 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 2019, a total of 2.30 million procedures were completed. This represents a decrease of 5% (133,000) compared with the 2.44 million procedures completed in 2018.

Of the 2.30 million procedures, 1.75 million (76%) were experimental procedures and 552,000 (24%) related to the creation and breeding of genetically altered animals that were not used in further procedures. Since 2018, experimental procedures have decreased by 4% (74,000) and creation and breeding procedures have decreased by 10% (59,000).

There were 2.23 million animals used for the first time in completed procedures in 2019, representing a decrease of 6% (131,000) compared with 2018.

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

Of the 1.75 million experimental procedures completed in 2019, the majority involved the use of mice (61%), fish[1] (16%) and rats (9%). Comparing with 2018, there were notable changes[2] to the number of procedures involving:

- Mice, which decreased by 29,000 (-3%) to 1.07 million procedures in 2019;
- birds[3], which decreased by 16,000 (-11%) to 131,000 procedures in 2019
- fish[4], which decreased by 20,000 (-7%) to 280,000 procedures in 2019;
- Mongolian Gerbil, which decreased by 240 (-47%) to 270 procedures in 2019;
- rana, which decreased by 530 (-78%) to 150 procedures in 2019;
- Other amphibians, which decreased by 400 (-54%) to 360 procedures in 2019;

Of the 522,000 procedures in 2019 related to the creation and breeding of genetically altered animals not used in further procedures, the majority involved mice (80%), fish (19%), and rats (1%). Comparing with 2018, there were notable changes[5] to the number of procedures involving:

- mice, which decreased by 39,000 (-8%) to 441,000 procedures in 2019;
- fish[6], which decreased by 22,000 (-17%) to 104,000 procedures in 2019;
- xenopus, which decreased by 1,300 (-77%) to 400 procedures in 2019;
- sheep, which decreased by 130 (-76%) to 40 procedures in 2019;
- rats, which increased by 2,900 (+102%) to 5,700 procedures in 2019;

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

Of the 1.75 million experimental procedures completed in 2019:

- 5% (85,000) were assessed as non-recovery, compared with 5% (90,000) in 2018;
- 63% (1.10 million) were assessed as (up to and including) mild, compared with 63% (1.16 million) in 2018;
- 28% (492,000) were assessed as moderate, compared with 27% (489,000) in 2018;
- 4% (73,000) were assessed as severe, compared with 5% (88,000) in 2018.

Of the 552,000 procedures in 2019 related to the creation and breeding of genetically altered animals not used in further procedures:

- 0.2% (1,100) were assessed as non-recovery, compared with 0.1% (500) in 2018;
- 85% (472,000) were assessed as (up to and including) mild, compared 87% (532,000) in 2018;
- 8% (46,000) were assessed as moderate, compared with 7% (41,000) in 2018;
- 6% (33,000) were assessed as severe, compared with 6% (38,000) in 2018.

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

[1] Specifically, Zebrafish and other fish species.
[2] Covers the three largest numeric and the three largest percentage changes between 2018 and 2019.
[3] Specifically, domestic fowl and other bird species.
[4] Specifically, Zebrafish and other fish species.
[5] Covers the three largest numeric and the three largest percentage changes between 2018 and 2019.
[6] Specifically, Zebrafish and other fish species.

death cannot be excluded from being procedural and an informed decision cannot be made that the animal did not experience severe suffering prior to death, it is recorded as 'severe'. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2019 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;
- Provision of material for ex vivo use (eg blood and tissues)
- Procedures for creation, archiving etc of GA animals where the purpose is not specified

Regulatory use, routine production "other":

- Antigens, infectious agents including parasites, oocytes, etc;

Regulatory use, quality control "other":

- Method development, agent standardisation;
- testing of seed materials;
- Cell line characterisation.

Regulatory use Other efficacy

PK testing and efficacy of enzyme additives, anti parasitic drugs
Dose ranging studies
Biocompatability testing

Regulatory use, toxicity "other":

- Effects on non-target (i.e. ASPA non-Schedule 2) species;
- Metabolism, DMPK
- Internal validation and pilot studies.
- Single dose extended period studies
- 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
- 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 2019

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	1066413	63.42%
Rats	162227	9.65%
Guinea-Pigs	6934	0.41%
Hamsters (Syrian)	1583	0.09%
Mongolian gerbil	271	0.02%
Other rodents	904	0.05%
Rabbits	10133	0.6%
Cats	28	0%
Dogs	2679	0.16%
Ferrets	428	0.03%
Other carnivores	343	0.02%

Horses, donkeys and cross-breeds	43	0%
Pigs	4371	0.26%
Goats	78	0%
Sheep	5573	0.33%
Cattle	6050	0.36%
Marmoset and tamarins	80	0%
Cynomolgus monkey	2007	0.12%
Rhesus monkey	69	0%
Other mammals	576	0.03%
Domestic fowl	122681	7.3%
Other birds	8378	0.5%
Rana	148	0.01%
Xenopus	2412	0.14%
Other amphibians	349	0.02%
Zebra fish	187334	11.14%
Other fish	89291	5.31%
Total	1681383	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	1582734	94.25%
Animals born in the EU but not at a registered breeder	85319	5.08%
Animals born in rest of Europe	257	0.02%
Animals born in rest of world	10917	0.65%
Total	1679227	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	220	10.2%
Animals born in Asia	782	36.27%
Animals born in Africa	1154	53.53%
Total	2156	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	295	13.68%
F2 or greater	120	5.57%
Self-sustaining colony	1741	80.75%
Total	2156	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	1066413	298	1066711
Rats	162227	1206	163433
Guinea-Pigs	6934		6934
Hamsters (Syrian)	1583		1583
Mongolian gerbil	271		271
Other rodents	904		904
Rabbits	10133	57	10190
Cats	28	124	152
Dogs	2679	1576	4255
Ferrets	428		428
Other carnivores	343	30	373
Horses, donkeys and cross-breeds	43	10469	10512
Pigs	4371	672	5043
Goats	78	5	83
Sheep	5573	48399	53972
Cattle	6050	736	6786
Marmoset and tamarins	80	30	110
Cynomolgus monkey	2007	609	2616
Rhesus monkey	69	55	124
Other mammals	576	2	578
Domestic fowl	122681	85	122766
Other birds	8378	352	8730
Rana	148		148
Xenopus	2412	2820	5232
Other amphibians	349	6	355
Zebra fish	187334	910	188244
Other fish	89291	2308	91599
Total	1681383	70749	1752132

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	998907	57.01%
Translational and applied research	283198	16.16%
Regulatory use and Routine production	437692	24.98%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	30738	1.75%
Preservation of species	315	0.02%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1249	0.07%
Forensic enquiries	33	0%
Total	1752132	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	154107	15.43%
Cardiovascular Blood and Lymphatic System	67697	6.78%
Nervous System	205371	20.56%

Respiratory System	13528	1.35%
Gastrointestinal System including Liver	26374	2.64%
Musculoskeletal System	25055	2.51%
Immune System	210785	21.1%
Urogenital/Reproductive System	23280	2.33%
Sensory Organs (skin, eyes and ears)	17064	1.71%
Endocrine System/Metabolism	34163	3.42%
Multisystemic	89309	8.94%
Ethology / Animal Behaviour /Animal Biology	52739	5.28%
Other basic research	79435	7.95%
Total	998907	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	81702	28.85%
Human Infectious Disorders	67613	23.87%
Human Cardiovascular Disorders	4312	1.52%
Human Nervous and Mental Disorders	47033	16.61%
Human Respiratory Disorders	9530	3.37%
Human Gastrointestinal Disorders including Liver	4080	1.44%
Human Musculoskeletal Disorders	2928	1.03%
Human Immune Disorders	5159	1.82%
Human Urogenital/Reproductive Disorders	1829	0.65%
Human Sensory Organ Disorders (skin, eyes and ears)	6506	2.3%
Human Endocrine/Metabolism Disorders	2104	0.74%
Other Human Disorders	8795	3.11%
Animal Diseases and Disorders	12750	4.5%
Animal Welfare	4790	1.69%
Diagnosis of diseases	3374	1.19%
Non-regulatory toxicology and ecotoxicology	20693	7.31%
Total	283198	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	118825	27.15%
Other efficacy and tolerance testing	20410	4.66%
Toxicity and other safety testing including pharmacology	145747	33.3%
Routine production	152710	34.89%
Total	437692	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	18757	15.79%
Batch potency testing	88607	74.57%
Other quality controls	11461	9.65%
Total	118825	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	14220	9.76%
Skin irritation/corrosion	87	0.06%
Skin sensitisation	95	0.07%
Eye irritation/corrosion	16	0.01%
Repeated dose toxicity	36618	25.12%
Carcinogenicity	5383	3.69%
Genotoxicity	5713	3.92%
Reproductive toxicity	41339	28.36%

Developmental toxicity	15584	10.69%
Neurotoxicity	593	0.41%
Kinetics	3916	2.69%
Pharmaco-dynamics (incl safety pharmacology)	3310	2.27%
Ecotoxicity	12963	8.89%
Safety testing in food and feed area	175	0.12%
Target animal safety	359	0.25%
Other toxicity/safety testing	5376	3.69%
Total	145747	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	10558	74.25%
Other lethal methods	32	0.23%
Non lethal methods	3630	25.53%
Total	14220	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	15524	42.39%
29 - 90 days	9844	26.88%
> 90 days	11250	30.72%
Total	36618	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	2464	19.01%
Chronic toxicity	8522	65.74%
Endocrine activity	832	6.42%
Bioaccumulation	1085	8.37%
Other ecotoxicity	60	0.46%
Total	12963	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	177677	62.35%
Legislation on medicinal products for veterinary use and their residues	44019	15.45%
Medical devices legislation	432	0.15%
Industrial chemicals legislation	36340	12.75%
Plant protection product legislation	16276	5.71%
Biocides legislation	472	0.17%
Food legislation including food contact material	2324	0.82%
Feed legislation including legislation for the safety of target animals, workers and environment	5758	2.02%
Other legislation	1684	0.59%
Total	284982	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	259781	91.16%
Legislation satisfying national requirements only [within EU]	996	0.35%
Legislation satisfying Non-EU requirements only	24205	8.49%
Total	284982	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	55072	36.06%
Other product types	97638	63.94%
Total	152710	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	1681383	95.96%
Yes	70749	4.04%
Total	1752132	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	85328	4.87%
Mild [up to and including]	1101484	62.87%
Moderate	492055	28.08%
Severe	73265	4.18%
Total	1752132	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	1026454	58.58%
Genetically altered without a harmful phenotype	602329	34.38%
Genetically altered with a harmful phenotype	123349	7.04%
Total	1752132	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	157314	365	157679
Rats	20		20
Pigs	145		145
Sheep	41		41
Other mammals	1		1
Domestic fowl	880		880
Xenopus	39		39
Zebra fish	37875	1236	39111
Other fish	47		47
Total	196362	1601	197963

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

Severity	Number of uses	Percentage
Non-recovery	279	0.14%
Mild [up to and including]	182025	91.95%
Moderate	14506	7.33%
Severe	1153	0.58%
Total	197963	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	33104	16.72%
Genetically altered without a harmful phenotype	152269	76.92%
Genetically altered with a harmful phenotype	12590	6.36%
Total	197963	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	30025	16.18%
Cardiovascular Blood and Lymphatic System	9511	5.13%
Nervous System	31205	16.82%
Respiratory System	566	0.31%
Gastrointestinal System including Liver	4207	2.27%
Musculoskeletal System	2996	1.61%
Immune System	39291	21.17%
Urogenital/Reproductive System	2866	1.54%
Sensory Organs (skin, eyes and ears)	5804	3.13%
Endocrine System/Metabolism	3584	1.93%
Multisystemic	39383	21.22%
Ethology / Animal Behaviour /Animal Biology	464	0.25%
Other basic research	15658	8.44%
Total	185560	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	7055	56.88%
Human Infectious Disorders	1363	10.99%

Human Nervous and Mental Disorders	66	0.53%
Human Respiratory Disorders	109	0.88%
Human Gastrointestinal Disorders including Liver	11	0.09%
Human Immune Disorders	260	2.1%
Human Urogenital/Reproductive Disorders	15	0.12%
Human Sensory Organ Disorders (skin, eyes and ears)	5	0.04%
Human Endocrine/Metabolism Disorders	248	2%
Animal Diseases and Disorders	3271	26.37%
Total	12403	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	282818	449	283267
Rats	5692		5692
Domestic fowl	405		405
Xenopus	189	171	360
Zebra fish	62521	1221	63742
Other fish	900		900
Total	352525	1841	354366

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

Severity	Number of uses	Percentage
Non-recovery	841	0.24%
Mild [up to and including]	289789	81.78%
Moderate	31963	9.02%
Severe	31773	8.97%
Total	354366	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	17075	4.82%
Genetically altered without a harmful phenotype	293773	82.9%
Genetically altered with a harmful phenotype	43518	12.28%
Total	354366	100.00%

Norway

Norway: Narrative 2019

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

The numbers for re-use in 2019 are significantly lower than for 2018.

The high numbers for re-use in 2018 were a result of two extensive field research projects which took place in 2017 and 2018. The purpose of both projects is to investigate genetic and ecological effects on wild populations of escaped farmed fish. The fish have been wrongly reported as reused. The projects were terminated in 2018.

We see some changes in the numbers of goats, sheep, cattle and “other mammals” from 2018 to 2019.

The number of goats used in procedures in Norway is usually low. In 2018 there were several small research projects which were terminated the same year. The number of animals used is so low that small changes have a large impact on the percentages in the statistics.

For sheep the numbers are overall higher, and we can see a significant decrease from 2018 to 2019.

This difference is in particular linked to one large field research project regarding vaccine development using animals in regular production sheep herds. This project was commenced and terminated in 2018.

The number of cattle reported in 2018 was particularly high due to one large field research project regarding subclinical endometritis. Samples were taken on dairy farms in connection with regular inseminations. The project was commenced and terminated in 2018.

For “other mammals” the numbers were particularly high in 2018.

This is due to a large field research project which was Norway`s contribution to the Environmental Monitoring Program of the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR). CCAMLR manages the krill fishery in the Southern Ocean. The project`s purpose was to characterise the foraging and reproductive ecology of krill-dependent marine predators at Bouvet Island.

The research project comprised several bird and mammal species, among them the Antarctic fur seal, which is the reason for the high number of reported “other mammals” for 2018.

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

There is an increase in number of fish used from 2018 till 2019. Projects with fish usually include a huge amount of fish, and 2-3 more projects from one year to another create a significant increase in the total number of animals.

We also see an increase in the purpose category **Protection of the natural environment in the interests of the health or welfare of human beings or animals.**

This increase is linked to a single project using exogenously feeding capelin larvae. Beach spawning capelin is a key pelagic fish species in the Barents Sea, and they are prone to exposure to toxic oil compounds from accidental oil spills in coastal areas. Due to interest in oil and gas development in the Arctic it is of importance to investigate the effects of exposure to low levels of crude oil WSF.

The numbers of animals reported as used in the maintenance of colonies of established genetically altered animals not used in other procedures have increased from 2018 to 2019.

We have approved a limited number of quite large breeding projects, each one with several genetically altered mouse lines, and we can see that the reporting from these projects fluctuates from year to year. Small changes in the projects influence the numbers significantly. When we evaluate applications for breeding programs, we emphasize the importance of good breeding protocols and planning to avoid the production of surplus animals. The fluctuation in numbers from year to year indicates that the breeding of specific lines is up- or downregulated according to need, which is a good reduction practice.

The number of reported animals used for Regulatory use, Legislation on medicinal products for human use was very high in 2018. This is due to an error in the reporting of more than 20000 salmon and sea bass which were used in batch potency tests of fish vaccines.

The number of animals used for the creation of new GA lines was reduced from 2018 to 2019. The number reported in this category was especially high in 2018, mainly because of two projects using salmon. One of them was a CRISPR/Cas 9-project, the other one a project producing double haploid individuals.

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

We have not observed any changes in trends from till 2019.

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.

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 2019

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	45296	3.57%
Rats	3159	0.25%
Guinea-Pigs	386	0.03%
Other rodents	1572	0.12%
Rabbits	14	0%
Cats	1	0%
Dogs	22	0%
Other carnivores	120	0.01%
Horses, donkeys and cross-breeds	130	0.01%
Pigs	466	0.04%
Sheep	511	0.04%
Cattle	28	0%
Other mammals	532	0.04%
Domestic fowl	1184	0.09%
Other birds	11517	0.91%
Reptiles	26	0%
Other amphibians	319	0.03%
Zebra fish	39085	3.08%
Other fish	1164530	91.77%
Total	1268898	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	879251	69.29%
Animals born in the EU but not at a registered breeder	382898	30.18%
Animals born in rest of Europe	5198	0.41%
Animals born in rest of world	1551	0.12%
Total	1268898	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	45296	24	45320
Rats	3159	1	3160
Guinea-Pigs	386		386
Other rodents	1572		1572
Rabbits	14		14
Cats	1		1
Dogs	22	44	66
Other carnivores	120		120
Horses, donkeys and cross-breeds	130	9	139
Pigs	466		466
Sheep	511	6	517
Cattle	28	82	110
Other mammals	532	110	642
Domestic fowl	1184		1184
Other birds	11517	53	11570
Reptiles	26		26
Other amphibians	319		319
Zebra fish	39085	44	39129
Other fish	1164530	461	1164991
Total	1268898	834	1269732

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	487776	38.42%
Translational and applied research	654707	51.56%
Regulatory use and Routine production	30762	2.42%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	91320	7.19%
Preservation of species	4034	0.32%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	788	0.06%
Forensic enquiries	345	0.03%
Total	1269732	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	12715	2.61%
Cardiovascular Blood and Lymphatic System	8109	1.66%
Nervous System	29339	6.01%
Respiratory System	1296	0.27%
Gastrointestinal System including Liver	3603	0.74%
Musculoskeletal System	1736	0.36%
Immune System	12976	2.66%
Urogenital/Reproductive System	2259	0.46%
Sensory Organs (skin, eyes and ears)	378	0.08%
Endocrine System/Metabolism	3007	0.62%
Multisystemic	2017	0.41%

Ethology / Animal Behaviour /Animal Biology	352469	72.26%
Other basic research	57872	11.86%
Total	487776	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	6351	0.97%
Human Infectious Disorders	869	0.13%
Human Cardiovascular Disorders	607	0.09%
Human Nervous and Mental Disorders	7186	1.1%
Human Respiratory Disorders	213	0.03%
Human Gastrointestinal Disorders including Liver	75	0.01%
Human Musculoskeletal Disorders	47	0.01%
Human Immune Disorders	141	0.02%
Human Endocrine/Metabolism Disorders	319	0.05%
Other Human Disorders	123	0.02%
Animal Diseases and Disorders	580623	88.68%
Animal Welfare	58026	8.86%
Diagnosis of diseases	12	0%
Non-regulatory toxicology and ecotoxicology	115	0.02%
Total	654707	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	30269	98.4%
Toxicity and other safety testing including pharmacology	413	1.34%
Routine production	80	0.26%
Total	30762	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	499	1.65%
Batch potency testing	29386	97.08%
Other quality controls	384	1.27%
Total	30269	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Target animal safety	413	100%
Total	413	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	1069	3.48%
Legislation on medicinal products for veterinary use and their residues	29613	96.52%
Total	30682	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	29485	96.1%
Legislation satisfying Non-EU requirements only	1197	3.9%
Total	30682	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	8	10%
Other product types	72	90%
Total	80	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	1268898	99.93%
Yes	834	0.07%
Total	1269732	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	36585	2.88%
Mild [up to and including]	866946	68.28%
Moderate	274767	21.64%
Severe	91434	7.2%
Total	1269732	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	1215307	95.71%
Genetically altered without a harmful phenotype	44335	3.49%
Genetically altered with a harmful phenotype	10090	0.79%
Total	1269732	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	1192		1192
Zebra fish	1885		1885
Other fish	650		650
Total	3727		3727

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

Severity	Number of uses	Percentage
Non-recovery	1329	35.66%
Mild [up to and including]	2333	62.6%
Moderate	65	1.74%
Total	3727	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	3727	100%
Total	3727	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	260	7.37%
Nervous System	444	12.59%
Gastrointestinal System including Liver	769	21.8%
Urogenital/Reproductive System	400	11.34%
Sensory Organs (skin, eyes and ears)	113	3.2%
Endocrine System/Metabolism	854	24.21%
Multisystemic	37	1.05%
Other basic research	650	18.43%
Total	3527	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	200	100%
Total	200	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	7838		7838
Rats	164		164
Zebra fish	114	20	134
Total	8116	20	8136

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

Severity	Number of uses	Percentage
Non-recovery	318	3.91%
Mild [up to and including]	4350	53.47%
Moderate	6	0.07%
Severe	3462	42.55%

Total	8136	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	7888	96.95%
Genetically altered with a harmful phenotype	248	3.05%
Total	8136	100.00%

VII Member State comparative tables for 2019

Introduction

Based on the submitted Member State data, four comparative tables are provided for 2019 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 EU in 2019, 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) (2019)

		AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals																
	Rodents															
	Mice	180,737	256,049	2,145	2,156	62,536	1,123,358	157,301	1,379	25,658	405,895	48,767	1,040,279	18,484	61,643	95,596
	Rats	4,748	16,985	2,310	0	19,925	189,538	36,407	285	1,984	48,495	9,904	157,486	6,446	31,247	22,994
	Guinea-Pigs	118	11,142	2,657	0	2,041	9,655	3,905	0	8	7,975	2	37,360	106	3,454	603
	Hamsters (Syrian)	291	806	20	0	20	1,054	6	0	0	848	180	5,907	0	0	6
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	17	0	0	0
	Mongolian gerbil	113	108	0	0	12	2,785	0	0	0	0	0	428	0	0	0
	Other rodents	14	166	0	0	168	13,857	23	0	0	1,279	2,315	1,374	0	0	0
	Rabbits															
	Rabbits	960	63,075	1,158	0	4,189	90,860	2,297	65	407	17,231	160	133,789	12	956	552
	Carnivores															
	Cats	35	208	0	0	25	680	1	0	12	163	178	448	0	24	0
	Dogs	138	542	0	0	259	1,678	365	0	0	1,091	2,037	3,011	0	244	0
	Ferrets	0	0	0	0	40	122	0	0	0	96	0	150	0	0	403
	Other carnivores	0	0	0	0	0	301	3,603	0	0	5	91	24	0	0	0
	Farm animals															
	Horses, donkeys and cross-breeds	14	46	0	0	110	519	47	0	0	265	36	88	0	0	19
	Pigs	1,836	5,091	27	0	2,044	18,701	8,478	4	332	9,403	919	12,478	2	2,485	323
	Goats	10	63	0	0	30	409	51	0	0	252	0	112	0	0	26
	Sheep	91	527	0	0	545	4,695	18	0	0	2,118	1,243	3,946	0	23	703
	Cattle	559	1,251	0	0	848	5,886	980	866	0	528	147	1,483	0	0	3,417
	Non-human primates															
	Prosimians	0	0	0	0	0	85	0	0	0	0	0	109	0	0	0
	Marmoset and tamarins	0	0	0	0	0	92	0	0	0	0	0	50	0	0	0
	Cynomolgus monkey	0	0	0	0	0	2,385	0	0	0	172	0	1,842	0	0	0
	Rhesus monkey	0	7	0	0	0	51	0	0	1	1	0	22	0	0	0
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	25	0	0	0
	Baboons	0	0	0	0	0	6	0	0	0	3	0	24	0	0	0
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	Other mammals															
	Other mammals	73	103	0	0	120	1,919	23	0	0	127	119	179	0	0	28
Birds																
	Domestic fowl	2,087	35,286	505	0	23,145	24,371	1,230	58	200	98,231	2,785	76,303	2,840	24,550	80
	Other birds	154	6,186	115	0	2,538	10,392	439	204	0	3,200	1,296	37,789	0	739	673
Reptiles																
	Reptiles	0	15	0	0	424	85	45	0	0	979	0	218	0	0	0
Amphibians																
	Rana	0	0	4,840	0	0	381	448	0	0	0	0	260	0	0	0
	Xenopus	673	267	0	0	75	10,472	91	0	0	401	0	3,950	0	0	16
	Other amphibians	3,587	14	305	0	0	5,208	59	0	0	775	0	253	0	6,280	0
Fish																
	Zebra fish	6,538	32,364	0	5	6,219	90,635	3,935	0	543	32,775	8,784	42,385	0	1,103	5,219
	Other fish	15,549	10,290	840	0	106,774	201,073	24,740	158	18,494	99,897	13,492	176,891	0	1,754	5,506
Cephalopods																
	Cephalopods	0	0	0	0	0	17	0	0	87	16,756	0	74	0	0	0
Totals																
	Total	**218,325**	**440,591**	**14,922**	**2,161**	**232,087**	**1,811,270**	**244,492**	**3,019**	**47,726**	**748,961**	**92,455**	**1,738,756**	**27,890**	**134,502**	**136,164**
	%	**2.1**	**4.2**	**0.1**	**0**	**2.2**	**17.4**	**2.4**	**0**	**0.5**	**7.2**	**0.9**	**16.7**	**0.3**	**1.3**	**1.3**

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) (2019)

		IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals																	
	Rodents																
	Mice	326,166	2,790	10,651	3,078	0	145,260	45,296	148,214	50,555	7,481	159,095	4,179	8,272	1,066,413	**5,459,433**	**52.5**
	Rats	100,936	886	117	717	0	79,937	3,159	46,668	6,273	4,551	15,472	91	8,517	162,227	**978,305**	**9.4**
	Guinea-Pigs	15,849	15	0	0	0	9,108	386	11,802	0	332	428	0	607	6,934	**124,487**	**1.2**
	Hamsters (Syrian)	434	0	0	0	0	684	0	242	0	50	0	0	0	1,583	**12,131**	**0.1**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**17**	**0**
	Mongolian gerbil	0	0	0	0	0	54	0	320	0	0	0	0	12	271	**4,103**	**0**
	Other rodents	642	0	0	0	0	1,066	1,572	10,972	7	0	304	0	0	904	**34,663**	**0.3**
	Rabbits																
	Rabbits	9,703	88	0	6	0	12,797	14	2,108	84	264	2,745	0	178	10,133	**353,831**	**3.4**
	Carnivores																
	Cats	0	0	0	0	0	52	1	24	0	0	288	0	13	28	**2,180**	**0**
	Dogs	542	0	0	0	0	235	22	18	0	0	215	0	0	2,679	**13,076**	**0.1**
	Ferrets	20	0	0	0	0	599	0	0	0	0	25	0	0	428	**1,883**	**0**
	Other carnivores	0	0	0	0	0	68	120	116	0	0	55	0	0	343	**4,726**	**0**
	Farm animals																
	Horses, donkeys and cross-breeds	0	0	0	0	0	49	130	0	0	0	65	0	0	43	**1,431**	**0**
	Pigs	1,382	213	0	24	0	10,773	466	2,068	208	39	1,144	8	0	4,371	**82,819**	**0.8**
	Goats	3	0	0	0	0	141	0	0	0	0	27	0	0	78	**1,202**	**0**
	Sheep	169	5	0	0	0	269	511	774	0	107	357	40	28	5,573	**21,742**	**0.2**
	Cattle	395	0	0	0	0	1,814	28	280	0	0	717	0	0	6,050	**25,249**	**0.2**
	Non-human primates																
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**194**	**0**
	Marmoset and tamarins	0	0	0	0	0	0	0	0	0	0	0	0	0	80	**222**	**0**
	Cynomolgus monkey	302	0	0	0	0	37	0	0	0	0	3	0	0	2,007	**6,748**	**0.1**
	Rhesus monkey	0	0	0	0	0	98	0	0	0	0	2	0	0	69	**251**	**0**
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**25**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**33**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**2**	**0**
	Other mammals																
	Other mammals	76	0	0	0	0	294	532	1,020	3	0	153	0	0	576	**5,345**	**0.1**
Birds																	
	Domestic fowl	36,361	0	0	0	0	52,287	1,184	12,550	0	228	1,958	127	249	122,681	**519,296**	**5**
	Other birds	718	187	0	80	0	13,723	11,517	13,470	367	0	10,795	0	31	8,378	**122,991**	**1.2**
Reptiles																	
	Reptiles	0	0	0	0	0	1	26	80	0	0	139	0	0	0	**2,012**	**0**
Amphibians																	
	Rana	0	0	0	0	0	0	0	0	0	240	0	0	0	148	**6,317**	**0.1**
	Xenopus	786	0	0	0	0	284	0	0	200	0	171	0	0	2,412	**19,798**	**0.2**
	Other amphibians	15	0	0	0	0	720	319	736	0	0	2,041	0	0	349	**20,661**	**0.2**
Fish																	
	Zebra fish	10,232	0	349	0	0	7,587	39,085	22,866	4,862	0	14,373	0	0	187,334	**517,193**	**5**
	Other fish	38,138	882	0	240	265	37,519	1,164,530	7,394	10,775	0	17,792	55	0	89,291	**2,042,339**	**19.6**
Cephalopods																	
	Cephalopods	34	0	0	0	0	0	0	0	0	0	0	0	0	0	**16,968**	**0.2**
Totals																	
	Total	**542,903**	**5,066**	**11,117**	**4,145**	**265**	**375,456**	**1,268,898**	**281,722**	**73,334**	**13,292**	**228,364**	**4,500**	**17,907**	**1,681,383**	**10,401,673**	**100**
	%	**5.2**	**0**	**0.1**	**0**	**0**	**3.6**	**12.2**	**2.7**	**0.7**	**0.1**	**2.2**	**0**	**0.2**	**16.2**	**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) (2019)

		AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals																
	Rodents															
	Mice	181,390	257,040	2,145	2,156	63,127	1,150,361	159,977	1,415	25,658	408,895	48,855	1,055,948	18,484	61,745	95,596
	Rats	4,748	17,075	2,310	0	20,071	194,586	37,726	285	2,030	48,536	9,960	162,120	6,446	31,663	22,994
	Guinea-Pigs	118	11,142	2,687	0	2,053	9,871	3,913	0	8	8,116	2	37,423	107	3,529	603
	Hamsters (Syrian)	291	806	20	0	20	1,054	6	0	0	848	180	5,912	0	0	6
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	17	0	0	0
	Mongolian gerbil	113	108	0	0	12	2,793	0	0	0	0	0	428	0	0	0
	Other rodents	14	166	0	0	168	13,861	33	0	0	1,279	2,315	1,582	0	0	0
	Rabbits															
	Rabbits	986	63,094	1,158	0	4,265	94,224	2,304	65	407	20,565	160	135,340	12	1,052	552
	Carnivores															
	Cats	35	227	54	0	25	954	1	0	12	542	178	1,007	0	24	0
	Dogs	155	1,302	8	0	442	3,519	379	0	8	1,463	2,196	4,888	0	367	0
	Ferrets	0	0	0	0	40	124	0	0	0	96	0	150	0	0	403
	Other carnivores	0	0	0	0	0	301	3,843	0	0	5	91	24	0	0	0
	Farm animals															
	Horses, donkeys and cross-breeds	90	110	10	0	125	773	51	0	0	281	45	695	18	19	29
	Pigs	1,840	5,285	36	0	2,592	19,831	8,643	4	332	9,410	919	12,603	2	2,528	323
	Goats	10	64	12	0	35	429	51	0	0	348	0	807	0	0	26
	Sheep	97	538	283	0	925	4,845	18	0	0	2,261	1,243	4,895	15	47	962
	Cattle	584	1,420	9	0	2,179	6,623	1,185	866	0	1,155	272	2,195	0	40	5,420
	Non-human primates															
	Prosimians	0	0	0	0	0	140	0	0	0	0	0	109	0	0	0
	Marmoset and tamarins	0	0	0	0	0	96	0	0	0	0	0	172	0	0	0
	Cynomolgus monkey	0	0	0	0	0	2,880	0	0	0	225	0	2,923	0	0	0
	Rhesus monkey	0	37	0	0	0	86	0	0	1	1	0	63	0	1	0
	Vervets Chlorocebus spp.	0	0	0	0	0	8	0	0	0	0	0	28	0	0	0
	Baboons	0	0	0	0	0	6	0	0	0	3	0	24	0	0	0
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	13	0	0	0	0	0	20	0	0	0
	Other mammals															
	Other mammals	73	177	0	0	154	1,942	42	0	0	127	119	179	0	0	31
Birds																
	Domestic fowl	2,087	35,292	605	0	23,195	24,740	1,269	58	200	98,252	2,785	76,624	2,840	24,612	80
	Other birds	155	6,411	115	0	2,562	10,772	439	204	0	3,200	1,296	37,982	0	739	673
Reptiles																
	Reptiles	0	301	0	0	424	95	53	0	0	979	0	6,151	0	0	0
Amphibians																
	Rana	0	0	4,840	0	0	381	452	0	0	0	0	260	0	0	0
	Xenopus	673	841	0	0	75	11,771	391	0	0	401	0	5,677	0	0	16
	Other amphibians	3,598	265	305	0	0	5,208	72	0	0	775	0	573	0	6,280	0
Fish																
	Zebra fish	6,538	32,365	0	5	6,219	90,788	3,935	0	543	32,995	8,784	42,464	0	1,103	5,219
	Other fish	15,583	10,692	840	0	107,393	202,703	24,742	158	18,569	99,982	13,492	177,188	0	1,754	5,506
Cephalopods																
	Cephalopods	0	0	0	0	0	17	0	0	87	16,756	0	96	0	0	0
Totals																
	Total	**219,178**	**444,758**	**15,437**	**2,161**	**236,101**	**1,855,795**	**249,525**	**3,055**	**47,855**	**757,496**	**92,892**	**1,776,567**	**27,924**	**135,503**	**138,439**
	%	**2.1**	**4.2**	**0.1**	**0**	**2.2**	**17.5**	**2.4**	**0**	**0.5**	**7.1**	**0.9**	**16.7**	**0.3**	**1.3**	**1.3**

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) (2019)

		IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Total	%
Mammals																	
	Rodents																
	Mice	326,803	2,790	10,694	3,178	0	146,997	45,320	148,256	50,589	7,581	160,174	4,932	8,272	**1,066,711**	**5,515,089**	52
	Rats	101,066	886	117	717	0	80,819	3,160	46,956	6,279	4,571	15,502	94	8,517	**163,433**	**992,667**	9.4
	Guinea-Pigs	16,102	15	0	0	0	9,108	386	11,802	0	332	437	0	607	**6,934**	**125,295**	1.2
	Hamsters (Syrian)	434	0	0	0	0	684	0	242	0	50	0	0	0	**1,583**	**12,136**	0.1
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**17**	0
	Mongolian gerbil	0	0	0	0	0	54	0	320	0	0	0	0	12	**271**	**4,111**	0
	Other rodents	642	0	0	0	0	1,066	1,572	10,972	7	0	304	0	0	**904**	**34,885**	0.3
	Rabbits																
	Rabbits	11,156	88	0	6	0	12,964	14	2,444	84	264	2,765	51	190	**10,190**	**364,400**	3.4
	Carnivores																
	Cats	0	0	0	0	0	171	1	24	0	0	288	0	13	**152**	**3,708**	0
	Dogs	657	0	0	0	0	550	66	22	0	0	364	0	0	**4,255**	**20,641**	0.2
	Ferrets	22	0	0	0	0	641	0	0	0	0	25	0	0	**428**	**1,929**	0
	Other carnivores	0	0	0	0	0	68	120	116	0	0	115	0	0	**373**	**5,056**	0
	Farm animals																
	Horses, donkeys and cross-breeds	15	0	0	0	0	101	139	42	0	2	340	2	0	**10,512**	**13,399**	0.1
	Pigs	1,421	213	0	24	0	11,544	466	2,072	208	39	1,730	8	0	**5,043**	**87,116**	0.8
	Goats	23	0	0	0	0	321	0	26	84	0	53	0	0	**83**	**2,372**	0
	Sheep	294	5	0	0	0	393	517	906	0	246	442	42	28	**53,972**	**72,974**	0.7
	Cattle	397	0	0	0	0	4,207	110	290	0	2	1,621	0	0	**6,786**	**35,361**	0.3
	Non-human primates																
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**249**	0
	Marmoset and tamarins	4	0	0	0	0	0	0	0	0	0	0	0	0	**110**	**382**	0
	Cynomolgus monkey	328	0	0	0	0	38	0	0	0	0	20	0	0	**2,616**	**9,030**	0.1
	Rhesus monkey	2	0	0	0	0	117	0	0	0	0	8	0	0	**124**	**440**	0
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**36**	0
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**33**	0
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**33**	0
	Other mammals																
	Other mammals	86	0	0	0	0	294	642	1,140	3	0	200	0	0	**578**	**5,787**	0.1
Birds																	
	Domestic fowl	38,578	0	0	0	0	52,430	1,184	12,550	0	283	1,994	127	249	**122,766**	**522,800**	4.9
	Other birds	718	187	0	80	0	13,864	11,570	13,580	422	6	10,810	0	31	**8,730**	**124,546**	1.2
Reptiles																	
	Reptiles	0	0	0	0	0	1	26	80	0	0	139	0	0	**0**	**8,249**	0.1
Amphibians																	
	Rana	0	0	0	0	0	0	0	0	0	240	0	0	0	**148**	**6,321**	0.1
	Xenopus	814	0	0	0	0	284	0	0	247	0	171	0	0	**5,232**	**26,593**	0.3
	Other amphibians	15	0	0	0	0	720	319	736	0	0	2,041	0	0	**355**	**21,262**	0.2
Fish																	
	Zebra fish	12,375	0	349	0	0	7,587	39,129	22,866	5,312	0	18,350	0	0	**188,244**	**525,170**	5
	Other fish	38,142	882	0	240	265	37,519	1,164,991	7,394	12,125	0	17,873	55	0	**91,599**	**2,049,687**	19.3
Cephalopods																	
	Cephalopods	34	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**16,990**	0.2
Totals																	
	Total	**550,128**	**5,066**	**11,160**	**4,245**	**265**	**382,542**	**1,269,732**	**282,836**	**75,360**	**13,616**	**235,766**	**5,311**	**17,919**	**1,752,132**	**10,608,764**	**100**
	%	**5.2**	**0**	**0.1**	**0**	**0**	**3.6**	**12**	**2.7**	**0.7**	**0.1**	**2.2**	**0.1**	**0.2**	**16.5**	**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)] (2019)

	Reuse[2)]	AT	BE	CY	CZ	DE	DK	EL	ES	FI	FR	HR	HU	IE	IT	LU	NL	NO	PL	PT	SE	SI	UK	Total	%
Mice	No	16,141	24,281	25	14,737	90,641	1,679	5,165	20,676	3,993	18,382	0	170	175	3,331	127	4,327	1,192	404	1,217	6,929	6	157,314	**370,912**	**99.7**
	Yes	0	0	0	0	527	0	0	35	0	5	0	0	0	0	0	0	0	0	0	115	0	365	**1,047**	**0.3**
	Total	**16,141**	**24,281**	**25**	**14,737**	**91,168**	**1,679**	**5,165**	**20,711**	**3,993**	**18,387**	**0**	**170**	**175**	**3,331**	**127**	**4,327**	**1,192**	**404**	**1,217**	**7,044**	**6**	**157,679**	371,959	100.0
Rats	No	0	396	0	319	332	51	0	0	0	2,534	0	0	0	3	0	0	0	0	0	0	0	20	**3,655**	**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**	**0.0**
	Total	**0**	**396**	**0**	**319**	**332**	**51**	**0**	**0**	**0**	**2,534**	**0**	**0**	**0**	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	3,655	100.0
Hamsters (Syrian)	No	0	80	0	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**116**	**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**	**0.0**
	Total	**0**	**80**	**0**	**36**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	116	100.0
Rabbits	No	0	0	0	0	16	0	0	21	0	268	0	0	0	0	0	0	0	0	0	0	0	0	**305**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**16**	**0**	**0**	**21**	**0**	**268**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	305	100.0
Pigs	No	0	0	0	0	91	0	0	0	0	14	0	0	0	15	0	0	0	0	0	0	0	145	**265**	**98.5**
	Yes	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**4**	**1.5**
	Total	**0**	**0**	**0**	**0**	**95**	**0**	**0**	**0**	**0**	**14**	**0**	**0**	**0**	**15**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**145**	269	100.0
Sheep	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	41	**41**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**41**	41	100.0
Cattle	No	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	**1**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	1	100.0
Marmoset and tamarins	No	0	0	0	0	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**43**	**91.5**
	Yes	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**4**	**8.5**
	Total	**0**	**0**	**0**	**0**	**47**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	47	100.0
Other mammals	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	1	**13**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**12**	**0**	**0**	**0**	**1**	13	100.0
Domestic fowl	No	0	0	0	90	196	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	880	**1,166**	**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**	**0.0**
	Total	**0**	**0**	**0**	**90**	**196**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**880**	1,166	100.0
Other birds	No	0	0	0	0	10	0	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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	10	100.0
Xenopus	No	0	0	0	0	1,748	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	39	**1,787**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**1,748**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**39**	1,787	100.0
Other amphibians	No	0	0	0	0	271	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**271**	**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**	**0.0**
	Total	**0**	**0**	**0**	**0**	**271**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	271	100.0
Zebra fish	No	2,443	6,750	0	0	48,498	722	0	4,097	1,296	3,964	28	960	0	354	88	1,243	1,885	72	269	16,022	0	37,875	**126,566**	**98.5**
	Yes	0	0	0	0	0	0	20	0	0	0	0	0	0	0	0	0	0	0	0	717	0	1,236	**1,973**	**1.5**
	Total	**2,443**	**6,750**	**0**	**0**	**48,498**	**722**	**20**	**4,097**	**1,296**	**3,964**	**28**	**960**	**0**	**354**	**88**	**1,243**	**1,885**	**72**	**269**	**16,739**	**0**	**39,111**	128,539	100.0
Other fish	No	226	0	0	0	1,385	0	0	861	0	0	0	0	0	0	0	0	650	0	0	0	0	47	**3,169**	**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**	**0.0**
	Total	**226**	**0**	**0**	**0**	**1,385**	**0**	**0**	**861**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**650**	**0**	**0**	**0**	**0**	**47**	3,169	100.0
All Species	**No**	**18,810**	**31,507**	**25**	**15,182**	**143,231**	**2,452**	**5,165**	**25,655**	**5,289**	**25,162**	**28**	**1,130**	**175**	**3,704**	**215**	**5,570**	**3,727**	**488**	**1,486**	**22,951**	**6**	**196,362**	**508,320**	**99.4**
	Yes	**0**	**0**	**0**	**0**	**535**	**0**	**20**	**35**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**832**	**0**	**1,601**	3,028	0.6
	Total	**18,810**	**31,507**	**25**	**15,182**	**143,766**	**2,452**	**5,185**	**25,690**	**5,289**	**25,167**	**28**	**1,130**	**175**	**3,704**	**215**	**5,570**	**3,727**	**488**	**1,486**	**23,783**	**6**	**197,963**	511,348	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] (2019)

	Reuse[2]	AT	BE	DE	DK	EL	ES	FI	FR	HR	IE	IT	NL	NO	PL	PT	RO	SE	SK	UK	Total	%
Mice	No	8,327	17,716	191,080	6,043	1,571	31,155	276	57,388	732	729	2,326	1,194	7,838	810	2,571	19	976	353	**282,818**	**613,922**	99.0
	Yes	0	1	5,727	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**449**	**6,177**	1.0
	Total	**8,327**	**17,717**	**196,807**	**6,043**	**1,571**	**31,155**	**276**	**57,388**	**732**	**729**	**2,326**	**1,194**	**7,838**	**810**	**2,571**	**19**	**976**	**353**	283,267	620,099	**100.0**
Rats	No	0	0	2,055	0	0	0	0	1,591	0	0	0	0	164	0	0	0	0	125	**5,692**	**9,627**	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
	Total	**0**	**0**	**2,055**	**0**	**0**	**0**	**0**	**1,591**	**0**	**0**	**0**	**0**	**164**	**0**	**0**	**0**	**0**	**125**	5,692	9,627	**100.0**
Dogs	No	0	0	0	0	0	0	0	10	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
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	0	10	**100.0**
Domestic fowl	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**405**	**405**	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
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	405	405	**100.0**
Xenopus	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**189**	**189**	52.5
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**171**	**171**	47.5
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	360	360	**100.0**
Zebra fish	No	0	0	3,258	0	0	3,401	0	4,680	0	0	0	17	114	0	30	0	0	0	**62,521**	**74,021**	98.4
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0	0	0	**1,221**	**1,241**	1.6
	Total	**0**	**0**	**3,258**	**0**	**0**	**3,401**	**0**	**4,680**	**0**	**0**	**0**	**17**	**134**	**0**	**30**	**0**	**0**	**0**	63,742	75,262	**100.0**
Other fish	No	0	0	911	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**900**	**1,811**	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**
	Total	**0**	**0**	**911**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	900	1,811	**100.0**
All Species	**No**	**8,327**	**17,716**	**197,304**	**6,043**	**1,571**	**34,556**	**276**	**63,669**	**732**	**729**	**2,326**	**1,211**	**8,116**	**810**	**2,601**	**19**	**976**	**478**	352,525	699,985	**98.9**
	Yes	**0**	**1**	**5,727**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	**0**	**0**	**0**	**0**	**0**	1,841	7,589	**1.1**
	Total	**8,327**	**17,717**	**203,031**	**6,043**	**1,571**	**34,556**	**276**	**63,669**	**732**	**729**	**2,326**	**1,211**	**8,136**	**810**	**2,601**	**19**	**976**	**478**	354,366	707,574	**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.