Member State: Belgium

All uses of animals by species

Animal Species	Number of uses	Percentage
Mice	251,913	57.61%
Rats	13,760	3.15%
Guinea-Pigs	11,656	2.67%
Hamsters (Syrian)	2,985	0.68%
Hamsters (Chinese)		
Mongolian gerbil	14	0.00%
Other rodents	213	0.05%
Rabbits	70,761	16.18%
Cats	253	0.06%
Dogs	1,519	0.35%
Ferrets		
Other carnivores		
Horses, donkeys and cross- breeds	199	0.05%
Pigs	5,767	1.32%
Goats	69	0.02%
Sheep	503	0.12%
Cattle	2,329	0.53%
Prosimians		
Marmoset and tamarins		
Cynomolgus monkey		
Rhesus monkey	36	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	110	0.03%
Domestic fowl	41,115	9.40%
Other birds	4,831	1.10%
Reptiles	105	0.02%
Rana		
Xenopus	957	0.22%
Other amphibians	54	0.01%
Zebra fish	22,804	5.22%
Other fish	5,322	1.22%
Cephalopods		
Total uses	437,275	100.00%

Year: 2020

Origin as registered at the first use

Place of Birth	Number of uses	Percentage
Animals born in the EU at a registered breeder	406,266	93.59%
Animals born in the EU but not at a registered breeder	24,707	5.69%
Animals born in rest of Europe	345	0.08%
Animals born in rest of world	2,761	0.64%
Total uses	434,079	100.00%

NHP Source (origin)	Number of uses	Percentage
Animals born at a registered breeder within EU	4	66.67%
Animals born in rest of Europe		
Animals born in Asia		
Animals born in America	2	33.33%
Animals born in Africa		
Animals born elsewhere		
Total uses	6	100.00%

NHP Generation	Number of uses	Percentage
F0		
F1		
F2 or greater	6	100.00%
Self-sustaining colony		
Total uses	6	100.00%

i aipose ioi willeli allillais ale asca

Purpose Category level 1	Number of uses	Percentage
Basic Research	168,821	38.61%
Translational and applied research	120,505	27.56%
Regulatory use and Routine production	127,262	29.10%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	743	0.17%
Preservation of species	371	0.08%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3,827	0.88%
Forensic enquiries		
Maintenance of colonies of established genetically altered animals, not used in other procedures	15,746	3.60%
Total uses	437,275	100.00%

Basic Research	Number of uses	Percentage
Oncology	40,181	23.80%
Cardiovascular Blood and Lymphatic System	9,645	5.71%
Nervous System	22,108	13.10%
Respiratory System	5,090	3.02%
Gastrointestinal System including Liver	17,033	10.09%
Musculoskeletal System	5,632	3.34%
Immune System	40,828	24.18%
Urogenital/Reproductive System	4,408	2.61%
Sensory Organs (skin, eyes and ears)	1,789	1.06%
Endocrine System/Metabolism	8,433	5.00%
Multisystemic	5,103	3.02%
Ethology / Animal Behaviour /Animal Biology	2,430	1.44%
Other basic research	6,141	3.64%
Total uses	168,821	100.00%

Translational and applied research	Number of uses	Percentage
Human Cancer	19,769	16.41%
Human Infectious Disorders	13,798	11.45%
Human Cardiovascular Disorders	1,738	1.44%
Human Nervous and Mental Disorders	22,278	18.49%
Human Respiratory Disorders	5,068	4.21%
Human Gastrointestinal Disorders including Liver	1,864	1.55%
Human Musculoskeletal Disorders	592	0.49%
Human Immune Disorders	3,413	2.83%
Human Urogenital/Reproductive Disorders	783	0.65%
Human Sensory Organ Disorders (skin, eyes and ears)	3,187	2.64%
Human Endocrine/Metabolism Disorders	1,524	1.26%
Other Human Disorders	1,242	1.03%
Animal Diseases and Disorders	27,406	22.74%
Animal Welfare	9,545	7.92%
Diagnosis of diseases	4,124	3.42%
Plant diseases		
Non-regulatory toxicology and ecotoxicology	4,174	3.46%
Total uses	120,505	100.00%

Generated on: 10/18/21 8:46:48 AM GMT+02:00

Regulatory use and routine Production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	45,709	35.92%
Other efficacy and tolerance testing	18,353	14.42%
Toxicity and other safety testing including pharmacology	3,404	2.67%
Routine production	59,796	46.99%
Total uses	127,262	100.00%
Regulatory use and routine production – Quality control (incl batch safety and potency testing)	Number of uses	Percentage
Batch safety testing	4,786	10.47%
Pyrogenicity testing		
Batch potency testing	36,849	80.62%
Other quality controls	4,074	8.91%
Total uses	45,709	100.00%
Regulatory use and routine production - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Acute and sub-acute	364	10.69%
Skin irritation/corrosion		
Skin sensitisation		
Eye irritation/corrosion		
Repeated dose toxicity	534	15.69%
Carcinogenicity		
Genotoxicity	81	2.38%
Reproductive toxicity		
Developmental toxicity		
Neurotoxicity	22	0.65%
Kinetics	861	25.29%
Pharmaco-dynamics (incl safety pharmacology)	29	0.85%
Phototoxicity		
Ecotoxicity	596	17.51%
Safety testing in food and feed area	356	10.46%
Target animal safety	546	16.04%
Other toxicity/safety testing	15	0.44%
Total uses	3,404	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	74	20.33%
Other lethal methods	200	70.0534
Non lethal methods	290	79.67%

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	74	20.33%
Other lethal methods		
Non lethal methods	290	79.67%
Total uses	364	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	514	96.25%
29 - 90 days	20	3.75%
> 90 days		
Total uses	534	100.00%
Regulatory use and routine production – Toxicity and other safety testing including pharmacology – Ecotoxicity	Number of uses	Percentage
	Number of uses	Percentage 100.00%
pharmacology – Ecotoxicity		
pharmacology – Ecotoxicity Acute toxicity		
pharmacology – Ecotoxicity Acute toxicity Chronic toxicity		
pharmacology – Ecotoxicity Acute toxicity Chronic toxicity Reproductive ecotoxicity		
pharmacology – Ecotoxicity Acute toxicity Chronic toxicity Reproductive ecotoxicity Endocrine activity		

Generated on: 10/18/21 8:46:48 AM GMT+02:00

Regulatory use and routine production – Routine production	Number of uses	Percentage
Blood based products	59,728	99.89%
Monoclonal antibody by mouse ascites method		
Other product types	68	0.11%
Total uses	59,796	100.00%

Use of animals to meet legislative requirements

Testing by Legislation	Number of uses	Percentage
Legislation on medicinal products for human use	103,180	81.08%
Legislation on medicinal products for veterinary use and their residues	22,863	17.97%
Medical devices legislation	277	0.22%
Industrial chemicals legislation		
Plant protection product legislation		
Biocides legislation		
Food legislation including food contact material	60	0.05%
Feed legislation including legislation for the safety of target animals, workers and environment	20	0.02%
Cosmetics legislation		
Other legislation	862	0.68%
Total uses	127,262	100.00%

Legislative Requirement	Number of uses	Percentage
Legislation satisfying EU requirements	119,188	93.66%
Legislation satisfying national requirements only [within EU]		
Legislation satisfying Non-EU requirements only	8,074	6.34%
Total uses	127,262	100.00%

First use and re-use

Re-Use	Number of uses	Percentage
No	434,085	99.27%
Yes	3,190	0.73%
Total uses	437,275	100.00%

Actual severity of uses

Severity	Number of uses	Percentage
Non-recovery	9,464	2.16%
Mild [up to and including]	241,487	55.23%
Moderate	139,284	31.85%
Severe	47,040	10.76%
Total uses	437,275	100.00%

Use in creation of a new genetic line

Creation of New GL	Number of uses	Percentage
No	411,974	94.21%
Yes	25,301	5.79%
Total uses	437,275	100.00%

Use by genetic status

Genetic Status	Number of uses	Percentage
Not genetically altered	313,625	71.72%
Genetically altered without a harmful phenotype	104,843	23.98%
Genetically altered with a harmful phenotype	18,807	4.30%
Total uses	437,275	100.00%

Generated on: 10/18/21 8:46:48 AM GMT+02:00

MEMBER STATE NARRATIVE 2020

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

Compared to 2019 (493982 uses), there is a decrease of 11,48% in the number of uses in 2020 (437275 uses). We can assume that the observed decrease is, at least partially, caused by the measures taken because of the Covid19 pandemic in 2020.

Number of use in 2018	Number of use in 2019	Number of use in 2020
556271	493982	437275

Since 2015, the number of re-use continues to decline. Compared to 2019 there is a decrease of 23,46% and even a decrease of 31,69% compared to the numbers of 2018.

Re-Use	Number of use in 2018	Number of use in 2019	Number of use in 2020
No	551601	489814	434085
Yes	4670	4168	3190
Total uses	556271	493982	437275

On the species grouping level, we observe a decrease in mammals, fish, reptiles and amphibians and a slight increase in the use of birds.

Species	Number of use in 2018	Number of use in 2019	Number of use in 2020
Mammals	454576	401065	362087
Birds	45412	41703	45946
Fish	54843	49807	28126
Amphibians	1116	1106	1011
Reptiles	324	301	105
Cephalopods	0	0	0
Total uses	556271	493982	437275

Within the mammals category we notice that the increasing trend in the use of mice has come to an end in 2019. In 2020 the use of mice dropped (decrease of 27,80% compared to 2018 and 15,76% compared to 2019).

There is a noteworthy increase in procedures on hamsters, rabbits and cattle.

The number of tests on hamsters increased from 886 in 2019 to 2985 in 2020 (+236,91%). This is largely due to research being conducted to develop a vaccine and medication against the SARS-CoV-2 virus. Hamsters were used in this type of research because the species is susceptible to corona infections.

The number of tests on rabbits increased from 63.094 in 2019 to 70.761 in 2020 (+12,15%). This increase is mainly due to a specific animal welfare study investigating group housing in rabbit farming.

The number of tests on cattle increased from 1420 in 2019 to 2329 in 2020 (+64,01%). Within the total number of uses of cattle in 2020, almost 75% of the uses can be explained by one specific project in which the genetic diversity of old cattle breeds was mapped by taking a small ear biopsy of a large number of farm animals.

Animal Species	Number of use in 2018	Number of use in 2019	Number of use in 2020
Mice	348937	299038	251913
Hamsters	772	886	2985
Rabbits	61575	63094	70761
Cattle	850	1420	2329

In the birds category, there is an increase for domestic fowl compared to 2019 (+16,49%). This is due to the increasing number of floorpen studies that are mainly performed in the context of the registration or re-registration of coccidiostats. The use of other birds decreased (-24,65%).

Animal Species	Number of use in 2018	Number of use in 2019	Number of use in 2020
Domestic fowl	39203	35292	41115
Other birds	6209	6411	4831

In the fish category, there was a significant decrease in the use of zebra fish (-41,7%) and other fish (-50,22%) in 2020 in comparison with 2019.

The decrease in the use of zebrafish was due on the one hand to the postponement of projects due to the corona measures, and on the other hand because several large-scale projects, in which zebrafish larvae were used for compound screening, ended in the previous year. The decrease observed in the use of other fish was mainly due to the end of 2 projects involving capers and eels in 2019.

Animal Species	Number of use in 2018	Number of use in 2019	Number of use in 2020
Zebra fish	25904	39115	22804
Other Fish	28939	10692	5322

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 2018	Number of use in 2019	Number of use in 2020
Basic Research	251704	222946	168821
Translational and applied research	121645	130724	120505
Regulatory use and Routine production	140896	115267	127262
Protection of the natural environment in the interests of the health or welfare of human beings or animals	359	798	743
5		2.42	074
Preservation of species	5598	243	371
Higher education or training for the acquisition, maintenance or improvement of vocational	7440	0007	2007
skills	7442	6287	3827
Forensic enquiries	0	0	0
Maintenance of colonies of established genetically altered animals, not used in other procedures	28627	17717	15746
in other procedures	20021	17717	13740
Non-EU Purpose	0	0	0
Total uses	556271	493982	437275

Between 2019 and 2020, Basic Research and Higher education or training diminished by 24,28% and 39,13% respectively. The observed decreases are, at least partially, caused by the measures taken because of the Covid19 pandemic in 2020.

The number of procedures concerning Regulatory use and Routine production increased in 2020 by 10,40%. This is mostly due to an increasing number of studies that are being done for the registration or re-registration of coccidiostats and similar products. In these studies, according to the EFSA guidelines and sample size calculations, sufficient repetitions must be done to demonstrate the statistical impact of the product on zootechnical parameters, so it concerns large studies (~1000 animals/trial).

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

Severity	Number of use in 2018	% in 2018	Number of use in 2019	% in 2019	Number of use in 2020	% in 2020
Non-recovery	20565	3,70%	14074	2,85%	9464	2,16%
Mild	311660	56,03%	284376	57,57%	241487	55,23%
Moderate	154633	27,80%	131963	26,71%	139284	31,85%
Severe	69413	12,48%	63569	12,87%	47040	10,76%
Total uses	556271	100,00%	493982	100,00%	437275	100,00%

Within the actual severities classification we note a decrease in the category severe. This is probably due to a decrease in Basic Research in the domain of Oncology.

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.

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

1. Other fish

18,92% 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 (32%) and Salmonidae (21%), followed by Anguillidae (19%), Nothobranchiidae (14%) and Pleuronectidae (4%).

Other fish	Number of uses
Cyprinus carpio	1719
Oncorhynchus mykiss	1135
Anguilla anguilla	1029
Nothobranchius furzeri	749
Pleuronectes platessa	225
Lota lota	160
Kryptolébias mormoratus	68
Psetta maxima	38
Dicentrarchus labrax	34
Pseudotropheus saulosi	26
Alosa falax	19
Diancistrus fusca	17
Carrassius auratus	11
Synodontis grandiops	11
Cichlidae	10
Pygocentrus nattereri	10
Haplochromis sp. tomato	9
Myloplus schomburgkii	6
Piaractus brachypomus	5
Pygopristis denticulata	5
Clarias geriepinus	4
Synodontis soloni	4
Metynnis hypsauchen	3
Myloplus rubripinnis	3
Serrasalmus maculatus	3
Synodontis ilebrevis	3
Synodontis nigriventris	3
Maylandia zebra	2
Pygocentrus piraya	2
Serrasalmus elongatus	2
Catoprion mento	1
Colossoma macropomum	1
Methynnis lippincottianus	1
Microsynodontis batesi	1
Pygocentrus cariba	1
Serrasalmus manueli	1
Synodontis victoriae	1

2. Other amphibians

alpestris (3,7%).

In 2020, 5,34% of the amphibians are reported under the "other" category. They are Ranidae (*Lithobates catesbeianus*) (55,5% of other amphibians), and Pleurodelinae (in order of importance: *Triturus helveticus* (40,7%) and *Triturus*

Other amphibiansNumber of usesLithobates catesbeianus30Triturus helveticus22Tristurus alpestris2

3. Other birds

10,51% of the birds are reported under the "other" category.

They are mostly Phasianidae (*Meleagris gallopavo*, *Perdix perdix*, *Coturnix coturnix* and *Coturnix japonica*) (86% of other birds). The other birds are members of Laridae (*Larus fuscus*) (3%), Paridae (*Parus major*), (3%), Anatidae (3%), Numididae (2%), Fringillidae (*Serinus canaria*) (1%), Zosteropidae (*Zosterops kikuyuensis*) (<1%), Psittaculidae (*Melopsittacus undulatus*) (<1%) Estrildidae (*Taeniopygia guttata*) (<1%), and Sturnidae (*Sturnus vulgaris*) (<1%).

Other birds	Number of uses
Meleagris gallopavo	2825
Perdix perdix	1037
Coturnix coturnix	170
Larus fuscus	162
Parus major	145
Anatidae	144
Coturnix japonica	139
Numididae	95
Serinus canaria	54
Zosterops kikuyuensis	25
Melopsittacus undulatus	24
Taeniopygia guttata	9
Sturnus vulgaris	2

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

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