Member State: Belgium

All uses of animals by species

Animal Species	Number of uses	Percentage
Mice	348,937	62.73%
Rats	20,003	3.60%
Guinea-Pigs	14,029	2.52%
Hamsters (Syrian)	772	0.14%
Hamsters (Chinese)		0.1170
Mongolian gerbil	105	0.02%
Other Rodents	55	0.01%
Rabbits	61,575	11.07%
Cats	34	0.01%
Dogs	1,684	0.30%
Ferrets	1,001	0.00%
Other carnivores		
Horses, donkeys & cross-breeds	302	0.05%
Pigs	5,429	0.98%
Goats	59	0.01%
Sheep	528	0.09%
Cattle	850	0.15%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey	2	0.00%
Rhesus monkey	41	0.01%
Vervets Chlorocebus spp.		
Baboons		
Squirrel monkey		
Other species of New World Monkeys (Ceboidea)		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of non-human primates		
Apes		
Other Mammals	171	0.03%
Domestic fowl	39,203	7.05%
Other birds	6,209	1.12%
Reptiles	324	0.06%
Rana		
Xenopus	839	0.15%
Other Amphibians	277	0.05%
Zebra fish	25,904	4.66%
Other Fish	28,939	5.20%
Cephalopods		
Total uses	556,271	100.00%

Year: 2018

Origin as registered at the first use

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	521,063	94.46%
Animals born in the EU but not at a registered breeder	25,545	4.63%
Animals born in rest of Europe	309	0.06%
Animals born in rest of world	4,677	0.85%
Total uses	551,594	100.00%

NHP Source (origin)	Number of uses	Percentage
Animals born at a registered breeder within EU	5	71.43%
Animals born in rest of Europe		
Animals born in Asia	2	28.57%
Animals born in America		
Animals born in Africa		
Animals born elsewhere		
Total uses	7	100.00%

NHP Generation	Number of uses	Percentage
F0		
F1		
F2 or greater	7	100.00%
Self-sustaining colony		
Total uses	7	100.00%

Purpose for which animals are used

Purpose Category level 1	Number of uses	Percentage
Basic Research	251,704	45.25%
Translational and applied research	121,645	21.87%
Regulatory use and Routine production	140,896	25.33%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	359	0.06%
Preservation of species	5,598	1.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	7,442	1.34%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	28,627	5.15%
Total uses	556,271	100.00%

Basic Research	Number of uses	Percentage
Oncology	56,000	22.25%
Cardiovascular Blood and Lymphatic System	17,701	7.03%
Nervous System	38,643	15.35%
Respiratory System	4,937	1.96%
Gastrointestinal System including Liver	19,826	7.88%
Musculoskeletal System	7,950	3.16%
Immune System	50,786	20.18%
Urogenital/Reproductive System	5,230	2.08%
Sensory Organs (skin, eyes and ears)	3,096	1.23%
Endocrine System/Metabolism	14,773	5.87%
Multisystemic	6,356	2.53%
Ethology / Animal Behaviour /Animal Biology	14,256	5.66%
Other basic research	12,150	4.83%
Total uses	251,704	100.00%

Translational and applied research	Number of uses	Percentage
Human Cancer	18,138	14.91%
Human Infectious Disorders	15,412	12.67%
Human Cardiovascular Disorders	1,332	1.09%
Human Nervous and Mental Disorders	28,971	23.82%
Human Respiratory Disorders	6,783	5.58%
Human Gastrointestinal Disorders including Liver	1,706	1.40%
Human Musculoskeletal Disorders	984	0.81%
Human Immune Disorders	2,435	2.00%
Human Urogenital/Reproductive Disorders	839	0.69%
Human Sensory Organ Disorders (skin, eyes and ears)	5,709	4.69%
Human Endocrine/Metabolism Disorders	1,749	1.44%
Other Human Disorders	22	0.02%
Animal Diseases and Disorders	22,693	18.66%
Animal Welfare	2,323	1.91%
Diagnosis of diseases	5,038	4.14%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	7,511	6.17%
Total uses	121,645	100.00%

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Quality control (incl batch safety and potency testing) 61,229 43.46% Other efficacy and tolerance testing 18,296 12,99% Toxicity and other safety testing including pharmacology 4,407 3.13% Routine production 56,964 40,43% Total uses 140,896 100,00% Regulatory use and routine production – Quality control (incl batch safety and potency testing) Number of uses Percentage Batch safety testing 5,225 8,53% Pyrogenicity testing 53,362 87,15% Other quality controls 2,642 4,31% Total uses 61,229 100,00% Regulatory use and routine production - Toxicity and other safety testing including pharmacology Number of uses Percentage Acute and sub-acute 821 18,63% Skin irritation/corrosion 821 18,63% Eye irritation/corrosion 850 19,29% Carcinogenicity 66,000 3 0,07%
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Repeated dose toxicity 850 19.29% Carcinogenicity
Carcinogenicity
0 070
Genetovicity 3 0.07%
Octionolity 0
Reproductive toxicity
Developmental toxicity
Neurotoxicity
Kinetics 486 11.03%
Pharmaco-dynamics (incl safety pharmacology)
Phototoxicity
Ecotoxicity 1,096 24.87%
Safety testing in food and feed area 971 22.03%
Target animal safety 4.08%
Other toxicity/safety testing
Total uses 4,407 100.00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Acute and sub-acute toxicity testing methods Number of uses Percentage
LD50, LC50 31.0 37.76%
Other lethal methods
Non lethal methods 511 62.24%
Total uses 821 100.00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Repeated dose toxicity Number of uses Percentage
up to 28 days 730 85.88%

Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Acute and sub-acute toxicity testing methods	Number of uses	Percentage
LD50, LC50	310	37.76%
Other lethal methods		
Non lethal methods	511	62.24%
Total uses	821	100.00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Repeated dose toxicity	Number of uses	Percentage
up to 28 days	730	85.88%
29 - 90 days	120	14.12%
> 90 days		
Total uses	850	100.00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Ecotoxicity	Number of uses	Percentage
Acute toxicity	1,096	100.00%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total uses	1,096	100.00%

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Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products	56,918	99.92%
Monoclonal antibody by mouse ascites method	11	0.02%
Other product types	35	0.06%
Total uses	56,964	100.00%

Use of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	112,808	80.06%
Legislation on medicinal products for veterinary use and their residues	25,097	17.81%
Medical devices legislation	1,047	0.74%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	740	0.53%
Feed legislation including legislation for the safety of target animals, workers and environment	62	0.04%
Cosmetics legislation		
Other legislation	1,142	0.81%
Total uses	140,896	100.00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	125,984	89.42%
Legislation satisfying national requirements only [within EU]	310	0.22%
Legislation satisfying Non-EU requirements only	14,602	10.36%
Total uses	140,896	100.00%

First use and re-use

Re-Use	Number of uses	Percentage
No	551,601	99.16%
Yes	4,670	0.84%
Total uses	556,271	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	20,565	3.70%
Mild [up to and including]	311,660	56.03%
Moderate	154,633	27.80%
Severe	69,413	12.48%
Total uses	556,271	100.00%

Use in creation of a new genetic line

Creation of New GL	Number of uses	Percentage
No	521,106	93.68%
Yes	35,165	6.32%
Total uses	556,271	100.00%

Use by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	393,969	70.82%
Genetically altered without a harmful phenotype	139,715	25.12%
Genetically altered with a harmful phenotype	22,587	4.06%
Total uses	556,271	100.00%

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MEMBER STATE NARRATIVE 2018

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

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

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

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

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

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

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

Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
Mammals	441476	442398	454576
Birds	30734	46812	45412
Fish	62221	52462	54843
Amphibians	1226	1241	1116
Reptiles	172	181	324
Cephalopods	0	0	0
Total uses	535829	543094	556271

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

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

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

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

Animal Species	Number of use in 2016	Number of use in 2017	Number of use in 2018
Domestic fowl	26230	39674	39203
Other birds	4504	7138	6209

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

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

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

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

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

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

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

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

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

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

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

1. Other fish

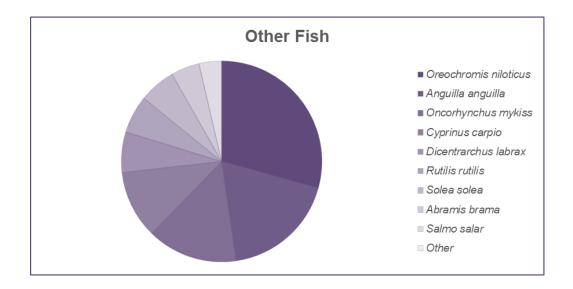
52,77% of the fishes are reported under the "other" category.

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

Other Species	Number of uses
Oreochromis niloticus	7656
Anguilla anguilla	4811
Oncorhynchus mykiss	3820
Cyprinus carpio	2853
Dicentrarchus labrax	1700
Rutilis rutilis	1600
Solea solea	1544
Abramis brama	1200
Salmo salar	955
Nothobranchius furzeri	567
Gasterosteus aculeatus	547
Kryptolebias marmoratus	460
Poecilia reticulata	300

Lota lota	270
Pleuronectes platessa	131
Limanda limanda	104
Gadus morhua	65
Clarias gariepinus	50
Raja clavata	38
Ophthalmotilapia ventralis	28
Synodontis grandiops	26
Microsynodontis batesii	16
Pseudotropheus saulosi	14
Neogobius melanostomus	12
Ophthalmotilapia nasuta	11
Pygocentrus nattereri	9
Poecilia sphenops	8
Raja brachyura	8
Nimbochromis venustus	7
Parophidion vasali	7
Myleus schomburgkii	6
Synodontis eupterus	6
Alosa fallax	5
Carassius auratus	5
Catoprion mento	5
Metynnis hypsauchen	5
Piaractus brachypomus	5
Pygopristis denticulata	5
Gerochromis niloticus	4
Raja undulata	4
Synodontis njassae	4
Synodontis soloni	4
Botia morleti	3
Chromobotia macracanthus	3
Idotropheus sprengerae	3
Myloplus rubripinnis	3
Pantodon buchholzi	3
Pygocentrus cariba	3
Sahyadria denisonii	3
Serrasalmus maculatus	3
Serrasalmus spilopleura	3
Synodontis ilebrevis	3
Ancistrus dolichopterus	2
Botia modesta	2
Epalzeorhynchos bicolor	2
Helostoma temminkii	2
Iodotropheus sprengerae	2
Maylandia zebra	2
Pangasianodon hypophthalmus	2
Pangasius sp.	2
Pygocentrus piraya	2
Raja montagui	2

Serrasalmus elongatus	2
Synodontis sp.	2
Colossoma macropomum	1
Corydoras panda	1
Corydoras sp.	1
Hyphessobrycon sp.	1
Hypostomus plecostomus	1
Metynnis lippincottianus	1
Pterophyllum confer scalare	1
Puntigrus tetrazona	1
Serrasalmus manueli	1
Synodontis victoriae	1
Total uses:	28939



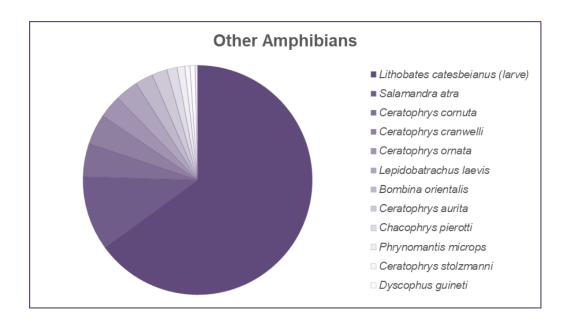
2. Other amphibians

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

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

Other Amphibians	Number of uses
Lithobates catesbeianus (larve)	180
Salamandra atra	29
Ceratophrys cornuta	13
Ceratophrys cranwelli	12
Ceratophrys ornata	9

Lepidobatrachus laevis	9
Bombina orientalis	7
Ceratophrys aurita	6
Chacophrys pierotti	4
Phrynomantis microps	3
Ceratophrys stolzmanni	2
Dyscophus guineti	2
Xenopus muelleri	1
Total uses:	277



3. Other birds

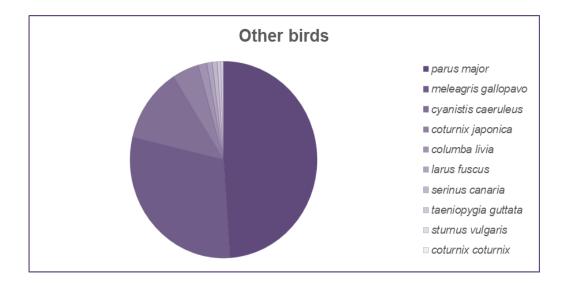
13,67% of the birds are reported under the "other" category.

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

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

Other Birds	Number of uses
Parus major	3038
Meleagris gallopavo	1847
Cyanistis caeruleus	764
Coturnix japonica	287
Columba livia	94
Larus fuscus	58

Serinus canaria	53
Taeniopygia guttata	38
Sturnus vulgaris	24
Coturnix coturnix	6
Total uses:	6209



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

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