## Member State: Belgium

## All uses of animals by species

Animal Species	Number of uses	Percentage
Mice	299038	60,54%
Rats	17471	3,54%
Guinea-Pigs	11142	2,26%
Hamsters (Syrian)	886	0,18%
Hamsters (Chinese)		
Mongolian gerbil	108	0,02%
Other rodents	166	0,03%
Rabbits	63094	12,77%
Cats	227	0,05%
Dogs	1302	0,26%
Ferrets		
Other carnivores		
Horses, donkeys and cross-	440	0.000/
breeds	110	0,02%
Pigs	5285	1,07%
Goats	64	0,01%
Sheep	538	0,11%
Cattle	1420	0,29%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	37	0,01%
Vervets (Chlorocebus spp.)		
Baboons		
Squirrel monkey		
Other species of Old World Monkeys (Cercopithecoidea)		
Other species of New World		
Monkeys (Ceboidea)		
Apes		
Other mammals	177	0,04%
Domestic fowl	35292	7,14%
Other birds	6411	1,30%
Reptiles	301	0,06%
Rana		
Xenopus	841	0,17%
Other amphibians	265	0,05%
Zebra fish	39115	7,92%
Other fish	10692	2,16%
Cephalopods		
Total uses	493982	100,00%

## Year: 2019

## Origin as registered at the first use

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	471718	96,31%
Animals born in the EU but not at a registered breeder	14822	3,03%
Animals born in rest of Europe	411	0,08%
Animals born in rest of world	2856	0,58%
Total uses	489807	100,00%

NHP Source (origin)	Number of uses	Percentage
Animals born at a registered breeder within EU	6	85,71%
Animals born in rest of Europe		
Animals born in Asia	1	14,29%
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	222946	45,13%
Translational and applied research	130724	26,46%
Regulatory use and Routine production	115267	23,33%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	798	0,16%
Preservation of species	243	0,05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6287	1,27%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	17717	3,59%
Total uses	493982	100,00%

Basic Research	Number of uses	Percentage
Oncology	49827	22,35%
Cardiovascular Blood and Lymphatic System	14890	6,68%

Nervous System	26973	12,10%
Respiratory System	6539	2,93%
Gastrointestinal System including Liver	23141	10,38%
Musculoskeletal System	9083	4,079
Immune System	53357	23,939
Urogenital/Reproductive System	5554	2,499
Sensory Organs (skin, eyes and ears)	2329	1,049
Endocrine System/Metabolism	9634	4,329
Multisystemic	5527	2,489
Ethology / Animal Behaviour /Animal Biology	7889	3,549
Other basic research	8203	3,689
Total uses	222946	100,00%
Translational and applied research	Number of uses	Percentaç
Human Cancer	18993	14,539
Human Infectious Disorders	16936	12,969
Human Cardiovascular Disorders	1473	1,139
Human Nervous and Mental Disorders	30580	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	2,430
Human Urogenital/Reproductive Disorders	1099	0,849
Human Sensory Organ Disorders (skin, eyes and ears)	4409	3,379
Human Endocrine/Metabolism Disorders	1756	1,34
Other Human Disorders	2144	1,649
Animal Diseases and Disorders	26379	20,189
Animal Welfare	2986	2,289
Diagnosis of diseases	5443	4,169
Plant diseases		, -
Non-regulatory toxicology and ecotoxicology	4893	3,749
Total uses	130724	100,00%
	!	
egulatory use and routine Production	Number of uses	Percentag
uality control (incl batch safety and potency testing)	42666	37,019
ther efficacy and tolerance testing	9029	7,839
oxicity and other safety testing including pharmacology	4938	4,289
outine production	58634	50,879
otal uses	115267	100,00%
Regulatory use and routine production – Quality control (incl batch safety and potency testing)	Number of uses	Percentag
Batch safety testing	3918	9,189
Pyrogenicity testing  Batch potency testing	36928	86,559
Other quality controls	1820	4,279
Total uses	<b>42666</b>	100,00%
pharmacology	Number of uses	Percentaç
Acute and sub-acute	604	12,239
Skin irritation/corrosion		
Skin sensitisation		
Eye irritation/corrosion		
Repeated dose toxicity	1017	20,60
Constitution and the		
Carcinogenicity	73	1,489
Carcinogenicity  Genotoxicity	73	
	73	
Genotoxicity	73	
Genotoxicity Reproductive toxicity	13	
Genotoxicity  Reproductive toxicity  Developmental toxicity	839	16,99 <sup>0</sup>
Genotoxicity  Reproductive toxicity  Developmental toxicity  Neurotoxicity		16,99 <sup>0</sup> 1,13 <sup>0</sup>
Genotoxicity Reproductive toxicity Developmental toxicity Neurotoxicity Kinetics	839	•
Genotoxicity Reproductive toxicity Developmental toxicity Neurotoxicity Kinetics Pharmaco-dynamics (incl safety pharmacology)	839	•

Target animal safety	1153	23,35%
Other toxicity/safety testing		
Total uses	4938	100,00%

Regulatory use and routine production – Toxicity and other safety testing including	Number of uses	Davaantawa
pharmacology – Acute and sub-acute toxicity testing methods		Percentage
LD50, LC50	290	48,01%
Other lethal methods		
Non lethal methods	314	51,99%
Total uses	604	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	1010	99,31%
29 - 90 days	7	0,69%
> 90 days		
Total uses	1017	100,00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Ecotoxicity	Number of uses	Percentage
Acute toxicity	443	100,00%
Chronic toxicity		
Reproductive ecotoxicity		
Endocrine activity		
Bioaccumulation		
Other ecotoxicity		
Total uses	443	100,00%

Regulatory use and routine production – Routine production	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 uses	58634	100,00%

## Use of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	97276	84,39%
Legislation on medicinal products for veterinary use and their residues	15280	13,26%
Medical devices legislation	853	0,74%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	222	0,19%
Feed legislation including legislation for the safety of target animals, workers and environment	1104	0,96%
Cosmetics legislation		
Other legislation	532	0,46%
Total uses	115267	100,00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	102111	88,59%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	13156	11,41%
Total uses	115267	100,00%

## First use and re-use

Re-Use	Number of uses	Percentage
No	489814	99,16%
Yes	4168	0,84%
Total uses	493982	100,00%

## Use in creation of a new genetic line

Creation of New GL	Number of uses	Percentage
No	462475	93,62%
Yes	31507	6,38%
Total uses	493982	100.00%

## Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	14074	2,85%
Mild [up to and including]	284376	57,57%
Moderate	131963	26,71%
Severe	63569	12,87%
Total uses	493982	100,00%

## Use by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	334862	67,79%
Genetically altered without a harmful phenotype	136259	27,58%
Genetically altered with a harmful phenotype	22861	4,63%
Total uses	493982	100,00%

#### **MEMBER STATE 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	9954	7440	2007
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 ornata, 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.